2019 MAGELLAN® CLINICAL GUIDELINES
FOR
MEDICAL NECESSITY REVIEW

Version: 3
Effective: January 2019
Guidelines for Clinical Review Determination

Preamble
Magellan is committed to the philosophy of supporting safe and effective treatment for patients. The medical necessity criteria that follow are guidelines for the provision of diagnostic imaging. These criteria are designed to guide both providers and reviewers to the most appropriate diagnostic tests based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice will be used when applying the guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient.

Guideline Development Process
These medical necessity criteria were developed by Magellan Healthcare for the purpose of making clinical review determinations for requests for diagnostic tests. The developers of the criteria sets included representatives from the disciplines of radiology, internal medicine, nursing, and cardiology and other specialty groups. They were developed following a literature search pertaining to established clinical guidelines and accepted diagnostic imaging practices.

All inquiries should be directed to:
Magellan Healthcare
PO Box 67390
Phoenix, AZ 85082-7390
Attn: Magellan Healthcare Chief Medical Officer
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Advanced Imaging Guidelines</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>70336 – MRI Temporomandibular Joint (TMJ)</td>
<td>7</td>
</tr>
<tr>
<td>70450 – CT Head/Brain</td>
<td>7</td>
</tr>
<tr>
<td>70480 – CT Orbit (Includes Sella and Posterior Fossa)</td>
<td>9</td>
</tr>
<tr>
<td>70486 – Maxillofacial/Sinus CT</td>
<td>16</td>
</tr>
<tr>
<td>70490 – CT Soft Tissue Neck</td>
<td>20</td>
</tr>
<tr>
<td>70496 – CT Angiography, Head/Brain</td>
<td>24</td>
</tr>
<tr>
<td>70498 – CT Angiography, Neck</td>
<td>28</td>
</tr>
<tr>
<td>70540 – MRI Orbit</td>
<td>31</td>
</tr>
<tr>
<td>70544 – MR Angiography Head/Brain</td>
<td>34</td>
</tr>
<tr>
<td>70547 – MR Angiography Neck</td>
<td>38</td>
</tr>
<tr>
<td>70551 – MRI Brain (includes Internal Auditory Canal)</td>
<td>41</td>
</tr>
<tr>
<td>70554 – Functional MRI Brain</td>
<td>44</td>
</tr>
<tr>
<td>71250 – CT Chest (Thorax)</td>
<td>52</td>
</tr>
<tr>
<td>71275 – CT Angiography, Chest (non coronary)</td>
<td>55</td>
</tr>
<tr>
<td>71550 – MRI Chest (Thorax)</td>
<td>61</td>
</tr>
<tr>
<td>71555 – MR Angiography Chest (excluding myocardium)</td>
<td>65</td>
</tr>
<tr>
<td>72125 – CT Cervical Spine</td>
<td>70</td>
</tr>
<tr>
<td>72128 – CT Thoracic Spine</td>
<td>75</td>
</tr>
<tr>
<td>72131 – CT Lumbar Spine</td>
<td>81</td>
</tr>
<tr>
<td>72141 – MRI Cervical Spine</td>
<td>87</td>
</tr>
<tr>
<td>72146 – MRI Thoracic Spine</td>
<td>95</td>
</tr>
<tr>
<td>72148 – MRI Lumbar Spine</td>
<td>102</td>
</tr>
<tr>
<td>72159 – MR Angiography Spinal Canal</td>
<td>108</td>
</tr>
<tr>
<td>72191 – CT Angiography, Pelvis</td>
<td>115</td>
</tr>
<tr>
<td>72192 – CT Pelvis</td>
<td>118</td>
</tr>
<tr>
<td>72196 – MRI Pelvis</td>
<td>123</td>
</tr>
<tr>
<td>72198 – MR Angiography, Pelvis</td>
<td>131</td>
</tr>
<tr>
<td>73200 – CT Upper Extremity (Hand, Wrist, Elbow, Long Bone or Shoulder)</td>
<td>139</td>
</tr>
<tr>
<td>73206 – CT Angiography, Upper Extremity</td>
<td>144</td>
</tr>
<tr>
<td>73220 – MRI Upper Extremity</td>
<td>151</td>
</tr>
<tr>
<td>73225 – MR Angiography Upper Extremity</td>
<td>154</td>
</tr>
<tr>
<td>73700 – CT Lower Extremity (Ankle, Foot, Hip or Knee)</td>
<td>161</td>
</tr>
<tr>
<td>73706 – CT Angiography, Lower Extremity</td>
<td>164</td>
</tr>
<tr>
<td>73720 – MRI Lower Extremity (Ankle, Foot, Knee, Hip, Leg)</td>
<td>170</td>
</tr>
<tr>
<td>73725 – MR Angiography, Lower Extremity</td>
<td>174</td>
</tr>
<tr>
<td>74150 – CT Abdomen</td>
<td>182</td>
</tr>
<tr>
<td>74174 – CT Angiography, Abdomen and Pelvis</td>
<td>185</td>
</tr>
<tr>
<td>74175 – CT Angiography, Abdomen</td>
<td>196</td>
</tr>
<tr>
<td>74176 – CT Abdomen and Pelvis Combo</td>
<td>202</td>
</tr>
<tr>
<td>74181 – MRI Abdomen</td>
<td>207</td>
</tr>
<tr>
<td>74185 – MR Angiography, Abdomen</td>
<td>217</td>
</tr>
<tr>
<td>74261 – CT Colonoscopy Diagnostic (Virtual)</td>
<td>224</td>
</tr>
<tr>
<td>74263 – CT Colonoscopy Screening (Virtual)</td>
<td>230</td>
</tr>
<tr>
<td>74263 – CT Colonoscopy Screening (Virtual)</td>
<td>232</td>
</tr>
</tbody>
</table>
74712 – Fetal MRI ____________________________236
75557 – MRI Heart______________________________238
75571 – Electron Beam Tomography (EBCT) _______________________________264
75572 – CT Heart ________________________________269
75574 – CTA Coronary Arteries (CCTA)_283
75635 – CT Angiography, Abdominal Arteries ___________________________293
76376 – 3D Rendering (CT Multiplanar Reconstruction) ___________________296
76390 – MR Spectroscopy ___________________________297
76497 – Unlisted CT Procedure________________________299
76498 – Unlisted MRI Procedure ________________________300
77012 – CT Needle Guidance ___________________________301
77014 – CT Guidance for Radiation Fields ______________________301
77021 – MRI Guidance for Needle Placement ______________________301
77046 – MRI Breast _______________________________302
77078 – CT Bone Density Study _________________________309
78205 – Liver SPECT __________________________________313
78320 – Bone and/or Joint SPECT ___________________________316
77084 – MRI Bone Marrow ____________________________319
78451 – Myocardial Perfusion Imaging (Nuc Card) ____________322
78459 – PET Scan, Heart (Cardiac) ______________________338
78472 – MUGA Scan __________________________________355
78608 – PET Scan, Brain ________________________________361
78647 – Cerebrospinal Fluid Flow SPECT ____________________363
78710 - Kidney SPECT __________________________________367
78813 – PET Scan_______________________________370
0042T – Cerebral Perfusion Analysis CT ______________________377
+0159T – CAD Breast MRI __________________________380
G0219 – PET Imaging whole body, melanoma · noncovered __________381
G0235 · PET imaging, any site, not otherwise specified_________382
G0252 · PET imaging, initial diagnosis of breast cancer __________383
0501T – Fractional Flow Reserve CT ___________________________384
S8037 – MR Cholangiopancreatography (MRCP) ______________394
G0297 – Low Dose CT for Lung Cancer Screening _____________398
S8042 – Low Field MRI ______________________________399
EXPANDED CARDIAC GUIDELINES _______________________________401
33225 – Cardiac Resynchronization Therapy (CRT) ___________________401
33249 – Implantable Cardioverter Defibrillator (ICD) _____________409
33208 – Pacemaker ______________________________________426
93307 – Transthoracic Echocardiography (TTE) ___________________436
93312 – Transesophageal Echocardiography (TEE) ________________460
93350 – Stress Echocardiography ______________________________465
93452 – Heart Catheterization _________________________________481
MUSCULOSKELETAL_SPINE SURGERY GUIDELINES __________________491
22600/63001 – Cervical Spinal Surgery _________________________491
22612/63030 – Lumbar Spinal Surgery _________________________505
<table>
<thead>
<tr>
<th>Code</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>62321</td>
<td>Spinal Epidural Injections</td>
</tr>
<tr>
<td>64490</td>
<td>Paravertebral Facet Joint Injections/Blocks</td>
</tr>
<tr>
<td>64633</td>
<td>Paravertebral Facet Joint Neurolysis</td>
</tr>
<tr>
<td>22532</td>
<td>Thoracic Spine Surgery</td>
</tr>
<tr>
<td>27096</td>
<td>Sacroiliac Joint Injections</td>
</tr>
<tr>
<td>27132</td>
<td>Hip Arthroplasty</td>
</tr>
<tr>
<td>29914</td>
<td>Hip Arthroscopy</td>
</tr>
<tr>
<td>27446</td>
<td>Knee Arthroplasty</td>
</tr>
<tr>
<td>27332</td>
<td>Knee Arthroscopy</td>
</tr>
<tr>
<td>23473</td>
<td>Shoulder Arthroplasty</td>
</tr>
<tr>
<td>23410</td>
<td>Shoulder Arthroscopy</td>
</tr>
<tr>
<td>3D Conformal Radiation Therapy (CRT), External Beam Radiation Therapy For Other Cancers</td>
<td></td>
</tr>
<tr>
<td>Anal Cancer</td>
<td></td>
</tr>
<tr>
<td>Bone Metastases</td>
<td></td>
</tr>
<tr>
<td>Brachytherapy</td>
<td></td>
</tr>
<tr>
<td>Breast Cancer</td>
<td></td>
</tr>
<tr>
<td>Cervical Cancer</td>
<td></td>
</tr>
<tr>
<td>Central Nervous System Metastatic Tumors</td>
<td></td>
</tr>
<tr>
<td>Central Nervous System Primary</td>
<td></td>
</tr>
<tr>
<td>Colorectal Cancer</td>
<td></td>
</tr>
<tr>
<td>Endometrial Cancer</td>
<td></td>
</tr>
<tr>
<td>Gastric Cancer</td>
<td></td>
</tr>
<tr>
<td>Head and Neck Cancer</td>
<td></td>
</tr>
<tr>
<td>Hodgkins Lymphoma</td>
<td></td>
</tr>
<tr>
<td>Hyperthermia</td>
<td></td>
</tr>
<tr>
<td>Intensity Modulated Radiation Therapy (IMRT)</td>
<td></td>
</tr>
<tr>
<td>Intraoperative Radiation Therapy (IORT)</td>
<td></td>
</tr>
<tr>
<td>Metastatic Disease</td>
<td></td>
</tr>
<tr>
<td>Neuton Beam Therapy</td>
<td></td>
</tr>
<tr>
<td>Non-Hodgkins Lymphoma</td>
<td></td>
</tr>
<tr>
<td>Non Small Cell Lung Cancer</td>
<td></td>
</tr>
<tr>
<td>Non-Cancerous Conditions</td>
<td></td>
</tr>
<tr>
<td>Pancreatic Cancer</td>
<td></td>
</tr>
<tr>
<td>Prostate Cancer</td>
<td></td>
</tr>
<tr>
<td>Proton Beam Radiation Therapy</td>
<td></td>
</tr>
<tr>
<td>Skin Cancer</td>
<td></td>
</tr>
<tr>
<td>Small Cell Lung Cancer</td>
<td></td>
</tr>
<tr>
<td>Stereotactic Radiotherapy (SRS)_Stereotactic Body Radiation (SBRT)</td>
<td></td>
</tr>
<tr>
<td>ULTRASOUND GUIDELINES</td>
<td></td>
</tr>
<tr>
<td>76536</td>
<td>Head and Neck Ultrasound</td>
</tr>
<tr>
<td>76700</td>
<td>Abdomen Ultrasound</td>
</tr>
<tr>
<td>76856</td>
<td>Pelvic Ultrasound</td>
</tr>
<tr>
<td>76870</td>
<td>Scrotum and Contents Ultrasound</td>
</tr>
</tbody>
</table>
All guidelines were reviewed between January 1, 2018 and September 15, 2018.

Prepared April 3, 2019
INTRODUCTION:

Temporomandibular joint (TMJ) dysfunction causes pain and dysfunction in the jaw joint and muscles controlling jaw movement. Symptoms may include: jaw pain, masticator muscle stiffness, limited movement or locking of the jaw, clicking or popping in jaw joint when opening or closing the mouth, and a change in how the upper and lower teeth fit together. The cause of the condition is not always clear but may include acute or chronic trauma to the jaw or temporomandibular joint, e.g., grinding of teeth, clenching of jaw, or impact in an accident. Osteoarthritis or rheumatoid arthritis may also contribute to the condition. The modality of choice for the evaluation of temporomandibular joint dysfunction is magnetic resonance imaging (MRI) which provides tissue contrast for visualizing the soft tissue and periarticular structures of the TMJ.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR TEMPOROMANDIBULAR JOINT (TMJ) MRI (Bag, 2014; Gauer, 2015; Ohnuki, 2003):

- For evaluation of dysfunctional temporomandibular joint after unsuccessful conservative therapy for at least four (4) weeks with bite block or splint and anti-inflammatory medicine.
- For pre-operative evaluation of dysfunctional temporomandibular joint in candidates for orthognathic surgery.
- For evaluation of locked or frozen jaw.
- For persistent temporomandibular joint dysfunction after surgical repair.
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
REFERENCES


CPT Codes: 70450 70460 70470

INTRODUCTION:

Computed tomography (CT) is an imaging technique used to view the structures of the brain and is useful in evaluating pathologies in the brain. It provides more detailed information on head trauma, brain tumors, stroke, and other pathologies in the brain than regular radiographs.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR BRAIN CT:

For evaluation of known or suspected seizure disorder (Krumholz, 2007; Gaillard, 2009; Ramli, 2015):
- New onset of seizures or newly identified change in seizure activity/pattern AND cannot have a Brain MRI.

For evaluation of neurologic symptoms or deficits (ACR, 2012a):
- Acute, new or fluctuating neurologic symptoms or deficits such as sensory deficits, limb weakness, speech difficulties, lack of coordination or mental status changes.

For evaluation of clinical assessment documenting cognitive impairment of unclear cause (AAN; Narayanan, 2016; HQO, 2014):
- Change in mental status with a mental status score of either MMSE or MoCA of less than 26 or other similar mental status instruments showing at least mild cognitive impairment AND a completed basic metabolic workup (such as thyroid function testing, liver function testing, complete blood count, electrolytes, and B12).

For evaluation of known or suspected trauma (Alrajhi, 2015; Jagoda, 2008; Menditto, 2012; Lee, 2005):
- Known or suspected trauma or injury to the head with documentation of one or more of the following acute, new, or fluctuating:
  o Focal neurologic findings
  o Motor changes
  o Mental status changes
  o Amnesia
  o Vomiting
  o Seizures
  o Headache
  o Signs of increased intracranial pressure
- Known coagulopathy
- Known or suspected skull fracture by physical exam and/or positive x-ray.
- Repeat scan 24 hours post head trauma for anticoagulated patients with suspected diagnosis of delayed subdural hematoma.

For evaluation of headache (Frischberg, 2000; Graham, 2000; Schafer, 2007; Edlow, 2008; Silberstein, 2000; Gunner, 2007; ACR, 2017a; Kerjnick, 2008):
• Chronic headache with a change in character/pattern (e.g., more frequent, increased severity or duration) and MRI is contraindicated or cannot be performed.
• New onset (< 48 hours) of “worst headache in my life” or “thunderclap” headache. Note: The duration of a thunderclap type headache lasts more than 5 minutes. Sudden onset new headache reaching maximum intensity within 2-3 minutes.
• New onset of headache with any acute, new, or fluctuating neurologic deficits such as sensory deficits, limb weakness, speech difficulties, lack of coordination, or mental status changes.
• Once in patients with cluster headaches to eliminate secondary causes
• Patient with history of cancer, or significantly immunocompromised, with new onset headache. New headache in individual > 55 years old.

New temporal headache in person > 55, with sedimentation rate (ESR) > 55 with tenderness over the temporal artery and MRI is contraindicated or cannot be performed.

With history or suspicion of aneurysm or AVM with new onset of headache.

**For evaluation of known or suspected brain tumor, mass, or metastasis (NCCN, 2017; Chase, 2011):**

- Follow up for known tumor.
- Suspected tumor with any acute, new, or fluctuating neurologic symptoms or deficits such as sensory deficits, limb weakness, speech difficulties, lack of coordination or mental status changes.
- Known lung cancer or rule out metastasis and/or preoperative evaluation.
- Metastatic melanoma (not all melanomas).
- For patient with history of cancer with suspected recurrence or metastasis [based on symptoms or examination findings (may include new or changing lymph nodes)].
- Patient with history of cancer that had a recent course of chemotherapy, radiation therapy (to the brain), or has been treated surgically within the last two (2) years.

Bone tumor or abnormality of the skull.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated, OR evaluation of suspected metastases (Sanellia, 2014):**

- ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine, or Lumbar Spine

**For evaluation of known or suspected stroke (Jauch, 2013; Tunkel, 2008; Smith, 1998):**

- Patient with history of a known stroke with new and sudden onset of severe headache.
- Known or suspected stroke with any acute, new, or fluctuating symptoms or deficits such as sensory deficits, limb weakness, speech difficulties, lack of coordination, or mental status changes or with a family history (brother, sister, parent or child) of aneurysm.
- Symptoms of transient ischemic attack (TIA) (episodic neurologic symptoms.)

**For evaluation of known or suspected inflammatory disease or infection (e.g., meningitis or abscess) and MRI is contraindicated or cannot be performed (Tarrant, 2009):**

- Suspected increased intracranial pressure or meningitis.
- Intracranial abscess or brain infection with acute altered mental status OR positive lab findings (such as elevated WBC’s) OR follow up assessment during or after treatment completed.
- Meningitis with positive physical findings (such as fever, stiff neck) and positive lab findings (such as elevated white blood cells or abnormal lumbar puncture fluid exam.)
- Suspected encephalitis with a severe headache, altered mental status, OR positive lab finding, (such as elevated WBC’s).
- Endocarditis with suspected septic emboli.
- Central Nervous System (CNS) involvement in patients with known or suspected vasculitis or autoimmune disease with positive lab findings.
For evaluation of known or suspected congenital abnormality (such as hydrocephalus, craniosynostosis) (Ashwal, 2009; Vinocur, 2010; Marchese, 2017; Lieb, 2015; Labuguen, 2006):
- Known or suspected congenital abnormality with any acute, new, or fluctuating neurologic, motor, or mental status changes.
- Microcephaly and MRI is contraindicated or cannot be performed
- Follow up shunt evaluation within six (6) months of placement or one (1) year follow up and/or with neurologic symptoms.
- Craniosynostosis and other head deformities.
- Suspected or known hydrocephalus.
- Prior or planned treatment for congenital abnormality.

Suspected normal pressure hydrocephalus, (NPH) with symptoms (Wilbrink, 2009).

Pre-operative evaluation for brain/skull surgery.

Post-operative/procedural evaluation:
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Other indications for a Brain CT (Tunkel, 2008; Thust, 2014; Arkuszewski, 2010; Agostoni, 2009; DeFoer, 2006; ACR, 2017b):
- Suspected acute subarachnoid hemorrhage (SAH).
- Follow up for known hemorrhage, hematoma, or vascular abnormalities.
- Developmental delay where MRI cannot be performed.
- Vertigo associated with headache, blurred or double vision, or a change in sensation after full neurologic examination and initial work-up and MRI is contraindicated or cannot be performed.
- Abnormal eye findings on physical or neurologic examination (papilledema, nystagmus, ocular nerve palsies, visual field deficit etc).
- Anosmia (loss of smell) (documented by objective testing).
- Known or suspected cerebrospinal fluid (CSF) leakage.
- Immunocompromised patient (e.g., transplant recipients, HIV with CD4<200, primary immunodeficiency syndromes, hematologic malignancies) with focal neurologic-symptoms, headaches, behavioral, cognitive, or personality changes.
- Suspected central venous thrombosis
- Neurological findings in sickle cell disease
- Prior to lumbar puncture in patients with suspected increased intracranial pressure or at risk for herniation.
- Suspected cholesteatoma.

Indication for Brain CT/Cervical CT combination studies:
- For evaluation of Arnold Chiari malformation where MRI cannot be performed.

Brain CT/Orbit CT:
- For approved indications as noted above and being performed in a child under 3 years of age who will need anesthesia for the procedure and there is a suspicion of concurrent intracranial tumor (e.g. “trilateral retinoblastoma”)
- Unilateral papilledema: to distinguish a compressive lesion on the optic nerve or optic disc swelling associated with acute demyelinating optic neuritis in multiple sclerosis from nonarteritic anterior ischemic optic neuropathy (NAION), central retinal vein occlusion, or optic nerve infiltrative disorders.
Brain CT/Neck CTA:
- Confirmed carotid stenosis >60%, surgery, or angioplasty candidate

ADDITIONAL INFORMATION RELATED TO BRAIN CT:

CT scan for congenital abnormalities - While MRI is preferred to CT for evaluation of most congenital CNS abnormalities, in some clinical situations CT is preferred (craniosynostosis) or equivalent to MRI. CT is appropriate in the follow up of hydrocephalus or VP shunt function where the etiology of hydrocephalus has been previously determined or in patients for which MRI evaluation would require general anesthesia.

CT scan for Headache - Generally, magnetic resonance imaging is the preferred imaging technique for evaluating the brain parenchyma and CT is preferable for evaluating subarachnoid hemorrhage. CT is faster and more readily available than MRI and is often used in urgent clinical situations. Neurologic imaging is warranted in patients with headache disorders along with abnormal neurologic examination results or predisposing factors for brain pathology.

CT scan for Head Trauma - Most types of head injury are minor injuries; clinical signs and symptoms help predict the need for brain CT following injury. CT has advantages in evaluating head injury due to its sensitivity for demonstrating mass effect, ventricular size and configuration, bone injuries and acute hemorrhage. A patient who presents with certain clinical risk factors may be more likely to benefit from CT imaging. Some of the clinical risk factors that may be used as a guide to predict the probability of abnormal CT following minor head injury are vomiting, skull fracture and age greater than 60 years. Patients with a Glasgow Coma Scale of 15 or less who also have vomiting or suspected skull fracture are likely to show abnormal results on CT scan. CT is also useful in detecting delayed hematoma, hypoxic-ischemic lesions, or cerebral edema in the first 72 hours after head injury.

CT scan for Stroke – Patients presenting with symptoms of acute stroke should receive prompt imaging to determine whether they are candidates for treatment with tissue plasminogen activator. Non-contrast CT can evaluate for hemorrhage that would exclude the patient from reperfusion therapy. Functional imaging can be used to select patients for thrombolytic therapy by measuring the mismatch between “infarct core” and “ischemic penumbra” which is a target for therapy. Contrast enhanced CT angiography (CTA) may follow the non-contrast CT imaging and may define ischemic areas of the brain with the potential to respond positively to reperfusion therapy.

CT scan and Meningitis – In suspected bacterial meningitis, contrast CT may be performed before lumbar puncture to show beginning meningeal enhancement. It may rule out causes for swelling. CT may be used to define the pathology of the base of the skull and that may require therapeutic intervention and surgical consultation. Some causes of the infection include fractures of the paranasal sinus and inner ear infection.

CT for Macrocephaly - Consider ultrasound for child <6 months of age for macrocephaly.

REDUCING RADIATION EXPOSURE:
Brain MRI is preferred to Brain CT in most circumstances where the patient can tolerate MRI and sufficient time is available to schedule the MRI examination. Assessment of subarachnoid hemorrhage, acute trauma or bone abnormalities of the calvarium (fracture, etc) may be better imaged with CT.
REFERENCES


CPT Codes: 70480, 70481, 70482

INTRODUCTION:

Computed tomography’s use of thin sections with multi-planar reconstruction, (e.g., axial, coronal and sagittal planes) along with its three-dimensional rendering permits thorough diagnosis and management of ocular and orbital disorders. Brain CT is often ordered along with CT of the orbit for head injury with orbital trauma.

Temporal bone, mastoid, and internal auditory canal computed tomography (CT) is a unique study performed for problems such as conductive hearing loss, chronic otitis media, mastoiditis, cholesteatoma, congenital hearing loss and cochlear implants. It is a modality of choice because it provides 3D positional information and offers a high degree of anatomic detail. It is rarely used for evaluation of VIIth of VIIIth nerve tumors.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ORBIT CT (Kennedy, 2017; Hande, 2012):

- Orbital asymmetry, exophthalmos (proptosis), or enophthalmos.
- Vision loss with etiology not identified on ophthalmologic examination and laboratory tests.
- Diplopia or ophthalmoplegia (paralysis or weakness of the eye muscles).
- Evaluation of ocular tumor.
- Suspected hyperthyroidism (such as Graves’ disease).
- Orbital trauma.
- Unilateral visual deficit.
- Suspected orbital pseudotumor (inflammatory orbital syndrome).
- Papilledema.
- Orbital infection.
- Known or suspected optic neuritis if MRI is contraindicated or is unable to be performed (Voss, 2011).

COMBINATION OF STUDIES WITH ORBIT CT:

- Brain CT/Orbit CT
  - For approved indications as noted above and being performed in a child under 8 years of age who will need anesthesia for the procedure and there is a suspicion of concurrent intracranial pathology (Lawson, 2000).
  - Unilateral papilledema to distinguish a compressive lesion on the optic nerve or optic disc swelling associated with acute demyelinating optic neuritis in multiple sclerosis from nonarteritic anterior ischemic optic neuropathy (NAION), central retinal vein occlusion or optic nerve infiltrative disorders.

INDICATIONS FOR SELLA CT:
• Evaluation of sellar and parasellar masses (Donovan, 1996).

**INDICATIONS FOR TEMPORAL/MASTOID/INTERNAL AUDITORY CANAL CT:**

**Hearing loss (documented on audiogram):**
• Sensorineural hearing loss with contraindication to MRI (Sharma, 2018).
• Conductive or mixed hearing loss (Sharma, 2018).
• Congenital hearing loss (Sharma, 2018; Baek, 2003; Ma, 2008; Westerhof, 2001).
• Cochlear implant evaluation (Sharma, 2018; Jain, 2003; Whiting, 2008).

**Tinnitus:**
• Pulsatile tinnitus (Kessler, 2017; Yew, 2014)
• Unilateral tinnitus with contraindication to MRI (Kessler, 2017; Yew, 2014)

**Other indications:**
• Acoustic neuroma or peripheral cranial nerve palsy with contraindication to MRI (Wu, 1986).
• Chronic otitis media (O’Reilly, 1991).
• Mastoiditis (Vazquez, 2003).
• Cholesteatoma (Alzoubi, 2009; Heilbrun, 2003).
• Dehiscence of the jugular bulb or carotid canal (Bozek, 2016).
• Aberrant blood vessels or malformations (Bozek, 2016).
• Episodic vertigo (peripheral vertigo) with abnormal neurologic findings (Sharma, 2018; Muncie, 2017).
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

**Pre-operative/procedural evaluation:**
• Pre-operative evaluation for a planned surgery or procedure.

**Post-operative/procedural evaluation:**
• When imaging, physical, or laboratory findings indicate surgical or procedural complications.
REFERENCES


CPT Codes: 70486, 70487, 70488, 76380

INTRODUCTION:

Computed tomography (CT) primarily provides information about bony structures, but may also be useful in evaluating soft tissue masses. It can help document the extent of facial bone fractures, facial infections and abscesses, and can aid in diagnosing salivary stones. Additionally, CT may be useful in characterizing and identifying tumor extent in the face and may be used in the assessment of chronic osteomyelitis.

CT scans can provide more detailed information about the anatomy and abnormalities of the paranasal sinuses than plain films. A CT scan provides greater definition of the sinuses and is more sensitive than plain radiography for detecting sinus pathology, especially within the sphenoid and ethmoid sinuses. CT scan findings can be nonspecific, however, and should not be used routinely in the diagnosis of acute sinusitis. The primary role of CT scans is to aid in the diagnosis and management of recurrent and chronic sinusitis, or to define the anatomy of the sinuses prior to surgery.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

A single authorization for CPT codes 70486, 70487, 70488, or 76380 includes imaging of the entire maxillofacial area including face and sinuses. Multiple authorizations are not required.

INDICATIONS FOR SINUS & MAXILLOFACIAL CT:

For evaluation of known or suspected infections or inflammatory disease:
• Unresolved sinusitis after four (4) consecutive weeks of medication, e.g., antibiotics, steroids or antihistamines (Rosenfeld, 2015; Kaplan, 2013).
• Immunocompromised patient (including but not limited to AIDS, transplant patient or patient with genetic or acquired deficiencies,) or conditions predisposed to sinusitis (e.g., cystic fibrosis and immotile cilia syndrome/Kartagener's syndrome).
• Known or suspected osteomyelitis (Pincus, 2009; Lee, 2016)
• Suspected orbital or intracranial complication of sinusitis (Kirsch, 2017)
• Suspected invasive fungal sinusitis (Kirsch, 2017)
• Known or suspected facial abscess.

For evaluation of known or suspected tumor:
• For known or suspected tumor based on exam or prior imaging (Das, 2005).

For evaluation of trauma (Echo, 2010):
• Suspected fracture AND prior imaging was nondiagnostic or equivocal.
• Complications of known fracture.
• Suspected post-traumatic CSF leak with suspected CSF rhinorrhea or otorrhea (Snetty, 2015).

Pre-operative/procedural evaluation:
• Pre-operative evaluation for a planned surgery or procedure.
Post-operative/procedural evaluation:
• When imaging, physical, or laboratory findings indicate surgical or procedural complications.

Other indications for Sinus and Maxillofacial CT:
• Asthma refractory to treatment (Sahay, 2016).
• Deviated nasal septum, polyp, or other structural abnormality seen on imaging or direct visualization that may be causing significant airway obstruction (Kirsch, 2017).
• New onset anosmia or hyposmia with contraindication to MRI (Policeni, 2017).
• Other conditions such as granulomatosis with polyangiitis (Wegener’s granulomatosis) that may present as rhinosinusitis.
• Parotid or other salivary stones (Gadodia, 2011).

COMBINATION OF STUDIES WITH SINUS & MAXILLOFACIAL CT:

Sinus CT/Chest CT:
• For poorly controlled asthma associated with upper respiratory tract infection. May be performed without failing 4 consecutive weeks of treatment with medication.
• Granulomatosis with polyangiitis (Wegener’s granulomatosis) disease (GPA) (Lohrmann, 2006).

ADDITIONAL INFORMATION RELATED TO SINUS & MAXILLOFACIAL CT:

Choosing Wisely: American Academy of Allergy, Asthma & Immunology (2012)
Don’t order sinus computed tomography (CT) or indiscriminately prescribe antibiotics for uncomplicated acute rhinosinusitis. Viral infections cause the majority of acute rhinosinusitis and only 0.5 percent to 2 percent progress to bacterial infections. Most acute rhinosinusitis resolves without treatment in two weeks. Uncomplicated acute rhinosinusitis is generally diagnosed clinically and does not require a sinus CT scan or other imaging. Antibiotics are not recommended for patients with uncomplicated acute rhinosinusitis who have mild illness and assurance of follow-up. If a decision is made to treat, amoxicillin should be first-line antibiotic treatment for most acute rhinosinusitis.

CT instead of MRI – MRI allows better differentiation of soft tissue structures within the sinuses. It is used occasionally in cases of suspected tumors or fungal sinusitis. Otherwise, MRI has no advantages over CT scanning in the evaluation of sinusitis. Disadvantages of MRI include high false-positive findings, poor bony imaging, and higher cost. MRI scans take considerably longer to accomplish than CT scans and may be difficult to obtain in patients who are claustrophobic.
REFERENCES


CPT Codes: 70490, 70491, 70492

INTRODUCTION:
High resolution CT can visualize both normal and pathologic anatomy of the neck. It is used in the evaluation of neck soft tissue masses, abscesses, and lymphadenopathy. For neck tumors, it defines the extent of the primary tumor and identifies lymph node spread. CT provides details about the larynx and cervical trachea and its pathology. Additional information regarding airway pathology is provided by three-dimensional images created from the CT dataset. Neck CT can also accurately depict and characterize tracheal stenoses.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR NECK CT:

**Known tumor or cancer of skull base, tongue, larynx, nasopharynx pharynx, or salivary glands**
- Initial staging (Kuno, 2014)
- Restaging during treatment
- Suspected recurrence or metastases based on symptoms or examination findings
  - New mass
  - Change in lymph nodes (King 2007)
- Diagnosed Primary Hyperparathyroidism when surgery planned
  - Previous nondiagnostic ultrasound or nuclear medicine scan (Keogh, 2008; Alexander, 2002)

**Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases:**
- ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.

**Suspected tumor or cancer:**
- Suspicious mass/tumor found on an imaging study and needing clarification or found by physical exam and remains non-diagnostic after x-ray or ultrasound is completed (Kuno, 2014).
- Palpable suspicious lesions in mouth or throat (Kuno, 2014).
- Non-thyroid neck mass
  - Increased risk for malignancy
    - No known infection and unknown duration with no fluctuation on exam OR
    - Any of these:
      - fixation to adjacent tissues
      - firm consistency
      - size > 1.5 cm
      - ulceration of overlying skin (Pynnomen, 2017)
    - Failed 2 weeks of treatment for suspected infectious cause (Schwetschenau, 2002)

**Known or suspected deep space infections or abscesses of the pharynx or neck** (Meyer, 2009).
Pre-operative evaluation.

Post-operative/procedural evaluation (e.g. post neck dissection):
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Other indications for a Neck CT:
- Vocal cord lesions or vocal cord paralysis (Dankbaar, 2014).
- Salivary gland stones or suspected gland abscess (Burke, 2011).
- For evaluation of tracheal stenosis (LoCicero, 1996)
- Brachial plexus dysfunction (Brachial plexopathy/Thoracic Outlet Syndrome) (Ferrante, 2012; Tharin, 2014).
REFERENCES


INTRODUCTION:

Computed tomography angiography (CTA) is recognized as a valuable diagnostic tool for the management of patients with cerebrovascular disease. With its three-dimensional reconstructions, CTA can simultaneously demonstrate the bony skull base and its related vasculature. CTA use of ionizing radiation and an iodine-based intravascular contrast medium is a disadvantage when compared to magnetic resonance angiography (MRA) but it is quicker and requires less patient cooperation than MRA. CTA is much less invasive than catheter angiography which involves injecting contrast material into an artery.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR BRAIN CTA:

For evaluation of known intracranial vascular disease (ACR, 2017; Sanelli, 2014; Colen, 2007; Khan, 2007; Zuccoli, 2011):
- Known intracranial aneurysm or arteriovenous malformation (AVM).
- Known vertebrobasilar insufficiency (VBI).
- Vascular abnormality visualized on previous brain imaging.
- Known vasculitis.

For evaluation of suspected intracranial vascular disease (Chalouhi, 2011; Villablanca, 2002; Jager, 2000; Leker, 1999; Hofmann, 2013):
- To screen for suspected intracranial aneurysm in patient whose parent, brother, sister, or child has history of intracranial aneurysm. Note: If there is a first degree familial history, repeat study is recommended every 5 years.
- Screening for aneurysm in polycystic kidney disease, Ehlers-Danlos syndrome, fibromuscular dysplasia, neurofibromatosis, or known aortic coarctation.
- Previously diagnosed subarachnoid hemorrhage (SAH).
- Suspected vertebrobasilar insufficiency (VBI) in patients with symptoms such as, vision changes, vertigo, or abnormal speech.
- Suspected arteriovenous malformation (AVM) in patient with previous or indeterminate imaging study.
- Suspected venous thrombosis (dural sinus thrombosis).
- Distinguishing benign intracranial hypertension (pseudotumor cerebri) from dural sinus thrombosis.
- Pulsatile tinnitus to identify vascular etiology.
- Suspected vasculitis with abnormal lab results suggesting acute inflammation or autoimmune antibodies.

Pre-operative evaluation for brain/skull surgery (Farsad, 2009):

Post-operative/procedural evaluation (Sanelli, 2004; Wallace, 2007):
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
**Indications for Brain CTA/Neck CTA combination studies:**
- Patients who have had a stroke or transient ischemic attack (TIA) within the past 2 weeks.
- Known or suspected vertebrobasilar insufficiency (VBI) in patients with symptoms such as vision changes, vertigo, or abnormal speech.
- Known or suspected carotid or cerebral artery occlusion in patients with a sudden onset of one-sided weakness, abnormal speech, vision defects, or severe dizziness.
- Head trauma in a patient with closed head injury for suspected carotid or vertebral artery dissection.
- Pulsatile tinnitus to identify vascular etiology.

**ADDITIONAL INFORMATION RELATED TO BRAIN CTA:**

**CTA for Evaluation of Aneurysm** – CTA is useful in the detection of cerebral aneurysms. The sensitivity of CTA to detect cerebral aneurysms ≤ 5 mm is higher than that with digital subtraction angiography (DSA). Most aneurysms missed with CTA are ≤ 3mm. Aneurysms in the region of the anterior clinoid process may extend into the subarachnoid space where they carry the threat of hemorrhage. CTA can help delineate the borders of the aneurysm in relation to the subarachnoid space and may help detect acute ruptured aneurysms. It may be used in the selection of patients for surgical or endovascular treatment of ruptured intracranial aneurysms.

**CTA for Screening of Patients with first degree relative (parent, brother, sister or child) have a history of aneurysm** – Data has suggested that individuals with a parent, brother, sister, or child harboring an intracranial aneurysm are at increased risk of aneurysms. It is likely that multiple genetic and environmental risk factors contribute to the increased risk.

**CTA for Evaluation of Vertebrobasilar Insufficiency (VBI)** – Multidetector CT angiography (MDCTA) may be used in the evaluation of vertebral artery pathologies. The correlation between MDCTA and color Doppler sonography is moderate. CTA is used for minimally invasive follow-up after intracranial stenting for VBI. It enables visualization of the patency of the stent lumen and provides additional information about all brain arteries and the brain parenchyma.

**CTA for evaluation of Arteriovenous Malformation (AVM)** – A good correlation has been found between catheter angiography and CTA in the detection of arteriovenous malformations. CTA allows calculation of the volume of an AVM nidus and identifies and quantifies embolic material within it. CTA may be used for characterization and stereotactic localization before surgical resection or radiosurgical treatment of arteriovenous malformations.
REFERENCES


CPT Code: 70498

INTRODUCTION:

Neck computed tomography angiography (CTA) uses a computerized analysis of x-ray images enhanced by contrast material injected into a peripheral vein. Neck CTA may be performed after initial carotid duplex imaging that does not provide adequate information or shows abnormal results. Neck CTA may be used for the evaluation of carotid body tumors and for post-operative evaluation of carotid endarterectomy.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR NECK CTA:

Suspected or known vascular disease:
- Asymptomatic patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 70%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries) (Marquardt, 2010; Brott, 2011).
- Symptomatic patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 50%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries) (Rerkasem, 2011; Rothwell, 2003; Brott, 2011).
- Head or neck blunt injury with suspected carotid or vertebral artery dissection.
  - Focal or lateralizing neurological deficits
  - Face or cervical fractures
  - Cervical hematomas
  - Injury by severe cervical hyperextension/rotation or hyperflexion, or “clothesline”
  - Thoracic injury
  (Franz, 2012; Mundinger, 2013)
- Findings of Takayasu arteritis in other blood vessels on previous imaging and Neck MRA cannot be done (Keenan, 2009).

Known of suspected tumor/mass
- Carotid body tumors, or other paraganglioma (Persky, 2002).
- Pulsatile neck mass after ultrasound has been performed when there is reasonable suspicion that it is not a vascular lesion (Pegge, 2017).

Pre-operative evaluation.

Post-operative/procedural evaluation (e.g. carotid endarterectomy):
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

**Indications for combination studies:**

**Neck CTA/Brain CTA:**
- New onset stroke or transient ischemic attack (TIA) (Easton, 2009)
- Known or suspected vertebrobasilar insufficiency (VBI) in patients with symptoms such as vision changes, vertigo, or abnormal speech (Searls, 2012).
- Head or neck blunt injury with suspected carotid or vertebral artery dissection.
  - Focal or lateralizing neurological deficits
  - Face or cervical fractures
  - Cervical hematomas
  - Injury by severe cervical hyperextension/rotation or hyperflexion, or “clothesline”
  - Thoracic injury
  (Franz, 2012; Mundinger, 2013)
- Pulsatile tinnitus for vascular etiology (Pegge, 2017).

**Neck CTA/Brain CT:**
- Asymptomatic patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 70%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries) and patient is surgery or angioplasty candidate. (Marquardt, 2010; Brott, 2011).
- Symptomatic patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 50%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries) and patient is surgery or angioplasty candidate. (Rerkasem, 2011; Rothwell, 2003; Brott, 2011).
REFERENCES


CPT Codes: 70540, 70542, 70543

INTRODUCTION:

Magnetic resonance imaging (MRI) is used in the evaluation of face and neck region masses, trauma, and infection. The soft-tissue contrast between normal and abnormal tissues provided by MRI is sensitive for differentiating between inflammatory disease and malignant tumors and permits the precise delineation of tumor margins. MRI is used for therapy planning and follow-up of face and neck neoplasms. It is also used for the evaluation of neck lymphadenopathy and vocal cord lesions.

CT scanning remains the study of choice for the imaging evaluation of acute and chronic inflammatory diseases of the sinonasal cavities. MRI is not considered the first-line study for routine sinus imaging because of limitations in the definition of the bony anatomy and length of imaging time. MRI for confirmation of diagnosis of sinusitis is discouraged because of hypersensitivity (overdiagnosis) in comparison to CT without contrast. MRI, however, is superior to CT in differentiating inflammatory conditions from neoplastic processes. MRI may better depict intraorbital and intracranial complications in cases of aggressive sinus infection, as well as differentiating soft-tissue masses from inflammatory mucosal disease. MRI may also identify fungal invasive sinusitis or encephaloceles.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

A single authorization for CPT code 70540, 70542, or 70543 includes imaging of the Orbit, Face, Sinuses, and Neck. Multiple authorizations are not required.

INDICATIONS FOR ORBIT MRI (Kennedy, 2017; Hande, 2012):
- Orbital asymmetry, exophthalmos (proptosis), or enophthalmos.
- Vision loss with etiology not identified on ophthalmologic examination and laboratory tests.
- Ophthalmoplegia (paralysis or weakness of the eye muscles) or diplopia.
- Evaluation of ocular tumor.
- Suspected hyperthyroidism (such as Graves’ disease).
- Orbital trauma.
- Unilateral visual deficit.
- Suspected orbital pseudotumor (inflammatory orbital syndrome).
- Papilledema.
- Orbital infection.
- Known or suspected optic neuritis (Voss, 2011).

INDICATIONS FOR FACE/SINUS MRI:
- Acute rhinosinusitis with suspected orbital or intracranial complications (Kirsch, 2017).
- Suspected invasive fungal sinusitis (Kirsch, 2017).
- Sinonasal obstruction (Kirsch, 2017).
- Known or suspected mass based on exam or previous imaging (Kirsch, 2017).
- Known or suspected osteomyelitis (Pincus, 2009; Lee, 2016).
INDICATIONS FOR NECK MRI:
• Vocal cord lesions or vocal cord paralysis (Dankbaar, 2014).
• Sialography for salivary gland stones.
• Suspected salivary gland abscess (Burke, 2011).
• Parotid or other salivary tumors.
• Brachial plexus dysfunction (Brachial plexopathy/Thoracic Outlet Syndrome) (Ferrante 2012; Tharin, 2014)
• Palpable suspicious lesions in mouth or throat (Kuno, 2014).
• Known or suspected inflammatory disease, infection, or abscess.
• Primary hyperparathyroidism with nondiagnostic ultrasound or nuclear medicine scan and surgery is planned (Keogh, 2008; Alexander 2002).
• Evaluation of non-thyroid neck mass
  o Present on physical exam after abnormal or non-diagnostic x-ray or ultrasound (Kuno, 2014; Kransdorf, 2017).
  o Increased risk of malignancy suggested by size > 1.5 cm, firm consistency, fixation to adjacent tissues, or ulceration of overlying skin (Pynnonen, 2017).
  o Failed 2 weeks of treatment for suspected infectious adenopathy (Haynes, 2015).

OTHER INDICATIONS FOR ORBIT/FACE/NECK MRI

Evaluation of known cancer
• Initial staging (Kuno, 2014)
• Restaging during treatment
• Suspected recurrence or new metastases based on symptoms or examination findings (King, 2009)

Pre-operative/procedural evaluation:
• Pre-operative evaluation for a planned surgery or procedure.

Post-operative/procedural evaluation:
• When imaging, physical, or laboratory findings indicate surgical or procedural complications.

INDICATIONS FOR COMBINATION STUDIES: ORBIT/FACE/NECK MRI WITH BRAIN MRI.
• Anosmia on objective testing (Policeni, 2017)
• Trigeminal neuralgia (Policeni, 2017)
• Cranial neuropathy (weakness or sensory abnormalities of the head and neck) (Policeni, 2017)
• Unilateral papilledema: to distinguish a compressive lesion on the optic nerve or optic disc swelling associated with acute demyelinating optic neuritis in multiple sclerosis from nonarteritic anterior ischemic optic neuropathy (NAION), central retinal vein occlusion or optic nerve infiltrative disorders.
• For approved indications as noted above and being performed in a child under 8 years of age who will need anesthesia for the procedure and there is a suspicion of concurrent intracranial pathology (Lawson, 2000).

INDICATIONS FOR COMBINATION STUDIES: Initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases:
• ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.
REFERENCES


INTRODUCTION:

Magnetic resonance angiography (MRA) or magnetic resonance venography (MRV) can be used as a first line investigation of intracranial vascular disease. It is an alternative to invasive intra-catheter angiography that was once the mainstay for the investigation of intracranial vascular disease. MRA/MRV may use a contrast agent, gadolinium, which is non-iodine-based, for better visualization. It can be used in patients who have history of contrast allergy and who are at high risk of kidney failure. A single authorization covers both MRA and MRV.

Three different techniques of MRA/MRV are: time of flight (both 2D and 3D TOF), phase contrast (PC), and contrasted enhanced angiography. Time of flight MRA takes advantage of the phenomena of flow related enhancement and is the preferred MRA technique due to the speed at which the exam can be acquired.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR BRAIN (HEAD) MRA/MRV:

For evaluation of known intracranial vascular disease (ACR, 2017; Sanelli, 2014; Obusez, 2014; Jageer, 2000):

- Known intracranial aneurysm or arteriovenous malformation (AVM).
- Known vertebrobasilar insufficiency (VBI).
- Vascular abnormality visualized on previous brain imaging.
- Known vasculitis.


- To screen for suspected intracranial aneurysm in patient whose parent brother, sister, or child has history of intracranial aneurysm. Note: If there is a first degree familial history, repeat study is recommended every 5 years.
- Screening for aneurysm in polycystic kidney disease, Ehlers-Danlos syndrome, fibromuscular dysplasia, neurofibromatosis, or known aortic coarctation.
- Previously diagnosed subarachnoid hemorrhage (SAH).
- Suspected vertebrobasilar insufficiency (VBI) in patients with symptoms such as vision changes, vertigo, or abnormal speech.
- Suspected arteriovenous malformation (AVM) in patient with previous or indeterminate imaging study.
- Suspected venous thrombosis (dural sinus thrombosis).
- Distinguishing benign intracranial hypertension (pseudotumor cerebri) from dural sinus thrombosis.
- Pulsatile tinnitus to identify vascular etiology.
- Suspected vasculitis with abnormal lab results suggesting acute inflammation or autoimmune antibodies.
- Stroke risk in sickle cell patients (2 - 16 years of age) with a transcranial doppler velocity >200.
• Neurological findings in sickle cell disease

**Pre-operative evaluation for brain/skull surgery.**

**Post-operative/procedural evaluation (Wong, 2007; Lee, 2009):**

- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

**Indications for Brain MRA/Neck MRA combination studies:**

- Patients who have had a stroke or transient ischemic attack (TIA) within the past 2 weeks.
- Known or suspected vertebrobasilar insufficiency (VBI) in patients with symptoms such as vision changes, vertigo, or abnormal speech.
- Known or suspected carotid or cerebral artery occlusion in patients with a sudden onset of one-sided weakness, abnormal speech, vision defects, or severe dizziness.
- Head trauma in a patient with closed head injury for suspected carotid or vertebral artery dissection.
- Pulsatile tinnitus to identify vascular etiology.

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**ADDITIONAL INFORMATION RELATED TO BRAIN (HEAD) MRA**

**MRA and Cerebral Aneurysms** – Studies that compared MRA with catheter angiography in detecting aneurysms found that MRA could find 77% - 94% of the aneurysms previously diagnosed by catheter angiography that were larger than 5 mm. For aneurysms smaller than 5 mm, MRI detected only 10% - 60% of those detected with catheter angiography. On the other hand, aneurysms that were missed by catheter angiography in patients with acute subarachnoid hemorrhage were detected with MRA, due to the much larger number of projections available with MRA.

**MRA and Cerebral Arteriovenous Malformations (AVM)** – Brain arteriovenous malformation (AVM) may cause intracranial hemorrhage and is usually treated by surgery. 3D TOF-MRA is commonly used during the planning of radio-surgery to delineate the AVM nidus, but it is not highly specific for the detection of a small residual AVM after radio-surgery.

**MRV** - A pitfall of the TOF technique, particularly 3D TOF, is that in areas of slowly flowing blood, turbulence or blood which flows in the imaging plane there can be regions of absent or diminished signal. The signal loss can be confused with vascular occlusion or thrombi. To avoid this pitfall MRA performed after the intravenous administration of gadolinium based contrast agents is utilized at many facilities.

Intracranial magnetic resonance venography (MRV) is used primarily to evaluate the patency of the venous sinuses. The study can be performed with TOF, Phase contrast and IV contrast enhanced techniques. Delayed images to allow for enhancement of the venous system are required to obtain images when intravenous gadolinium enhanced studies are undertaken.

Saturation pulses are utilized in studies not undertaken with intravenous contrast to help eliminate flow related signal in a specified direction and thus display the desired arterial or venous structures on their own. In cranial applications, saturation pulses applied at the inferior margin of the imaging field eliminate signal from arterial flow in order to visualize the veins. Conversely, superior saturation pulses are used to eliminate venous flow related enhancement when evaluation of the arterial structures is desired.
REFERENCES


CPT Codes: 70547, 70548, 70549

INTRODUCTION:

Magnetic resonance angiography (MRA) of the neck uses magnetic resonance imaging (MRI) technology and may be performed after abnormal results are found on carotid duplex imaging. MRA is used for the evaluation and imaging of vessels in the head and the neck.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR NECK MRA:

For evaluation of vascular disease:
- For evaluation of asymptomatic patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 70%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries) (Brott, 2011).
- For evaluation of symptomatic patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 50%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries) (Brott, 2011).
- For evaluation of head or neck blunt injury for suspected carotid or vertebral artery dissection.
  - Focal or lateralizing neurological deficits
  - Face or cervical fractures
  - Cervical hematomas
  - Injury by severe cervical hyperextension/rotation or hyperflexion, or “clothesline”
  - Thoracic injury
  (Franz, 2012; Mundinger, 2013)
- Findings of Takayasu arteritis in other blood vessels (Keenan, 2009)

For evaluation of known or suspected tumor/mass:
- For evaluation of carotid body tumors, or other paragangliomas.
- For evaluation of pulsatile neck mass after ultrasound has been performed when there reasonable suspicion that it is not a vascular lesion (Pegge, 2017).

Pre-operative evaluation.

Post-operative/procedural evaluation (e.g. carotid endarterectomy):
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Indications for combination studies:

Neck MRA/Brain MRA:
• Evaluation of new onset stroke or transient ischemic attack (TIA)
• For evaluation of known or suspected vertebrobasilar insufficiency (VBI) in patients with symptoms such as vision changes, vertigo, or abnormal speech.
• For evaluation of known or suspected carotid or cerebral artery occlusion in patients with a sudden onset of one-sided weakness, abnormal speech, vision defects or severe dizziness.
• For evaluation of head or neck blunt injury for suspected carotid or vertebral artery dissection.
  o Focal or lateralizing neurological deficits
  o Face or cervical fractures
  o Cervical hematomas
  o Injury by severe cervical hyperextension/rotation or hyperflexion, or “clothesline”
  o Thoracic injury
  (Franz 2012; Mundinger 2013)

• For evaluation of pulsatile tinnitus for vascular etiology (Pegge, 2017).

**Neck MRA/Brain MRI:**
• For evaluation of asymptomatic patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 70%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries) and patient is surgery or angioplasty candidate (Brott, 2011).
• For evaluation of symptomatic patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 50%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries) and patient is surgery or angioplasty candidate (Brott, 2011).

**ADDITIONAL INFORMATION RELATED TO NECK MRA:**

**MRA and Carotid Body Tumor** – Carotid body tumors are found in the upper neck at the branching of the carotid artery. Although most of them are benign they may be locally aggressive with a small malignant potential. MRA may be used to identify a carotid body tumor due to its ability to define the extension of the tumor in relation to the carotid arteries, involvement of the base of the skull and bilateral tumors.

**Post-operative evaluation of carotid endarterectomy** – Carotid endarterectomy is a vascular surgical procedure that removes plaque from the carotid artery. MRA with multiprojection volume reconstruction is a non-invasive imaging modality that is an alternative to postoperative angiography following carotid endarterectomy. It allows the surgeon to get informative and comparative data.
REFERENCES


INTRODUCTION:

Brain (head) MRI is the procedure of choice for most brain disorders. It provides clear images of the brainstem and posterior brain, which are difficult to view on a CT scan. It is also useful for the diagnosis of demyelinating disorders (disorders such as multiple sclerosis (MS) that cause destruction of the myelin sheath of the nerve). The evaluation of blood flow and the flow of cerebrospinal fluid (CSF) is possible with this non-invasive procedure.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR BRAIN MRI:

For evaluation of suspected multiple sclerosis (MS) (Traboulsee, 2016):
- For evaluation of patient with neurologic symptoms or deficits within the last four (4) weeks.

For evaluation of known multiple sclerosis (MS) (Traboulsee, 2016):
- Stable condition with no prior imaging within the past ten (10) months or within the past six (6) months if patient has relapsing disease
- Exacerbation of symptoms or change in symptom characteristics such as frequency or type and demonstrated compliance with medical therapy.

For evaluation of known or suspected seizure disorder (Krumholz, 2007; Gaillard, 2009; Ramli, 2015):
- New onset of a seizure.
- Medically refractory epilepsy.

For evaluation of suspected Parkinson’s disease (Pyatigorskaya, 2014):
- For evaluation of suspected Parkinson’s disease as a baseline study.

For evaluation of known Parkinson’s disease (Pyatigorskaya, 2014):
- For evaluation of new non-Parkinson symptoms complicating the evaluation of the current condition.

For evaluation of neurologic symptoms or deficits (ACR, 2012a):
- Acute, new, or fluctuating neurologic symptoms or deficits such as sensory deficits, limb weakness, speech difficulties, lack of coordination, or mental status changes.

For evaluation of clinical assessment documenting cognitive impairment of unclear cause (Narayanan, 2016; HQO, 2014):
- Change in mental status with a mental status score of either MMSE or MoCA of less than 26 or other similar mental status instruments showing at least mild cognitive impairment AND a completed basic metabolic workup (such as thyroid function testing, liver function testing, complete blood count, electrolytes, and B12).
For evaluation of known or suspected trauma (Lee, 20015; Jagoda, 2008):

- Known or suspected trauma or injury to the head with documentation of one or more of the following acute, new, or fluctuating:
  - Focal neurologic findings
  - Motor changes
  - Mental status changes
  - Amnesia
  - Vomiting
  - Seizures
  - Headache
  - Signs of increased intracranial pressure
- Known coagulopathy
- Known or suspected skull fracture by physical exam and positive x-ray.

For evaluation of headache (Holle, 2013; Edlow, 2008; Schaefer, 2007; Silberstein, 2000; Wilbrink, 2009; ACR, 2012b; Gunner, 2007):

- Chronic headache with a change in character/pattern (e.g., more frequent, increased severity, or duration).
- New onset (< 48 hours) of “worst headache in my life” or “thunderclap” headache. Note: The duration of a thunderclap type headache lasts more than 5 minutes. Sudden onset new headache reaching maximum intensity within 2-3 minutes.
- New onset of headache with any acute, new or fluctuating neurologic deficits such as sensory deficits, limb weakness, speech difficulties, lack of coordination, or mental status changes
- MRI is indicated once in patients with cluster headaches to eliminate secondary causes.
- Patient with history of cancer, or significantly immunocompromised, with new onset headache.
- New headache in individual > 55 years old.
- New temporal headache in person > 55, with sedimentation rate (ESR) > 55 with tenderness over the temporal artery.
- Acute, sudden onset of headache with a family history (brother, sister, parent or child) of brain aneurysm or AVM (arteriovenous malformation).
- New severe unilateral headache with radiation to or from the neck. Associated with suspicion of carotid or vertebral artery dissection.
- New onset of headache in pregnancy.

For evaluation of known or suspected brain tumor, mass or metastasis (Kerjnick, 2008):

- Known tumor and new onset of headache.
- Follow up for known tumor.
- Evaluation of suspected tumor with any acute, new or fluctuating neurologic symptoms or deficits such as sensory deficits, limb weakness, speech difficulties, lack of coordination, or mental status changes.
- Known lung cancer or rule out metastasis and/or preoperative evaluation.
- Evaluation of metastatic melanoma (not all melanomas).
- Known or suspected pituitary tumor with corroborating physical exam (galactorrhea) neurologic findings and/or lab abnormalities.

Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated, OR evaluation of suspected metastases (NCCN, 2017):

- ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.
For evaluation of known or suspected stroke (Jauch, 2013):
- To evaluate patient with history of a known stroke with new and sudden onset of severe headache.
- Known or suspected stroke with any acute, new or fluctuating symptoms or deficits such as sensory deficits, limb weakness, speech difficulties, lack of coordination or mental status changes or with a family history (brother, sister, parent, or child) of aneurysm.
- Symptoms of transient ischemic attack (TIA) (episodic neurologic symptoms).

For evaluation of known or suspected inflammatory disease or infection (e.g., meningitis or abscess) (Lummel, 2016; Oliveira, 2014; Tarrant, 2009):
- Intracranial abscess or brain infection with acute altered mental status OR positive lab findings (such as elevated WBC’s) OR follow up assessment during or after treatment completed.
- Meningitis with positive physical findings (such as fever, stiff neck) and positive lab findings (such as elevated white blood cells or abnormal lumbar puncture fluid exam.)
- Suspected encephalitis with a severe headache, altered mental status OR positive lab finding, (such as elevated WBC’s).
- Endocarditis with suspected septic emboli.
- Evaluation for Central Nervous System (CNS) involvement in patients with known or suspected vasculitis or autoimmune disease with positive lab findings.

For evaluation of known or suspected congenital abnormality (such as hydrocephalus, craniosynostosis) (Ashwal, 2009; Vinocur, 2010):
- Known or suspected congenital abnormality with any acute, new, or fluctuating neurologic, motor, or mental status changes.
- Evaluation of macrocephaly with child >6 months of age.
- Evaluation of microcephaly.
- Follow up shunt evaluation within six (6) months of placement or one (1) year follow up and/or with neurologic symptoms.
- Evaluation of craniosynostosis and other skull deformities. CT is preferred imaging to assess bony structures; MRI imaging is preferred to assess intracranial soft tissue.
- To evaluate patient for suspected or known hydrocephalus.
- To evaluate patient for prior treatment OR treatment planned for congenital abnormality.

Suspected normal pressure hydrocephalus (NPH) with symptoms (Valvassori, 2000).

Pre-operative evaluation for brain/skull surgery:

Post-operative/procedural evaluation:
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Indications for a Brain MRI with Internal Auditory Canal (IAC) (Labuguen, 2006):
- Unilateral non-pulsatile tinnitus.
- Pulsatile tinnitus.
- Suspected acoustic neuroma (Schwannoma) or cerebellar pontine angle tumor with any of the following signs and symptoms: unilateral hearing loss by audiometry, headache, disturbed balance or gait, unilateral tinnitus, facial weakness, or altered sense of taste.
- Suspected cholesteatoma.
- Suspected glomus tumor.
- Asymmetric sensorineural hearing loss on audiogram.
Other indications for a Brain MRI (Meadows, 2000; Thust, 2014; Agostoni, 2009; ACR, 2017b; ACR, 2017a; Mackin, 2014; Silva, 2009p; Strickberger, 2006):

- Evaluation of suspected acute subarachnoid hemorrhage (SAH).
- Follow up for known hemorrhage, hematoma or vascular abnormalities.
- Suspected central venous thrombosis.
- Evaluation of neurological findings in sickle cell disease.
- Developmental delay.
- Vertigo associated with headache, blurred or double vision, or a change in sensation after full neurologic examination and initial work-up.
- Abnormal eye findings on physical or neurologic examination (papilledema, nystagmus, ocular nerve palsies, visual field deficit etc).
- Anosmia (loss of smell) (documented by objective testing).
- Evaluation of known or suspected cerebrospinal fluid (CSF) leakage.
- Immunocompromised patient (e.g., transplant recipients, HIV with CD4<200, primary immunodeficiency syndromes, hematologic malignancies) with focal neurologic-symptoms, headaches, behavioral, cognitive or personality changes.
- Initial imaging of a suspected or known Arnold Chiari malformation (ACM)
- Optic neuritis.
- Initial evaluation for a known syrinx or syringomyelia.
- Suspected cholesteatoma.

**Indications for combination studies:**

- **Brain MRI/Neck MRA** –
  - Confirmed carotid occlusion >60%, surgery or angioplasty candidate.

- **Brain MRI/Cervical MRI** –
  - For evaluation of Arnold Chiari Malformation.
  - For follow-up of known multiple sclerosis (MS).

- **Brain MRI/Orbit MRI** –
  - For approved indications as noted above and being performed in a child under 3 years of age who will need anesthesia for the procedure and there is a suspicion of concurrent intracranial tumor (e.g. “trilateral retinoblastoma”).
  - Unilateral papilledema: to distinguish a compressive lesion on the optic nerve or optic disc swelling associated with acute demyelinating optic neuritis in multiple sclerosis from nonarteritic anterior ischemic optic neuropathy (AION), central retinal vein occlusion or optic nerve infiltrative disorders.

**ADDITIONAL INFORMATION RELATED TO BRAIN MRI:**

**MMSE** - The Mini Mental State Examination (MMSE) is a tool that can be used to systematically and thoroughly assess mental status. It is an 11-question measure that tests five areas of cognitive function: orientation, registration, attention and calculation, recall, and language. The MMSE has been the most commonly used measure of cognitive function in dementia research, but researchers have recognized that it is relatively insensitive and variable in mildly impaired individuals. The maximum score is 30. A score of 23 or lower is indicative of cognitive impairment. The MMSE takes only 5-10 minutes to administer and is therefore practical to use repeatedly and routinely.
MoCA - The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. MoCA differs from the MMSE mainly by including tests of executive function and abstraction, and by putting less weight on orientation to time and place. Ten of the MMSE's 30 points are scored solely on the time-place orientation test, whereas the MoCA assigns it a maximum of six points. The MoCA also puts more weight on recall and attention-calculation performance, while de-emphasizing language skill. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

Combination MRI/MRA of the Brain – This is one of the most misused combination studies and these examinations should be ordered in sequence, not together. Vascular abnormalities can be visualized on the brain MRI.

MRI for Headache - Generally, magnetic resonance imaging is the preferred imaging technique for evaluating the brain parenchyma and CT is preferable for evaluating subarachnoid hemorrhage. CT is faster and more readily available than MRI and is often used in urgent clinical situations. Neurologic imaging is warranted in patients with headache disorders along with abnormal neurologic examination results or predisposing factors for brain pathology. Contrast enhanced MRI is performed for evaluation of inflammatory, infectious, neoplastic and demyelinating conditions.

MRI for Macrocephaly - Consider ultrasound for child <6 months of age for macrocephaly.

MRI and Positron Emission Tomography (PET) for Chronic Seizures – When MRI is performed in the evaluation of patients for epilepsy surgery, almost a third of those with electrographic evidence of temporal lobe epilepsy have normal MRI scans. Interictal positron emission tomography (PET) may be used to differentiate patients with MRI-negative temporal lobe epilepsy.

MRI and Multiple Sclerosis – Current advances in MRI improve the ability to diagnose, monitor and understand the pathophysiology of MS. Different magnetic resonance methods are sensitive to different aspects of MS pathology and by the combining of these methods, an understanding of the mechanisms underlying MS may be increased.

MRI and Vertigo – Magnetic resonance imaging is appropriate in the evaluation of patients with vertigo who have neurologic signs and symptoms, progressive unilateral hearing loss or risk factors for cerebrovascular disease. MRI is more appropriate than CT for diagnosing vertigo due to its superiority in visualizing the posterior portion of the brain, where most central nervous system disease that causes vertigo is found. MRI is helpful in diagnosing vascular causes of vertigo.
REFERENCES


CPT Codes: 70554, 70555

INTRODUCTION:

Functional MRI (fMRI) of the brain is a non-invasive imaging technique, using radio waves and a strong magnetic field, to image the brain activity of a patient prior to undergoing brain surgery for tumors or epilepsy. It is based on the increase in blood flow to the local vasculature when parts of the brain are activated and helps to determine the location of vital areas of brain function. fMRI images capture blood oxygen levels in parts of the brain that are responsible for perception, cognition, and movement allowing neurosurgeons to operate with less possibility of harming areas that are critical to the patient’s quality of life.

fMRI is also used to image and localize abnormal brain function in patients with seizures.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR FUNCTIONAL BRAIN MRI (ACR, 2017; ACR, 2014; Carmichael, 2007; Chakraborty, 2008; Hall, 2009; Owen, 2007; Petrella, 2006; Chandrasekharan, 2008):

Pre-operative Evaluation:
• With brain tumors where fMRI may have a significant role in mapping lesions.
• With seizures where fMRI may have a significant role in mapping lesions.

Post-operative Evaluation:
• To assess progress after surgery. A documented medical reason must clearly explain the medical necessity for the post-operative follow up.

ADDITIONAL INFORMATION RELATED TO FUNCTIONAL BRAIN MRI:

fMRI and Brain Tumors – fMRI may significantly affect therapeutic planning in patients who have potentially resectable brain tumors. Due to its non-invasiveness, its relatively high spatial resolution, and its pre-operative results, fMRI is used before surgery in the evaluation of patients with brain tumors. fMRI may have a significant role in mapping lesions that are located in close proximity to vital areas of brain function (language, sensory motor, and visual). It can determine the precise spatial relationship between the lesion and adjacent functionally essential parenchyma, allowing removal of as much pathological tissue as possible during resection of brain tumors without compromising essential brain functions. fMRI provides an alternative to other invasive tests such as the Wada test and direct electrical stimulation.

fMRI and Seizures – Brain fMRI can influence the diagnostic and therapeutic decisions of the seizure team, thereby affecting the surgical approach and outcomes. Brain surgery is often the treatment for patients with epilepsy, especially patients with a single seizure focus. fMRI may have a significant role in mapping lesions that are located in close proximity to vital areas of brain function (language, sensory motor, and visual).
fMRI can determine the location of the brain functions of areas bordering the lesion, resulting in better outcomes with less neurologic deficit.

**fMRI as an Alternative to the Invasive WADA test and Direct Electrical Stimulation** – fMRI is considered an alternative to the Wada test and direct electrical stimulation as it is a non-invasive method for location of vital brain areas. The Wada test is used for the pre-operative evaluations of patients with brain tumors and seizures to determine which side of the brain is responsible for vital cognitive functions, e.g., speech and memory. It can assess the surgical risk of damaging the vital areas of the brain. The Wada test is invasive, involving an angiography procedure to guide a catheter to the internal carotid where a barbiturate is injected, putting one hemisphere of the brain to sleep. Direct electrical stimulation mapping is invasive requiring the placement of electrodes in the brain. The electrodes are used to stimulate multiple cortical sites in the planned area of resection to allow the surgeons to identify and mark which areas can be safely resected.
REFERENCES


CPT Codes: 71250, 71260, 71270, G0297

INTRODUCTION:

Computed tomography (CT) scans provide greater clarity than regular x-rays and are used to further examine abnormalities found on chest x-rays. They may be used for detection and evaluation of various disease and conditions in the chest, e.g., tumor, inflammatory disease, vascular disease, congenital abnormalities, trauma and symptoms such as hemoptysis.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CHEST CT:

For annual lung cancer screening:
The use of low-dose, non-contrast spiral (helical) multi-detector CT imaging as an annual screening technique for lung cancer is considered medically necessary ONLY when used to screen for lung cancer for certain high-risk asymptomatic individuals when ALL of the following criteria are met:

- Individual is between 55-77 years of age; AND
- There is at least a 30 pack-year history of cigarette smoking; AND
- If the individual is a former smoker, that individual had quit smoking within the previous 15 years (Medicare, ACCP).

For evaluation of known tumor, cancer or mass:
- Initial evaluation of diagnosed cancer.
- Evaluation of known tumor or cancer for patient undergoing active treatment to assess impact of treatment.
- Evaluation of known tumor or cancer or history of prior cancer presenting with new signs (i.e., physical, laboratory, or imaging findings) or new symptoms.
- Active monitoring for recurrence as clinically indicated.

Evaluation of suspicious mass/tumor (unconfirmed cancer diagnosis):
- Initial evaluation of suspicious mass/tumor found on an imaging study and needing clarification or found by physical exam and remains non-diagnostic after x-ray or ultrasound is completed.
- Known distant cancer with suspected chest/lung metastasis based on a sign, symptom, imaging study or abnormal lab value.
- For the follow-up evaluation of a nodule with a previous CT (follow-up intervals approximately 3, 6, 12 and 24 months):
  - f/u evaluation of ground glass > 5mm up to 36 months.
  - no further f/u of solid nodules < 6mm if unchanged at 12 month

Known or suspected interstitial lung disease (e.g. idiopathic interstitial lung diseases, idiopathic pulmonary fibrosis, hypersensitivity pneumonitis, pneumoconiosis, sarcoidosis, silicosis and asbestosis) and initial x-ray has been performed:
- With abnormal physical, laboratory, and/or imaging findings requiring further evaluation.
Known or suspected infection or inflammatory disease (i.e., complicated pneumonia not responding to treatment, abscess, tuberculosis (TB), empyema or immunosuppression post-organ transplant with new symptoms or findings) and initial x-ray has been performed:

- With abnormal physical, laboratory, and/or imaging findings requiring further evaluation.
- For evaluation of known inflammatory disease:
  - Initial evaluation
  - During treatment
  - With new signs and symptoms
- For evaluation of non-resolving pneumonia documented by at least two imaging studies:
  - Unimproved with 4 weeks of antibiotic treatment OR
  - Not resolved at 8 weeks
- For evaluation of lung abscess, cavitary lesion, or empyema, demonstrated or suggested on prior imaging.

Suspected vascular disease, (e.g., aneurysm, dissection):

- For evaluation of known or suspected superior vena cava (SVC) syndrome.
- Suspected thoracic/thoracoabdominal aneurysm or dissection (documentation of clinical history may include hypertension and reported “tearing or ripping type” chest pain) when contrast is contraindicated.

Known vascular disease:

- For follow up of known vascular disease (aneurysm) and contrast is not appropriate for the clinical indication

Suspected Pulmonary Embolism (PE):

Patients at intermediate risk for PE and positive D-dimer or at high risk for PE

Patients with intermediate risk for PE with negative D-dimer or low risk for PE should be directed to Chest CTA although this is controversial and Chest CT optimized as to enhancement of the pulmonary vessels may be acceptable in select circumstances

Patients can be excluded from imaging with low risk for PE and negative D-dimer results

D-dimer is a blood test that measures fibrin degradation products that are increased when increased clotting and clot degradation is going on in the body.

*Low risk defined as NO to ALL of the following questions with intermediate and high risk defined based on the number of positive responses:
1) Evidence of current or prior DVT;
2) HR > 100;
3) Cancer diagnosis;
4) Recent surgery or prolonged immobilization;
5) Hemoptysis;
6) History of PE;
7) Another diagnosis beside PE is less likely.

All patients should have prior Chest x-ray to evaluate other possible causes for the patient symptoms (i.e. CHF) and patients in low and intermediate risk groups for PE should have preceding D-dimer level to better stratify patient into risk categories to decide if test is necessary or proper protocol for Chest CT.

Known or suspected congenital abnormality:

- For evaluation of known or suspected congenital abnormality
• Vascular - suggest Chest CTA or Chest MRA depending on age and radiation safety issues.
• Nonvascular - abnormal imaging and/or physical examination finding.

Hemoptysis:
• For evaluation of hemoptysis and prior x-ray performed.

Post-operative/procedural evaluation:
• Post-surgical follow up when records document medical reason requiring additional imaging

Other indications for Chest CT:
• Pre-operative evaluation.
• Re-evaluation after abnormal imaging within past 30 - 60 days and with no improvement on x-ray, (not indicated with known rib fractures).
• Evaluation of persistent unresolved cough of at least four weeks duration, unresponsive to medical treatment and chest x-ray has been performed.
• Evaluation of other chest or thorax adenopathy.
• Evaluation of pneumothorax.
• Evaluation of vocal cord paralysis.
• Suspected thymoma with myasthenia gravis.
• Pre-operative evaluation for Electromagnetic Navigation Bronchoscopy (Khan et al, 2016)

Combination of studies with Chest CT:
• Abdomen CT/Pelvis CT/Chest CT/Neck MRI/Neck CT with MUGA – known tumor/cancer for initial staging or evaluation before starting chemotherapy or radiation treatment.

COMBINATION OF STUDIES WITH CHEST CT/SINUS CT:
• For poorly controlled asthma associated with upper respiratory tract infection. May be performed without failing 4 consecutive weeks of sinus treatment with medication.
• Granulomatosis with polyangiitis (GPA) (Wegener’s).

ADDITIONAL INFORMATION RELATED TO CHEST CT:

LDCT for Lung Cancer Screening - Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery

CT for Management of Hemoptysis – High-resolution CT (HRCT) is useful for estimating the severity of hemoptysis, localizing the bleeding site and determining the cause of the bleeding. Its results can be related to the severity of bleeding. The volume of expectorated blood and the amount of blood that may be retained within the lungs without being coughed up are important. HRCT is a way to evaluate the amount of bleeding and its severity. It may also help in the localization of bleeding sites and help in detecting the cause of bleeding.

CT and Solitary Pulmonary Nodules – Solitary Pulmonary nodules are abnormalities that are solid, semisolid and non solid; another term to describe a nodule is focal opacity. CT makes it possible to find smaller nodules and contrast-enhanced CT is used to differentiate benign from malignant pulmonary nodules. When a nodule is increasing in size or has spiculated margins or mixed solid and ground-glass
attenuation, malignancy should be expected. Patients who have pulmonary nodules and who are immunocompromised may be subject to inflammatory processes.

**CT and Empyema** – Contrast-enhanced CT used in the evaluation of the chest wall may detect pleural effusion and differentiate a peripheral pulmonary abscess from a thoracic empyema. CT may also detect pleural space infections and help in the diagnosis and staging of thoracic empyema.

**CT and Superior Vena Cava (SVC) Syndrome** – SVC is associated with cancer, e.g., lung, breast and mediastinal neoplasms. These malignant diseases cause invasion of the venous intima or an extrinsic mass effect. Adenocarcinoma of the lung is the most common cause of SVC. SVC is a clinical diagnosis with typical symptoms of shortness of breath along with facial and upper extremity edema. Computed tomography (CT), often the most readily available technology, may be used as confirmation and may provide information including possible causes.
REFERENCES


Medicare.gov.


CPT Codes: 71275

INTRODUCTION:

Computed tomography angiography (CTA) is a non-invasive imaging modality that may be used in the evaluation of thoracic vascular problems. Chest CTA (non-coronary) may be used to evaluate vascular conditions, e.g., pulmonary embolism, thoracic aneurysm, thoracic aortic dissection, aortic coarctation, or pulmonary vascular stenosis. CTA depicts the vascular structures as well as the surrounding anatomical structures.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CHEST CTA:

For evaluation of suspected or known pulmonary embolism (excludes low risk*) (ACR, 2016; Kirsch, 2017; ACCP, 2013):

For evaluation of suspected or known vascular abnormalities:
- For evaluation of a thoracic/thoracoabdominal aneurysm or dissection (documentation of clinical history may include hypertension and reported “tearing or ripping type” chest pain) (ACR, 2017).
- Characterization of congenital thoracic vascular anomalies (e.g., coarctation of the aorta or vascular ring) suggested on initial imaging (Chest X-ray, Echo, CT or GI study)) (Hellinger, 2011; Karaosmanoglu, 2015; Poletto, 2017).
- Signs or symptoms of vascular insufficiency of the neck or arms (e.g., venous or arterial thoracic outlet syndrome (ACR, 2014; Povlsen, 2018) or subclavian steal syndrome with abnormal or inconclusive ultrasound (Potter, 2014)).
- Follow-up evaluation of progressive vascular disease when new signs or symptoms are present.
- Determine etiology of pulmonary hypertension after initial diagnosis (echocardiography, or incidentally on right heart catheterization) (Ascha, 2017; Rose-Jones, 2015).

Preoperative evaluation
- Known or suspected vascular abnormalities seen on prior imaging
- Ablation procedure for atrial fibrillation.

Postoperative or post-procedural evaluation
- Physical evidence of post-operative bleeding complication or re-stenosis.
- Post-surgical follow up when records document medical reason requiring additional imaging

Chest CTA and Abdomen CTA or Abdomen/Pelvis CTA or Pelvis CTA combo (ACR, 2017; Achenbach, 2012):
- For evaluation of extensive vascular disease involving the chest and abdominal cavities such as aortic dissection, vasculitic diseases such as Takayasu’s arteritis, significant post-traumatic or post-procedural vascular complications, etc.
- For preoperative or preprocedural evaluation such as transcatheter aortic valve replacement (TAVR).
ADDITIONAL INFORMATION RELATED TO CHEST CTA:

CTA and Coarctation of the Aorta – Coarctation of the aorta is a common vascular anomaly characterized by a constriction of the lumen of the aorta distal to the origin of the left subclavian artery near the insertion of the ligamentum arteriosum. The clinical sign of coarctation of the aorta is a disparity in the pulsations and blood pressures in the legs and arms. Chest CTA may be used to evaluate either suspected or known aortic coarctation and patients with significant coarctation should be treated surgically or interventionaly.

CTA and Pulmonary Embolism (PE) – Note: D-Dimer blood test in patients at low risk* for DVT is indicated prior to CTA imaging. Negative D-Dimer suggests alternative diagnosis in these patients.

*Low risk defined as NO to ALL of the following questions:
   1) Evidence of current or prior DVT;
   2) HR > 100;
   3) Cancer diagnosis;
   4) Recent surgery or prolonged immobilization;
   5) Hemoptysis;
   6) History of PE;
   and another diagnosis is more likely.

CTA has high sensitivity and specificity and is the primary imaging modality to evaluate patients suspected of having acute pulmonary embolism. When high suspicion of pulmonary embolism on clinical assessment is combined with a positive CTA, there is a strong indication of pulmonary embolism. Likewise, a low clinical suspicion and a negative CTA can be used to rule out pulmonary embolism.

CTA and Thoracic Aortic Aneurysms – Computed tomographic angiography (CTA) allows the examination of the precise 3-D anatomy of the aneurysm from all angles and shows its relationship to branch vessels. This information is very important in determining the treatment: endovascular stent grafting or open surgical repair.

CTA and Thoracic Aorta Endovascular Stent-Grafts – CTA is an effective alternative to conventional angiography for postoperative follow-up of aortic stent grafts. It is used to review complications after thoracic endovascular aortic repair. CTA can detect luminal and extraluminal changes to the thoracic aortic after stent-grafting and can be performed efficiently with fast scanning speed and high spatial and temporal resolution.
REFERENCES


CPT Codes: 71550, 71551, 71552

INTRODUCTION:

Magnetic Resonance Imaging (MRI) is a noninvasive imaging technique for detection and evaluation of various disease and conditions in the chest, e.g., congenital anomalies and aneurysms. MRI may be used instead of computed tomography (CT) in patients with allergies to radiographic contrast or with impaired renal function.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CHEST MRI:

• For evaluation of mediastinal or hilar mass of patient with renal failure or allergy to contrast material (Carter, 2017; Azizad, 2016; Erasmus, 2000).
• For evaluation of chest wall masses (Carter, 2016; Carter, 2015).
• For evaluation of myasthenia gravis with suspected thymoma (Carter, 2015; Conti-Fine, 2006).
• For evaluation of brachial plexus dysfunction (brachial plexopathy/thoracic outlet syndrome) (Amrami, 2005; Demondion, 2006; Dillman, 2006; Medina, 2008; Smith, 2015).
• For evaluation of a thoracic/thoracoabdominal aneurysm or dissection (documentation of clinical history may include hypertension and reported “tearing or ripping type” chest pain (Lau, 2017; Mongeon, 2016; Dudzinski, 2015; Dillman, 2008; Goitein, 2005; Konen, 2004; Russo, 2006; Norenberg, 2016).
• For evaluation of congenital heart disease or cardiac and non-cardiac malformations, [e.g., vascular rings or pulmonary slings, aortic arch anomalies and patent ductus arteriosus (PDA)] (Smith, 2015; Gutierrez, 2002; Konen, 2004; McMahon, 2007; Russo, 2006; Ruano, 2015; Baez, 2015).
• For evaluating whether masses invade into specific thoracic structures (e.g. aorta, pulmonary artery, brachial plexus, subclavian vessels, or thoracic spine) (Zapala, 2017; Mueller, 2015; Cline, 2017; Hazenfield, 2016; Carter, 2016; Carter, 2015).
• To determine the consistency of thoracic masses (cystic vs. solid vs. mixed) (Hansen, 2015).
• Initial evaluation of suspicious abnormality found on an imaging study and needing clarification or found by physical exam and remains non-diagnostic after x-ray or ultrasound is completed.
• Post-surgical follow up when records document medical reason requiring additional imaging.

ADDITIONAL INFORMATION RELATED TO CHEST MRI:

MRI and Myasthenia Gravis – Myasthenia Gravis is a chronic autoimmune disease characterized by weakness of the skeletal muscles causing fatigue and exhaustion that is aggravated by activity and relieved by rest. It most often affects the ocular and other cranial muscles and is thought to be caused by the presence of circulating antibodies. Symptoms include ptosis, diplopia, chewing difficulties, and dysphagia. Thymoma has a known association with myasthenia. Contrast-enhanced MRI may be used to identify the presence of a mediastinal mass suggestive of myasthenia gravis in patients with renal failure or allergy to contrast material.
**MRI and Thoracic Outlet Syndrome** – Thoracic outlet syndrome is a group of disorders involving compression at the superior thoracic outlet that affects the brachial plexus, the subclavian artery and veins. It refers to neurovascular complaints due to compression of the brachial plexus or the subclavian vessels. Magnetic resonance multi-plane imaging shows bilateral images of the thorax and brachial plexus and can demonstrate the compression of the brachial plexus and venous obstruction.

**MRI and Brachial Plexus** - MRI is the only diagnostic tool that accurately provides high resolution imaging of the brachial plexus. The brachial plexus is formed by the cervical ventral rami of the lower cervical and upper thoracic nerves which arise from the cervical spinal cord, exit the bony confines of the cervical spine, and traverse along the soft tissues of the neck, upper chest, and course into the arms.
REFERENCES


INTRODUCTION:

Magnetic resonance angiography (MRA) is a noninvasive technique used to provide cross-sectional and projection images of the thoracic vasculature, including large and medium sized vessels, e.g., the thoracic aorta. It provides images of normal as well as diseased blood vessels and quantifies blood flow through these vessels. Successful vascular depiction relies on the proper imaging pulse sequences. MRA may use a contrast agent, gadolinium, which is non-iodine-based, for better visualization. It can be used in patients who have history of contrast allergy and who are at high risk of kidney failure.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CHEST MRA:

For evaluation of suspicious mass and CTA is contraindicated due to a history of contrast allergy or high risk for contrast induced renal failure.

For evaluation of suspected or known pulmonary embolism (excludes low risk*) (ACCP, 2013; Douma, 2009; Schiebler, 2013; Li, 2009).

For evaluation of suspected or known vascular abnormalities (ACR, 2017):
- Thoracic/thoracoabdominal aneurysm or dissection (documentation of clinical history may include hypertension and reported “tearing or ripping type” chest pain) (Miller, 2008; Bonci, 2017).
- Congenital thoracic vascular anomaly (e.g., coarctation of the aorta or evaluation of a vascular ring suggested by GI study) (Russo, 2006).
- Signs or symptoms of vascular insufficiency of the neck or arms (e.g., subclavian steal syndrome with abnormal ultrasound) (Bauer, 2009).
- Follow-up evaluation of progressive vascular disease when new signs or symptoms are present (Araoz, 2003).
- Primary or secondary pulmonary hypertension (Swift, 2012; Lopez-Costa, 2014).
- Pulmonary sequestration (Xu, 2001).
- Central venous thrombosis (Kim, 2008).

Preoperative Evaluation

- Known vascular abnormalities
- Ablation procedure for atrial fibrillation (Cirillo, 2004).

Postoperative or post-procedural evaluation

- Physical evidence of post-operative bleeding complication or re-stenosis.
- Post-surgical follow up when records document medical reason requiring additional imaging (Araoz, 2003).
ADDITIONAL INFORMATION RELATED TO CHEST MRA:

**MRA and Coarctation of the Aorta** – One of the most common congenital vascular anomalies is coarctation of the aorta which is characterized by obstruction of the juxtaductal aorta. Clinical symptoms, e.g., murmur, systemic hypertension, difference in blood pressure in upper and lower extremities, absent femoral or pedal pulses, may be present. Gadolinium enhanced 3D MRA may assist in preoperative planning as it provides angiographic viewing of the aorta, the arch vessels and collateral vessels. It may also assist in the identification of postoperative complications.

**MRA and Pulmonary Embolism (PE)** – Note: D-Dimer blood test in patients at low risk* for DVT is indicated to prior to MRA imaging. Negative D-Dimer suggests alternative diagnosis in these patients.

*Low risk defined as NO to ALL of the following questions:
   1) Evidence of current or prior DVT;
   2) HR > 100;
   3) Cancer diagnosis;
   4) Recent surgery or prolonged immobilization;
   5) Hemoptysis;
   6) History of PE;
and another diagnosis is more likely

Studies show mixed results regarding the value of MRA v CTA in detecting pulmonary embolism. A systematic review and meta-analysis found MRA to be inferior to CTA in detecting PE. Therefore, MRA should be used only if CTA is not available or contraindicated in a specific patient (Li, 2009).

**MRA and Thoracic Aortic Aneurysm** – One of the most common indications for thoracic MRA is thoracic aortic aneurysm, most often caused by atherosclerosis. These aneurysms may also be due to aortic valvular disease. Aneurysms are defined by their enlargement and patients with rapidly expanding aortas, or with aortic diameters greater than five or six centimeters, are at high risk of rupture and may require surgery.

**MRA and Thoracic Aortic Dissection** – The most common clinical symptom of aortic dissection is tearing chest pain and the most common risk factor is hypertension. An intimal tear is the hallmark for aortic dissection and intramural hematoma may also be detected. Unfortunately, patients with aortic dissection may be unstable and not good candidates for routine MR evaluation; MRA may be indicated as a secondary study. 3D MRA is also useful in postoperative evaluation of patients with repaired aortic dissections.

**MRA and Central Venous Thrombosis** – MRA is useful in the identification of venous thrombi. Venous thrombosis can be evaluated by gadolinium enhanced 3D MRA as an alternative to CTA which may not be clinically feasible due to allergy to iodine contrast media or renal insufficiency.

**Other MRA Indications** – MRA is useful in the assessment for postoperative complications of pulmonary venous stenosis.

**MRI and Patent Ductus Arteriosus** – Patent ductus arteriosus (PDA) is a congenital heart problem in which the ductus arteriosus does not close after birth. It remains patent allowing oxygen-rich blood from the aorta to mix with oxygen-poor blood from the pulmonary artery. MRI can depict the precise anatomy...
of a PDA to aid in clinical decisions. It allows imaging in multiple planes without a need for contrast administration. Patients are not exposed to ionizing radiation.
REFERENCES


INTRODUCTION:

Computed tomography (CT) is performed for the evaluation of the cervical spine. CT may be used as the primary imaging modality or it may complement other modalities. Primary indications for CT include conditions, e.g., traumatic, neoplastic, and infectious. CT is often used to study the cervical spine for conditions such as degenerative disc disease when MRI is contraindicated. CT provides excellent depiction of bone detail and is used in the evaluation of known fractures of the cervical spine and for evaluation of postoperative patients.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CERVICAL SPINE CT:

For evaluation of known fracture (ACR, 2012):
- To assess union of a fracture when physical examination, plain radiographs, or prior imaging suggest delayed or non-healing
- To determine the position of fracture fragments.

For evaluation of neurologic deficits when Cervical Spine MRI is contraindicated or inappropriate (ACR, 2013; Carette, 2005):
- With any of the following new neurological deficits: extremity weakness; abnormal reflexes; or abnormal sensory changes along a particular dermatome (nerve distribution) as documented on physical exam.

For evaluation of suspected myelopathy when Cervical Spine MRI is contraindicated (Behrbalk, 2013; ACR, 2015; Vitzthum, 2007):
- Progressive symptoms including hand clumsiness, worsening handwriting, difficulty with grasping and holding objects, diffuse numbness in the hands, pins and needles sensation, increasing difficulty with balance and ambulation (unsteadiness, broad-based gait, increased muscle tone, weakness and wasting of the upper and lower limbs; diminished sensation to light touch, temperature, proprioception, vibration; bowel and bladder dysfunction in more severe cases).

For evaluation of chronic neck pain, with any of the following when Cervical Spine MRI is contraindicated (ACR, 2013):
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic or cervical spine pain (NASS, 2013)).

For evaluation of new onset of neck pain when Cervical Spine MRI is contraindicated:
• Failure of conservative treatment*, for at least six (6) weeks within the last six (6) months (NASS, 2013).
• With progression or worsening of symptoms during the course of conservative treatment*.
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic or cervical spine pain (NASS, 2013)).

For evaluation of trauma or acute injury (ACR, 2012):
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With progression or worsening of symptoms during the course of conservative treatment*.
• When the patient is clinically unevaluable or there are preliminary imaging findings (X-ray or CT) needing further evaluation.
  (“MRI and CT provide complementary information”. When indicated, “It is appropriate to perform both examinations” (ACR, 2012)).

For evaluation of known tumor, cancer, or evidence of metastasis with any of the following (MRI is usually the preferred study but CT may help characterize solitary indeterminate lesions (Kim, 2012)):
• For staging of known tumor.
• For follow-up evaluation of patient undergoing active cancer treatment.
• Presents with new signs or symptoms (e.g. physical, laboratory, and/or imaging findings) of new tumor or change in tumor.
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
• With evidence of metastasis on bone scan or previous imaging study.

For evaluation of suspected tumor when Cervical Spine MRI is contraindicated or inappropriate (ACR, 2013):
• Prior abnormal or indeterminate imaging that requires further clarification.

Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases:
• < 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine, or Lumbar Spine.

For evaluation of known or suspected infection, abscess, or inflammatory disease when Cervical Spine MRI is contraindicated (ACR, 2013):
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

For evaluation of spine abnormalities related to immune system suppression, e.g., HIV, chemotherapy, leukemia, or lymphoma when Cervical Spine MRI is contraindicated (Nagashima, 2010; Williams, 1999):
• As evidenced by signs/symptoms, laboratory, or prior imaging findings.

As part of initial post-operative/procedural evaluation (“CT best examination to assess for hardware complication, extent of fusion” (ACR, 2013) and MRI for cord, nerve root compression, disc pathology, or post-op infection):
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
• Changing neurologic status post-operatively.
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
• Surgical infection as evidenced by signs/symptoms, laboratory, or prior imaging findings.
• Continuing or recurring symptoms of any of the following neurological deficits: Lower extremity weakness, lower extremity asymmetric reflexes.

Other indications for a Cervical Spine CT:
• For preoperative evaluation and Cervical Spine MRI is contraindicated
• CT myelogram or discogram.
• Suspected cord compression with any of the following neurologic deficits, e.g., extremity weakness, abnormal gait, asymmetric reflexes.
• Suspicious sacral dimple (those that are deep, larger than 0.5 cm, located within the superior portion of the gluteal crease or above the gluteal crease, or associated with other cutaneous markers) when Cervical Spine MRI is contraindicated (D’Alessandro, 2009).
• Known Arnold-Chiari syndrome and Cervical Spine MRI is contraindicated.
• Congenital abnormalities in the presence of neurologic deficit, progressive spinal deformity, or for preoperative planning (Trenga, 2016).
• Syrinx or syringomyelia and Cervical Spine MRI is contraindicated.

COMBINATION OF STUDIES WITH CERVICAL SPINE CT:
Cervical/Thoracic/Lumbar CTs:
• CT myelogram or discogram.
• Any combination of these for scoliosis survey in infant/child (Strahle, 2015).
• Any combination of these for spinal survey in patient with metastases.
• For evaluation of spinal abnormalities associated with Arnold-Chiari Malformation. (C/T/L spine due to association with tethered cord and syringomyelia) (Milhorat, 2009; Strahle, 2015).

Cervical MRI/CT - unstable craniocervical junction.
Brain CT/Cervical CT – for evaluation of Arnold-Chiari Malformation and Cervical Spine MRI is contraindicated.

ADDITIONAL INFORMATION RELATED TO CERVICAL SPINE CT:

*Conservative Therapy: (spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (epidural, facet, bursal, and/or joint, not including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
• Information provided on exercise prescription/plan AND
• Follow up with member with documentation provided regarding completion of HEP (after suitable 6 week period), or inability to complete HEP due to physical reason- i.e. increased pain, inability to
physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

**Myelopathy:** Symptom severity varies and a high index of suspicion is essential for making the proper diagnosis in early cases. Symptoms of pain and radiculopathy may not be present. The natural history of myelopathy is characterized by neurological deterioration. The most frequently encountered symptom is gait abnormality (86%) followed by increased muscular reflexes (79.1%), pathological reflexes (65.1%), paresthesia of upper limb (69.8%) and pain (67.4%) (Vitzthum, 2007).

**CT and Infection of the spine** - Infection of the spine is not easy to differentiate from other spinal disorders, e.g., degenerative disease, spinal neoplasms, and non-infective inflammatory lesions. Infections may affect different parts of the spine, e.g., vertebrae, intervertebral discs, and paraspinal tissues. Imaging is important to obtain early diagnosis and treatment to avoid permanent neurologic deficits. When MRI is contraindicated, CT may be used to evaluate infections of the spine.

**CT and Degenerative Disc Disease** – Degenerative disc disease is very common and CT may be indicated, when MRI is contraindicated, when chronic degenerative changes are accompanied by conditions, e.g., new neurological deficits; onset of joint tenderness of a localized area of the spine; new abnormal nerve conduction studies; exacerbation of chronic neck or back pain unresponsive to conservative treatment; and unsuccessful physical therapy/home exercise program.

**Sacral Dimples** - Simple midline dimples are the most commonly encountered dorsal cutaneous stigmata in neonates and indicate low risk for spinal dysraphism. Only atypical dimples are associated with a high risk for spinal dysraphism, particularly those that are large (>5 mm), high on the back (>2.5 cm from the anus), or appear in combination with other lesions (D’Alessandro, 2009). High-risk cutaneous stigmata in neonates include hemangiomas, upraised lesions (i.e., masses, tails, and hairy patches), and multiple cutaneous stigmata.
REFERENCES


CPT Codes: 72128, 72129, 72130

INTRODUCTION:

Computed tomography is used for the evaluation, assessment of severity, and follow-up of diseases of the spine. Its use in the thoracic spine is limited, however, due to the lack of epidural fat in this part of the body. CT myelography improves the contrast severity of CT, but it is also invasive. CT may be used for conditions, e.g., degenerative changes, infection, and immune suppression, when magnetic resonance imaging (MRI) is contraindicated. It may also be used in the evaluation of tumors, cancer, or metastasis in the thoracic spine and it may be used for preoperative and post-surgical evaluations. CT obtains images from different angles and uses computer processing to show a cross-section of body tissues and organs. CT is fast and is often performed in acute settings. It provides good visualization of cortical bone.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR THORACIC SPINE CT:

For evaluation of known fracture:
- To assess union of a fracture when physical examination, plain radiographs, or prior imaging suggest delayed or non-healing
- To determine the position of fracture fragments.

For evaluation of neurologic deficits when Thoracic Spine MRI is contraindicated or inappropriate:
- With any of the following new neurological deficits: lower extremity weakness; abnormal reflexes; or abnormal sensory changes along a particular dermatome (nerve distribution) as documented on physical exam.

For evaluation of suspected myelopathy when Thoracic Spine MRI is contraindicated (Behrbalk, 2013; ACR, 2015; Vitzthum, 2007):
- Progressive symptoms including unsteadiness, broad-based gait, increased muscle tone, pins and needles sensation, weakness and wasting of the lower limbs, and diminished sensation to light touch, temperature, proprioception, and vibration; bowel and bladder dysfunction in more severe cases.

For evaluation of chronic back pain with any of the following when Thoracic MRI is contraindicated (Jarvik, 2015; Miller, 2006):
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic, or cervical spine pain (NASS, 2013)).

For evaluation of new onset of back pain when Thoracic Spine MRI is contraindicated (AANSCNS, 2014):
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic, or cervical spine pain (NASS, 2013)).

**For evaluation of trauma or acute injury:**
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With progression or worsening of symptoms during the course of conservative treatment*.

**For evaluation of known tumor, cancer, or evidence of metastasis with any of the following (Miller 2006) (MRI is usually the preferred study but CT may help characterize solitary indeterminate lesions (Kim 2012)):**
• For staging of known tumor.
• For follow-up evaluation of patient undergoing active cancer treatment.
• Presents with new signs or symptoms (e.g. physical, laboratory, and/or imaging findings) of new tumor or change in tumor.
• Present with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
• With evidence of metastasis on bone scan or previous imaging study.

**For evaluation of suspected tumor when Thoracic Spine MRI is contraindicated or inappropriate (ACR 2015):**
• Prior abnormal or indeterminate imaging that requires further clarification.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated, OR evaluation of suspected metastases:**
• ≤5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine, or Lumbar Spine.

**For evaluation of known or suspected infection, abscess, or inflammatory disease when Thoracic MRI is contraindicated (ACR, 2015; Miller, 2006):**
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

**For evaluation of spine abnormalities related to immune system suppression, e.g., HIV, chemotherapy, leukemia, or lymphoma when Thoracic MRI is contraindicated (ACR, 2015):**
• As evidenced by signs/symptoms, laboratory or prior imaging findings.
• As part of initial post-operative / procedural evaluation (“CT best examination to assess for hardware complication, extent of fusion” (ACR 2015) and MRI for cord, nerve root compression, disc pathology, or post-op infection):
  • A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
  • Changing neurologic status post-operatively.
  • With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
  • Surgical infection as evidenced by signs/symptoms, laboratory, or prior imaging findings.
Continuing or recurring symptoms of any of the following neurological deficits: Lower extremity weakness, lower extremity asymmetric reflexes.

**Other indications for a Thoracic Spine CT:**

- For pre-operative evaluation and **Thoracic MRI is contraindicated**
- CT myelogram or discogram.
- Suspected cord compression with any of the following neurologic deficits, e.g., extremity weakness, abnormal gait, asymmetric reflexes, and Thoracic Spine MRI is contraindicated.
- Suspicious sacral dimples (those that are deep, larger than 0.5 cm, located within the superior portion of the gluteal crease or above the gluteal crease, or associated with other cutaneous markers) when Thoracic Spine MRI is contraindicated (D’Alessandro, 2009).
- Ankylosing Spondylitis/Spondyloarthropathies - For diagnosis when suspected as a cause of insidious onset (usually > 3 month) of back or sacroiliac pain associated with morning stiffness not relieved with rest (usually age at onset <40) AND satisfying any of the following (Akgul, 2011; Bennett, 2010; Ostergaard, 2012; Seiper, 2009):
  - Sedimentation rate and/or C-reactive protein (not an essential criteria).
  - HLA B27 (not an essential criteria).
  - Non-diagnostic or indeterminate x-ray
  - Personal or family history of sacroilitis, peripheral inflammatory arthritis, and/or inflammatory bowel disease.
- Known Arnold-Chiari syndrome and Thoracic MRI is contraindicated (Milhorat, 2009; Strahle, 2015).
- Syrinx or syringomyelia and Thoracic Spine MRI is contraindicated.
- Congenital abnormalities when Thoracic Spine MRI is contraindicated or for characterization of bone detail (Trenga, 2016):
  - Back pain and vertebral anomalies (hemivertebrae, hypoplasia, agenesis, butterfly, segmentation defect, bars, or congenital wedging) in a child on preliminary imaging.
  - Scoliosis with progressive spinal deformity, neurologic deficit or pre-operative planning.

**COMBINATION OF STUDIES WITH THORACIC SPINE CT:**

**Cervical/Thoracic/Lumbar CTs:**

- CT myelogram or discogram.
- Any combination of these for scoliosis survey in infant/child (Strahle, 2015).
- Any combination of these for spinal survey in patient with metastases.
- For evaluation of spinal abnormalities associated with Arnold-Chiari Malformation and Spine MRI is contraindicated. (C/T/L spine due to association with tethered cord and syringomyelia) (Milhorat, 2009; Strahle, 2015).

**ADDITIONAL INFORMATION RELATED TO THORACIC SPINE CT:**

**Conservative Therapy:** (spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (epidural, facet, bursal, and/or joint, not including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
• Information provided on exercise prescription/plan AND
• Follow up with member with documentation provided regarding completion of HEP (after suitable 6 week period), or inability to complete HEP due to physical reason—i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

Myelopathy: Symptom severity varies and a high index of suspicion is essential for making the proper diagnosis in early cases. Symptoms of pain and radiculopathy may not be present. The natural history of myelopathy is characterized by neurological deterioration. The most frequently encountered symptom is gait abnormality (86%) followed by increased muscular reflexes (79.1%), pathological reflexes (65.1%), paresthesia of upper limb (69.8%), and pain (67.4%) (Vitzthum, 2007).

CT and Infection of the spine · Infection of the spine is not easy to differentiate from other spinal disorders, e.g., degenerative disease, spinal neoplasms, and non-infective inflammatory lesions. Infections may affect different parts of the spine, e.g., vertebrae, intervertebral discs, and paraspinal tissues. Imaging is important to obtain early diagnosis and treatment to avoid permanent neurology deficits. When MRI is contraindicated, CT may be used to evaluate infections of the spine.

CT and Degenerative Disc Disease – Degenerative disc disease is very common and CT may be indicated when MRI is contraindicated, when chronic degenerative changes are accompanied by conditions, e.g., new neurological deficits; onset of joint tenderness of a localized area of the spine; new abnormal nerve conduction studies; exacerbation of chronic back pain unresponsive to conservative treatment; and unsuccessful physical therapy/home exercise program.

Sacral Dimples · Simple midline dimples are the most commonly encountered dorsal cutaneous stigmata in neonates and indicate low risk for spinal dysraphism. Only atypical dimples are associated with a high risk for spinal dysraphism, particularly those that are large (>5 mm), high on the back (>2.5 cm from the anus), or appear in combination with other lesions (D’Alessandro, 2009). High-risk cutaneous stigmata in neonates include hemangiomas, upraised lesions (i.e., masses, tails, and hairy patches), and multiple cutaneous stigmata.
REFERENCES


CPT Codes: 72131, 72132, 72133

INTRODUCTION:

Computed tomographic scans provide bone detail and define the bony anatomy in multiple planes. It demonstrates the lumbar subarachnoid space and provides moderately good visualization of the vertebral canal. Three-dimensional reconstructions using CT help to demonstrate the anatomy of the vertebral canal.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR LUMBAR SPINE CT:

For evaluation of known fracture:
- To assess union of a fracture where physical examination, plain radiographs, or prior imaging suggest delayed or non-healing
- To determine position of known fracture fragments.

For evaluation of neurologic deficits when Lumbar Spine MRI is contraindicated or inappropriate:
- With any of the following new neurological deficits: lower extremity weakness; abnormal reflexes; abnormal sensory changes along a particular dermatome (nerve distribution) as documented on exam; evidence of Cauda Equina Syndrome; bowel or bladder dysfunction; new foot drop.

For evaluation of chronic back pain with any of the following when Lumbar Spine MRI is contraindicated (ACR, 2015; AAFP, 2012; ACEP, 2014; NASS, 2013; Chou, 2007; Jarvik, 2015; Miller, 2006):
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic, or cervical spine pain (NASS, 2013)).

For evaluation of new onset of back pain when Lumbar Spine MRI is contraindicated (ACR, 2015; AANSCNS, 2014; ACA, 2017; ACEP, 2014; Chou, 2007):
- Failure of conservative treatment*, for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
- With an abnormal electromyography (EMG) or nerve conduction study if (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic, or cervical spine pain (NASS, 2013))

For evaluation of trauma or acute injury (ACR, 2012; Chou, 2007):
- Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes [along a particular dermatome (nerve distribution)].
- With progression or worsening of symptoms during the course of conservative treatment*. 
For evaluation of known tumor, cancer, or evidence of metastasis with any of the following (Miller, 2006) (MRI is usually the preferred study but CT may help characterize solitary indeterminate lesions (Kim, 2012)):

- For staging of known tumor.
- For follow-up evaluation of patient undergoing active cancer treatment.
- Presents with new signs or symptoms (e.g. physical, laboratory, and/or imaging findings) of new tumor or change in tumor.
- Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
- With evidence of metastasis on bone scan or previous imaging study.

For evaluation of suspected tumor when Lumbar Spine MRI is contraindicated or inappropriate (ACR, 2015):

- Prior abnormal or indeterminate imaging that requires further clarification

Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases:

- ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.

For evaluation of known or suspected infection, abscess, or inflammatory disease when Lumbar Spine MRI is contraindicated (ACR, 2015):

- As evidenced by signs/symptoms, laboratory or prior imaging findings.

For evaluation of spine abnormalities related to immune system suppression, e.g., HIV, chemotherapy, leukemia, or lymphoma and Lumbar Spine MRI is contraindicated (ACR, 2015):

- As evidenced by signs/symptoms, laboratory, or prior imaging findings.

Post-operative / procedural evaluation (“CT best examination to assess for hardware complication, extent of fusion” (ACR, 2015) and MRI for cord, nerve root compression, disc pathology, or post-op infection):

- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
- Changing neurologic status post-operatively.
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
- Surgical infection as evidenced by signs/symptoms, laboratory or prior imaging findings.
- Continuing or recurring symptoms of any of the following neurological deficits: Lower extremity weakness, lower extremity asymmetric reflexes.

Other indications for a Lumbar Spine CT:

- For preoperative evaluation and Lumbar Spine MRI is contraindicated
- CT myelogram or discogram.
- Suspicious sacral dimple (those that are deep, larger than 0.5 cm, located within the superior portion of the gluteal crease or above the gluteal crease, or associated with other cutaneous markers) when Lumbar Spine MRI is contraindicated (D’Alessandro, 2009).
• Tethered cord or spinal dysraphism (known or suspected) based on preliminary imaging, neurological exam, and/or cutaneous stigmata (AANS: Duz, 2008; Milhorat, 2009; NIH) when Lumbar Spine MRI is contraindicated.

• Ankylosing Spondylitis/Spondyloarthropathies - For diagnosis when suspected as a cause of insidious onset (usually > 3 month) of back or sacroiliac pain associated with morning stiffness not relieved with rest (usually age at onset <40) AND satisfying any of the following when Lumbar Spine MRI is contraindicated (Akgul, 2011; Bennett, 2010; Ostergaard, 2012; Seiper, 2009):
  o Sedimentation rate and/or C-reactive protein (not an essential criteria).
  o HLA B27 (not an essential criteria).
  o Non-diagnostic or indeterminate x-ray
  o Personal or family history of sacroilitis, peripheral inflammatory arthritis, and/or inflammatory bowel disease.

• Known Arnold-Chiari syndrome and Lumbar Spine MRI is contraindicated (Milhorat, 2009; Strahle, 2015).

• Congenital abnormalities when Lumbar Spine MRI is contraindicated or for characterization of boney detail (Trenga, 2016):
  o Back pain and vertebral anomalies (hemivertebrae, hypoplasia, agenesis, butterfly, segmentation defect, bars, or congenital wedging) in a child on preliminary imaging.
  o Scoliosis with progressive spinal deformity, neurologic deficit or pre-operative planning.

COMBINATION OF STUDIES WITH LUMBAR SPINE CT:

Cervical/Thoracic/Lumbar CTs:
• CT myelogram or discogram
• Any combination of these for scoliosis survey in infant/child when MRI is contraindicated (Strahle, 2015).
• Any combination of these for spinal survey in patient with metastasis.
• For evaluation of spinal abnormalities associated with Arnold-Chiari Malformation (C/T/L spine due to association with tethered cord and syringomyelia) (Milhorat, 2009; Strahle, 2015) and Lumbar Spine MRI is contraindicated.

ADDITIONAL INFORMATION RELATED TO LUMBAR SPINE CT:

*Conservative Therapy:* (spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (epidural, facet, bursal, and/or joint, not including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:
  o Information provided on exercise prescription/plan AND
  o Follow up with member with documentation provided regarding completion of HEP (after suitable 6 week period), or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).
**CT and Fracture of the Lumbar Spine** – CT scans of the lumbar spine generate high-resolution spinal images; this and the absence of superimposed structures allow accurate diagnosis of lumbar fractures.

**CT and Radiculopathy** – Lumbar radiculopathy is caused by compression of a nerve root and/or inflammation that has progressed enough to cause neurologic symptoms, e.g., numbness, tingling, and weakness in leg muscles. These are warning signs of a serious medical condition which needs medical attention. Multidetector CT may be performed to rule out or localize lumbar disk herniation before surgical intervention, when MRI is contraindicated. Radiation dose should be kept as low as possible in young individuals undergoing CT of the lumbar spine.

**CT and Infection of the Spine** – Infection of the spine is not easy to differentiate from other spinal disorders, e.g., degenerative disease, spinal neoplasms, and non-infective inflammatory lesions. Infections may affect different parts of the spine, e.g., vertebrae, intervertebral discs, and paraspinal tissues. Imaging is important to obtain early diagnose and treatment to avoid permanent neurology deficits. When MRI is contraindicated, CT may be used to evaluate infections of the spine.

**CT and Degenerative Disease of the Lumbar Spine** – Stenosis of the lumbar canal may result from degenerative changes of the discs, ligaments and facet joints surrounding the lumbar canal. Compression of the microvasculature of the bundle of nerve roots in the lumbosacral spine may lead to significant effects on the cauda equina. This is a surgical emergency and CT may be performed to help assess the problem when MRI is contraindicated or inappropriate. CT scans can provide visualization of the vertebral canal and may demonstrate encroachment of the canal by osteophytes, facets, pedicles or hypertrophied lamina.

**CT and Low Back Pain** – Low back pain by itself is a self-limited condition which does not warrant any imaging studies. One of the “red flags” signifying a more complicated status is focal neurologic deficit with progressive or disabling symptoms. When magnetic resonance imaging (MRI) is contraindicated, CT of the lumbar spine with or without contrast is indicated for low back pain accompanied by a “red flag” symptom. Myelography combined with post-myelography CT is accurate in diagnosing disc herniation and may be useful in surgical planning. CT may be indicated when MRI is contraindicated, and chronic back pain unresponsive to conservative treatment; and unsuccessful physical therapy/home exercise program.

**Tethered spinal cord syndrome** – a neurological disorder caused by tissue attachments that limit the movement of the spinal cord within the spinal column. Although this condition is rare, it can continue undiagnosed into adulthood. The primary cause is myelomeningocele and lipomyelomeningocele; the following are other causes that vary in severity of symptoms and treatment.

- Dermal sinus tract (a rare congenital deformity)
- Diastematomyelia (split spinal cord)
- Lipoma
- Tumor
- Thickened/tight filum terminale
- History of spine trauma/surgery
- Arnold Chiari Malformation

**Sacral Dimples** – Simple midline dimples are the most commonly encountered dorsal cutaneous stigmata in neonates and indicate low risk for spinal dysraphism. Only atypical dimples are associated with a high risk for spinal dysraphism, particularly those that are large (>5 mm), high on the back (>2.5 cm from the anus), or appear in combination with other lesions (D’Alessandro, 2009). High-risk cutaneous stigmata in
neonates include hemangiomas, upraised lesions (i.e., masses, tails, and hairy patches), and multiple cutaneous stigmata.
REFERENCES


CPT Codes: 72141, 72142, 72156

INTRODUCTION:

Magnetic resonance imaging (MRI) produces high quality multiplanar images of organs and structures within the body without radiation. It is the preferred modality for evaluating the internal structure of the spinal cord, providing assessment of conditions such as degenerative disc pathology, osteomyelitis, and discitis.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CERVICAL SPINE MRI:

For evaluation of known or suspected multiple sclerosis (MS) (ACR, 2015; Filippi, 2016):
- Evidence of MS on recent baseline Brain MRI.
- Suspected MS with new or changing symptoms consistent with cervical spinal cord disease.
- Follow up of known Multiple Sclerosis.
- Follow up to the initiation or change in medication for patient with known Multiple Sclerosis.
- Cervical and/or Thoracic MRI for evaluation of suspected multiple sclerosis (MS) when Brain MRI does not fulfill diagnostic criteria (Filippi, 2016).

For evaluation of neurologic deficits (ACR, 2013; Carette, 2005):
- With any of the following new neurological deficits: extremity weakness; abnormal reflexes; or abnormal sensory changes along a particular dermatome (nerve distribution) as documented on physical exam.

For evaluation of suspected myelopathy (Behrbalk, 2013; ACR, 2015; Vitzthum, 2007):
- Progressive symptoms including hand clumsiness, worsening handwriting, difficulty with grasping and holding objects, diffuse numbness in the hands, pins and needles sensation, increasing difficulty with balance and ambulation (unsteadiness, broad-based gait, increased muscle tone, weakness and wasting of the upper and lower limbs; diminished sensation to light touch, temperature, proprioception, vibration; bowel and bladder dysfunction in more severe cases).

For evaluation of chronic neck pain with any of the following (ACR, 2013; Ahmed, 2007):
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic or cervical spine pain (NASS, 2013))

For evaluation of new onset of neck pain:
- Failure of conservative treatment*, for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic or cervical spine pain (NASS, 2013)).

**For evaluation of trauma or acute injury (ACR, 2012):**
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With progression or worsening of symptoms during the course of conservative treatment*.
• When the patient is clinically unevaluable or there are preliminary imaging findings (X-ray or CT) needing further evaluation.
  (“MRI and CT provide complementary information”. When indicated, “It is appropriate to perform both examinations” (ACR, 2012)).

**For evaluation of known tumor, cancer, or evidence of metastasis with any of the following (MRI is usually the preferred study but CT may help characterize solitary indeterminate lesions (Kim, 2012)):**
• For staging of known tumor.
• For follow-up evaluation of patient undergoing active cancer treatment.
• Presents with new signs or symptoms (e.g. physical, laboratory, and/or imaging findings) of new tumor or change in tumor.
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality
• With evidence of metastasis on bone scan or previous imaging study.

**For evaluation of suspected tumor (ACR, 2013):**
• Prior abnormal or indeterminate imaging that requires further clarification.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated, OR evaluation of suspected metastases:**
• < 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.

**For evaluation of known or suspected infection, abscess, or inflammatory disease (ACR, 2013):**
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

**For evaluation of spine abnormalities related to immune system suppression, e.g., HIV, chemotherapy, leukemia, or lymphoma (Nagashima, 2010; Williams, 1999):**
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

**As part of initial post-operative / procedural evaluation (“CT best examination to assess for hardware complication, extent of fusion” (ACR, 2013) and MRI for cord, nerve root compression, disc pathology or post-op infection):**
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
• Changing neurologic status post-operatively.
• With an abnormal electromyography (EMG) or nerve conduction study if radicular symptoms are present.
• Surgical infection as evidenced by signs/symptoms, laboratory or prior imaging findings.
• Continuing or recurring symptoms of any of the following neurological deficits: Lower extremity weakness, lower extremity asymmetric reflexes.

**Other indications for a Cervical Spine MRI:**
• For preoperative evaluation.
• Suspected cord compression with any of the following neurological deficits: extremity weakness; abnormal gait; asymmetric reflexes.
• Suspicious sacral dimple (those that are deep, larger than 0.5 cm, located within the superior portion of the gluteal crease or above the gluteal crease, or associated with other cutaneous markers).
• Known Arnold-Chiari syndrome.
• Congenital abnormalities in the presence of neurologic deficit, progressive spinal deformity, or for preoperative planning (Trenta, 2016):
• Syringo or syringomyelia.

**COMBINATION OF STUDIES WITH CERVICAL SPINE MRI:**

**Cervical/Thoracic/Lumbar MRIs:**
• Any combination of these for scoliosis survey in infant/child (Strahle, 2015).
• Any combination of these for spinal survey in patient with metastases.
• For evaluation of spinal abnormalities associated with Arnold-Chiari Malformation. (C/T/L spine due to association with tethered cord and syringomyelia) (Milhorat, 2009; Strahle, 2015).

**Cervical MRI/CT**
• For unstable craniocervical junction.

**Brain MRI/Cervical MRI** –
• For evaluation of Arnold Chiari malformation.
• For follow-up of known Multiple Sclerosis (MS) (Filippi, 2016).

**ADDITIONAL INFORMATION RELATED TO CERVICAL SPINE MRI:**

*Conservative Therapy:* (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (epidural, facet, bursal, and/or joint, not including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:
• Information provided on exercise prescription/plan AND
• Follow up with member with documentation provided regarding completion of HEP (after suitable 6 week period), or inability to complete HEP due to physical reason i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

**Cervical myelopathy:** Symptom severity varies and a high index of suspicion is essential for making the proper diagnosis in early cases. Symptoms of pain and radiculopathy may not be present. The natural history of myelopathy is characterized by neurological deterioration. The most frequently encountered
Symptom is gait abnormality (86%) followed by increased muscular reflexes (79.1%), pathological reflexes (65.1%), paresthesia of upper limb (69.8%), and pain (67.4%) (Vitzthum, 2007).

**MRI for Evaluation of Discitis** – Discitis is a known complication of cervical discography. Postoperative discitis in the cervical spine does not occur frequently but can result from accidental inoculation of bacteria into the disc space intra-operatively by a contaminated spinal needle being used as a radiological marker. There may be other causes for postoperative discitis, e.g., esophageal perforation, hematogenous spread, inoculation of bacteria during surgery. Patients with an alteration in the nature of their symptoms after cervical discectomy and fusion may have discitis. Symptoms may include complaints of mild paresthesia in extremities and neck pain. MRI may be performed to reveal feature of discitis with associated abscesses and may help to confirm the diagnosis and decide on the further management.

**MRI for Cervical Radiculopathy** – MRI is a useful test to evaluate the spine because it can show abnormal areas of the soft tissues around the spine; it addition to the bones, it can also show pictures of the nerves and discs and is used to find tumors, herniated discs or other soft-tissue disorders. MRI has a role both in the pre-operative screening and post-operative assessment of radicular symptoms due to either disc or osteophyte.

**MRI and Multiple Sclerosis (MS)** – MRI is a sensitive method of detecting the white matter lesions of MS. These plaques on MRI generally appear as multiple, well demarcated, homogenous, small ovoid lesions which often lack mass effect and are oriented perpendicular to the long axis of the lateral ventricles. Sometimes they present as large, space occupying lesions that may be misinterpreted as tumors, abscesses, or infarcts.

**MRI and Neck Pain** – Neck pain is common in the general population and usually relates to musculoskeletal causes but it may also be caused by spinal cord tumors. When neck pain is accompanied by extremity weakness, abnormal gait, or asymmetric reflexes, spinal MRI may be performed to evaluate the cause of the pain. MRI may reveal areas of cystic expansion within the spinal cord. Enhancement with gadolinium contrast may suggest that the lesion is neoplastic.

**Back Pain with Cancer History** - Radiographic (x-ray) examination should be performed in cases of back pain when a patient has a cancer history. This can make a diagnosis in many cases. This may occasionally allow for selection of bone scan in lieu of MRI in some cases. When radiographs do not answer the clinical question, then MRI may be appropriate after a consideration of conservative care.

For example, bone metastases occur in a minority of all breast cancer patients. Low stage breast cancer patients are very unlikely to have bone metastases (Coleman, 1985). Radiographic (X-ray) evaluation prior to MRI is appropriate. A trial of conservative care in back pain is also indicated and appropriate in these low stage patients.

Advanced stage breast cancer patients do develop bone metastases in a slight majority of cases (Coleman, 1985). Back pain in advanced stage breast cancer patients should still be initially evaluated with X-ray (which has the chance of demonstrating cause of pain, or identifying multiple metastases and may change the subsequent imaging choice for optimal staging). However, these patients should, in most cases, not undergo a trial of conservative care.”

**Sacral Dimples** - Simple midline dimples are the most commonly encountered dorsal cutaneous stigmata in neonates and indicate low risk for spinal dysraphism. Only atypical dimples are associated with a high risk for spinal dysraphism, particularly those that are large (>5 mm), high on the back (>2.5 cm from the anus), or appear in combination with other lesions (D’ Alessandro, 2009). High-risk cutaneous stigmata in
neonates include hemangiomas, upraised lesions (i.e., masses, tails, and hairy patches), and multiple cutaneous stigmata.


INTRODUCTION:

Magnetic resonance imaging (MRI) produces high quality multiplanar images of organs and structures within the body without using ionizing radiation. It is used for evaluation, assessment of severity, and follow-up of diseases of the spine and is the preferred modality for imaging intervertebral disc degeneration. High contrast resolution (soft tissue contrast) and multiplanar imaging (sagittal as well as axial planes) are helpful in the evaluation of possible disc herniation and detecting nerve root compression. MRI is one of the most useful techniques to evaluate spine infection and is also used to evaluate tumors, cancer, and immune system suppression.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR THORACIC SPINE MRI:

Cervical and/or Thoracic MRI for evaluation of suspected multiple sclerosis (MS) when Brain MRI does not fulfill diagnostic criteria (Filippi, 2016).

For evaluation of neurologic deficits:
- With any of the following new neurological deficits: extremity weakness; abnormal reflexes; or abnormal sensory changes along a particular dermatome (nerve distribution) as documented on physical exam.

For evaluation of suspected myelopathy (Behrbalk, 2013; ACR, 2015; Vitzthum, 2007):
- Progressive symptoms including unsteadiness, broad-based gait, increased muscle tone, pins and needles sensation, weakness and wasting of the lower limbs, and diminished sensation to light touch, temperature, proprioception, and vibration; bowel and bladder dysfunction in more severe cases.

For evaluation of chronic back pain with any of the following (Jarvik, 2015; Miller, 2006):
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic or cervical spine pain (NASS, 2013)).

For evaluation of new onset of back pain (ANSCNS, 2014):
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*.
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic or cervical spine pain (NASS 2013)).

For evaluation of trauma or acute injury:
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With progression or worsening of symptoms during the course of conservative treatment*.

For evaluation of known tumor, cancer, or evidence of metastasis with any of the following (Miller 2006) (MRI is usually the preferred study but CT may help characterize solitary indeterminate lesions (Kim 2012)):
• For staging of known tumor.
• For follow-up evaluation of patient undergoing active cancer treatment.
• Presents with new signs or symptoms (e.g. physical, laboratory and/or imaging findings) of new tumor or change in tumor
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
• With evidence of metastasis on bone scan or previous imaging study.

For evaluation of suspected tumor (ACR 2015):
• Prior abnormal or indeterminate imaging that requires further clarification.

Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated, OR evaluation of suspected metastases:
• \leq 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.

For evaluation of known or suspected infection, abscess, or inflammatory disease (ACR 2015; Miller 2006):
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

For evaluation of spine abnormalities related to immune system suppression, e.g., HIV, chemotherapy, leukemia, or lymphoma (ACR 2015):
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

As part of initial post-operative / procedural evaluation (“CT best examination to assess for hardware complication, extent of fusion” (ACR 2015) and MRI for cord, nerve root compression, disc pathology or post-op infection):
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
• Changing neurologic status post-operatively.
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
• Surgical infection as evidenced by signs/symptoms, laboratory or prior imaging findings.
• Continuing or recurring symptoms of any of the following neurological deficits: Lower extremity weakness, lower extremity asymmetric reflexes.

Other indications for a Thoracic Spine MRI:
• For preoperative evaluation
• Suspected cord compression with any of the following neurological deficits: extremity weakness; abnormal gait; asymmetric reflexes.
• Suspicious sacral dimples (those that are deep, larger than 0.5 cm, located within the superior portion of the gluteal crease or above the gluteal crease, or associated with other cutaneous markers) (D’Alessandro, 2009).
• Ankylosing Spondylitis/Spondyloarthropathies - For diagnosis when suspected as a cause of insidious onset (usually > 3 month) of back or sacroiliac pain associated with morning stiffness not relieved with rest (usually age at onset <40) AND satisfying any of the following (Akgul, 2011; Bennett, 2010; Ostergaard, 2012; Seiper, 2014):
  o Sedimentation rate and/or C-reactive protein (not an essential criteria).
  o HLA B27 (not an essential criteria).
  o Non-diagnostic or indeterminate x-ray
  o Personal or family history of sacroilitis, peripheral inflammatory arthritis and/or inflammatory bowel disease.
• Known Arnold-Chiari syndrome (Milhorat, 2009; Strahle, 2015).
• Congenital abnormalities (Trenga, 2016):
  o Back pain and vertebral anomalies (hemivertebrae, hypoplasia, agenesis, butterfly, segmentation defect, bars, or congenital wedging) in a child on preliminary imaging.
  o Scoliosis with progressive spinal deformity, neurologic deficit or pre-operative planning.
• Syrinx or syringomyelia.

COMBINATION OF STUDIES WITH THORACIC SPINE MRI:

Cervical/Thoracic/Lumbar MRIs:
• Any combination of these for scoliosis survey in infant/child (Strahle, 2015).
• Any combination of these for spinal survey in patient with metastases.
• For evaluation of spinal abnormalities associated with Arnold-Chiari Malformation. (C/T/L spine due to association with tethered cord and syringomyelia) (Milhorat, 2009; Strahle, 2015).

ADDITIONAL INFORMATION RELATED TO THORACIC SPINE MRI

*Conservative Therapy: (spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (epidural, facet, bursal, and/or joint, not including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
  o Information provided on exercise prescription/plan AND
  o Follow up with member with documentation provided regarding completion of HEP (after suitable 6 week period), or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

Myelopathy: Symptom severity varies and a high index of suspicion is essential for making the proper diagnosis in early cases. Symptoms of pain and radiculopathy may not be present. The natural history of myelopathy is characterized by neurological deterioration. The most frequently encountered symptom is gait abnormality (86%) followed by increased muscular reflexes (79.1%), pathological reflexes (65.1%), paresthesia of upper limb (69.8%), and pain (67.4%) (Vitzthum, 2007).
**MRI and Spinal Infections** – Infection of the spine is not easy to differentiate from other spinal disorders, e.g., degenerative disease, spinal neoplasms, and noninfectious inflammatory lesions. Infections may affect different parts of the spine, e.g., vertebrae, intervertebral discs and paraspinal tissues. Imaging is important to obtain early diagnose and treatment to avoid permanent neurologic deficits. MRI is the preferred imaging technique to evaluate infections of the spine. With its high contrast resolution and direct multiplanar imaging, it has the ability to detect and delineate infective lesions irrespective of their spinal location.

**MRI and Degenerative Disc Disease** – Degenerative disc disease is very common and MRI is indicated when chronic degenerative changes are accompanied by conditions, e.g., new neurological deficits; onset of joint tenderness of a localized area of the spine; new abnormal nerve conduction studies; exacerbation of chronic back pain unresponsive to conservative treatment; and unsuccessful physical therapy/home exercise program.

**MRI and Multiple Sclerosis (MS)** – MRI is a sensitive method of detecting the white matter lesions of MS. These plaques on MRI generally appear as multiple, well demarcated, homogenous, small ovoid lesions which lack mass effect and are oriented perpendicular to the long axis of the lateral ventricles. Sometimes they present as large, space occupying lesions that may be misinterpreted as tumors, abscesses or infarcts.

**Back Pain with Cancer History** - Radiographic (x-ray) examination should be performed in cases of back pain when a patient has a cancer history. This can make a diagnosis in many cases. This may occasionally allow for selection of bone scan in lieu of MRI in some cases. When radiographs do not answer the clinical question, then MRI may be appropriate after a consideration of conservative care.

For example, bone metastases occur in a minority of all breast cancer patients. Low stage breast cancer patients are very unlikely to have bone metastases (Coleman 1985). Radiographic (X-ray) evaluation prior to MRI is appropriate. A trial of conservative care in back pain is also indicated and appropriate in these low stage patients.

Advanced stage breast cancer patients do develop bone metastases in a slight majority of cases (Coleman 1985). Back pain in advanced stage breast cancer patients should still be initially evaluated with X-ray (which has the chance of demonstrating cause of pain, or identifying multiple metastases, and may change the subsequent imaging choice for optimal staging). However, these patients should in most cases, not undergo a trial of conservative care.”

**Sacral Dimples** - Simple midline dimples are the most commonly encountered dorsal cutaneous stigmata in neonates and indicate low risk for spinal dysraphism. Only atypical dimples are associated with a high risk for spinal dysraphism, particularly those that are large (>5 mm), high on the back (>2.5 cm from the anus), or appear in combination with other lesions (D’ Alessandro, 2009). High-risk cutaneous stigmata in neonates include hemangiomas, upraised lesions (i.e., masses, tails, and hairy patches), and multiple cutaneous stigmata.
REFERENCES


CPT Codes: 72148, 72149, 72158

INTRODUCTION:
Magnetic resonance imaging (MRI) is used in the evaluation, diagnosis, and management of spine related conditions, e.g., degenerative disc disease, cauda equine compression, radiculopathy, infections, or cancer in the lumbar spine. MRI provides high quality multiplanar images of organs and structures within the body without the use of x-rays or radiation. In the lumbar area where gonadal exposure may occur, MRI's lack of radiation is an advantage.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR LUMBAR SPINE MRI:

For evaluation of neurologic deficits:
- With any of the following new neurological deficits: lower extremity weakness; abnormal reflexes; abnormal sensory changes along a particular dermatome (nerve distribution) as documented on exam; evidence of Cauda Equina Syndrome; bowel or bladder dysfunction; new foot drop.

For evaluation of chronic back pain with any of the following (ACR, 2015; AAFP, 2012; ACEP, 2014; NASS, 2013; Chou, 2007; Jarvik, 2015; Miller, 2006):
- Failure of conservative treatment* for at least six (6) weeks within the last six (6) months
- With progression or worsening of symptoms during the course of conservative treatment*
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality. (EMG is not recommended to determine the cause of axial lumbar, thoracic or cervical spine pain (NASS, 2013)).

For evaluation of new onset of back pain (ACR, 2015; AANSCNS, 2014; ACA, 2017; ACEP, 2014; Chou, 2007):
- Failure of conservative treatment*, for at least six (6) weeks within the last six (6) months.
- With progression or worsening of symptoms during the course of conservative treatment*
- With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality (EMG is not recommended to determine the cause of axial lumbar, thoracic or cervical spine pain (NASS, 2013)).

For evaluation of trauma or acute injury (ACR 2012; Chou 2007):
- Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
- With progression or worsening of symptoms during the course of conservative treatment*.

For evaluation of known tumor, cancer, or evidence of metastasis with any of the following (Miller, 2006) (MRI is usually the preferred study but CT may help characterize solitary indeterminate lesions (Kim, 2012)):
- For staging of known tumor.
- For follow-up evaluation of patient undergoing active cancer treatment.
• Presents with new signs or symptoms (e.g. physical, laboratory and/or imaging findings) of new tumor or change in tumor
• Presents with radiculopathy, muscle weakness, abnormal reflexes, and/or sensory changes along a particular dermatome (nerve distribution).
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
• With evidence of metastasis on bone scan or previous imaging study.

For evaluation of suspected tumor (ACR, 2015):
• Prior abnormal or indeterminate imaging that requires further clarification.

Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated, OR evaluation of suspected metastases:
• ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.

For evaluation of known or suspected infection, abscess, or inflammatory disease (ACR, 2015; Miller, 2006):
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

For evaluation of spine abnormalities related to immune system suppression, e.g., HIV, chemotherapy, leukemia, or lymphoma (ACR, 2015):
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

As part of initial post-operative / procedural evaluation (“CT best examination to assess for hardware complication, extent of fusion” (ACR, 2015) and MRI for cord, nerve root compression, disc pathology, or post-op infection):
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
• Changing neurologic status post-operatively.
• With an abnormal electromyography (EMG) or nerve conduction study (if performed) indicating a spinal abnormality.
• Surgical infection as evidenced by signs/symptoms, laboratory or prior imaging findings.
• Continuing or recurring symptoms of any of the following neurological deficits: Lower extremity weakness, lower extremity asymmetric reflexes.

Other indications for a Lumbar Spine MRI:
• For preoperative evaluation.
• Tethered cord, or spinal dysraphism (known or suspected) based on preliminary imaging, neurological exam, and/or cutaneous stigmata (AANS; Duz, 2008; Milhorat, 2009; NIH).
• Suspicious sacral dimple (those that are deep, larger than 0.5 cm, located within the superior portion of the gluteal crease or above the gluteal crease, or associated with other cutaneous markers) (D’Alessandro, 2009).
• Ankylosing Spondylitis/Spondyloarthropathies - For diagnosis when suspected as a cause of insidious onset (usually > 3 month) of back or sacroiliac pain associated with morning stiffness not relieved with rest (usually age at onset <40) AND satisfying any of the following: (Akgul, 2011; Bennett, 2010; Ostergaard, 2012; Seiper, 2014):
  o Sedimentation rate and/or C-reactive protein (not an essential criteria).
  o HLA B27 (not an essential criteria).
- Non-diagnostic or indeterminate x-ray
- Personal or family history of sacroilitis, peripheral inflammatory arthritis, and/or inflammatory bowel disease.

- Known Arnold-Chiari syndrome (Milhorat, 2009; Strahle, 2015).
- Congenital abnormalities (Trenga, 2016):
  - Back pain and vertebral anomalies (hemivertebrae, hypoplasia, agenesis, butterfly, segmentation defect, bars, or congenital wedging) in a child on preliminary imaging.
  - Scoliosis with progressive spinal deformity, neurologic deficit, or pre-operative planning.

COMBINATION OF STUDIES WITH LUMBAR SPINE MRI:

Cervical/Thoracic/Lumbar MRIs:
- Any combination of these for scoliosis survey in infant/child (Strahle, 2015).
- Any combination of these for spinal survey in patient with metastasis.
- For evaluation of spinal abnormalities associated with Arnold-Chiari Malformation (C/T/L spine due to association with tethered cord and syringomyelia) (Milhorat, 2009; Strahle, 2015).

ADDITIONAL INFORMATION RELATED TO LUMBAR SPINE MRI:

*Conservative Therapy*: (spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (epidural, facet, bursal, and/or joint, not including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:
- Information provided on exercise prescription/plan AND
- Follow up with member with documentation provided regarding completion of HEP (after suitable 6 week period), or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

MRI and Back Pain – MRI is the initial imaging modality of choice in the evaluation of complicated low back pain. Contrast administration may be used to evaluate suspected inflammatory disorders, e.g., discitis, and it is useful in evaluating suspected malignancy. Radiculopathy, disease of the nerve roots is the most common indication for MRI of patients with low back pain. The nerve roots become irritated and inflamed, due to direct pressure from degenerative changes in the lumbar spine, creating pain and numbness. Symptoms of radiculopathy also include muscle weakness. MRI is indicated for this condition if the symptoms do not improve after conservative treatment over six weeks. MRI is also performed to evaluate Cauda equina syndrome, severe spinal compression.

Sacral Dimples - Simple midline dimples are the most commonly encountered dorsal cutaneous stigmata in neonates and indicate low risk for spinal dysraphism. Only atypical dimples are associated with a high risk for spinal dysraphism, particularly those that are large (>5 mm), high on the back (>2.5 cm from the anus), or appear in combination with other lesions (D’ Alessandro, 2009). High-risk cutaneous stigmata in neonates include hemangiomas, upraised lesions (i.e., masses, tails, and hairy patches), and multiple cutaneous stigmata.
**Tethered spinal cord syndrome** - a neurological disorder caused by tissue attachments that limit the movement of the spinal cord within the spinal column. Although this condition is rare, it can continue undiagnosed into adulthood. The primary cause is myelomeningocele and lipomyelomeningocele; the following are other associations that vary in severity of symptoms and treatment.

- Dermal sinus tract (a rare congenital deformity)
- Diastematomyelia (split spinal cord)
- Lipoma
- Tumor
- Thickened/tight filum terminale
- History of spine trauma/surgery
- Arnold Chiari Malformation

Magnetic resonance imaging (MRI) can display the low level of the spinal cord and a thickened filum terminale, the thread-like extension of the spinal cord in the lower back. Treatment depends upon the underlying cause of the tethering. If the only abnormality is a thickened, shortened filum then limited surgical treatment may suffice.

**Back Pain with Cancer History** - Radiographic (x-ray) examination should be performed in cases of back pain when a patient has a cancer history. This can make a diagnosis in many cases. This may occasionally allow for selection of bone scan in lieu of MRI in some cases. When radiographs do not answer the clinical question, then MRI may be appropriate after a consideration of conservative care.

For example, bone metastases occur in a minority of all breast cancer patients. Low stage breast cancer patients are very unlikely to have bone metastases (Coleman, RE). Radiographic (X-ray) evaluation prior to MRI is appropriate. A trial of conservative care in back pain is also indicated and appropriate in these low stage patients.

Advanced stage breast cancer patients do develop bone metastases in a slight majority of cases (Coleman, RE). Back pain in advanced stage breast cancer patients should still be initially evaluated with X-ray (which has the chance of demonstrating cause of pain, or identifying multiple metastases, and may change the subsequent imaging choice for optimal staging). However, these patients should, in most cases, not undergo a trial of conservative care.”
REFERENCES


CPT Codes: 72159

INTRODUCTION:

Application of spinal magnetic resonance angiography (MRA) allows for more effective and noninvasive screening for vascular lesions than magnetic resonance imaging (MRI) alone. It may improve characterization of normal and abnormal intradural vessels while maintaining good spatial resolution. Spinal MRA may be used for the evaluation of spinal arteriovenous malformations, as well as injuries to blood vessels supplying the spine and cord.

INDICATIONS FOR SPinal CANAL MRA:

- For the evaluation of spinal arteriovenous malformation (AVM) (Backes, 2008; Mathur, 2017; Mull, 2007; NIH, 2009; Rohany, 2007; Saraf-Lavi, 2002).
- For the evaluation of a known cervical spine fracture, disc herniation, infection or venous thrombosis where there is concern for vascular pathology (compression or thrombosis) compromising spinal cord blood flow or venous drainage (ACR, 2015; Vargas, 2015).
- For the evaluation of known or suspected vertebral artery injury when there is also concern for vascular compromise to the spinal canal and its contents (otherwise Neck MRA or CTA is sufficient to evaluate vertebral artery injury).
- Preoperative evaluation (e.g. localization of the spinal arteries prior to complex spinal surgery, aortic aneurysm repair, or characterization of suspected vascular lesion of the spinal canal and its contents) (Backes, 2008).
- Myelopathy when the suspected etiology is compromising of blood flow or drainage to the spinal cord (ACR, 2015; Vargas, 2015).
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested (Mathur, 2017).

ADDITIONAL INFORMATION RELATED TO SPINAL CANAL MRA:

Spinal Arteriovenous Malformations (AVMs) – Spinal cord arteriovenous malformations are comprised of snarled tangles of arteries and veins which affect the spinal cord. They are fed by spinal cord arteries and drained by spinal cord veins. Magnetic resonance angiography (MRA) can record the pattern and velocity of blood flow through vascular lesions as well as the flow of cerebrospinal fluid throughout the spinal cord. MRA defines the vascular malformation and may assist in determining treatment.

Spinal MRA/MRV (Backes, 2008; Vargas, 2015; Mathur, 2017):

Typically, contrast enhanced 3D time of flight techniques and contrast enhanced CT angiography (CTA) are used for evaluation of the spinal arteries and veins as a non-invasive alternative to catheter angiography. The detection rate of the Adamkiewicz artery (AKA) by MRA is in the range of 69-100% but with modern equipment both MRA and CTA detection rates should approach 100% (Backes, 2008). Magnetic resonance angiography is well suited to patients who cannot receive iodinated contrast and undergo CTA. CTA has the advantage over MRA of providing greater spatial resolution, can image the
entire spine during one contrast bolus, and provides for a faster exam time that is less prone to motion artifact. MRA is limited by a finite field of view typically <= 50 cm (Backes, 2008). MRI has the advantage over CT of being able to detect areas of ischemia through the use of diffusion weighted imaging. Mathur et al showed a 100% sensitivity in detecting recurrent spinal arteriovenous fistulas post treatment (Mathur, 2017).

**Spinal Arteries/Veins (Vargas, 2015):**
Vascular malformations, trauma, disc herniations, neoplasms, and coagulopathies or infection causing thrombosis can compromise the spinal cord blood supply and drainage. The spinal cord arterial supply is derived from the anterior spinal artery, posterolateral spinal artery, and the arteria radicularis magna or artery of Adamkiewicz (AKA). The anterior spinal artery supplies the anterior two-thirds of the cord and arises from the vertebral arteries. It receives contributions from the ascending cervical artery, the inferior thyroid artery, the intercostal arteries, the lumbar artery, the iliolumbar artery, lateral sacral arteries, and the artery of Adamkiewicz. The AKA arises on the left side of the aorta between the T8 and L1 segments, to anastomose with the anterior spinal artery and supply the lower two-thirds of the spinal. Two posterolateral spinal arteries arise from the postero inferior cerebellar arteries and supply the posterior third (posterior columns, posterior roots, and dorsal horns) of the spinal cord. The spinal venous system is divided into intrinsic and extrinsic veins differentiated by their location within the spinal canal or extrinsic to the canal, respectively. They drain into the radiculomedullary veins, subsequently to paravertebral and intervertebral plexuses then to the segmental veins that eventually drain into the ascending lumbar veins, azygos system, and pelvic venous plexuses.
REFERENCES


INTRODUCTION:

Computed tomographic angiography (CTA) is used in the evaluation of many conditions affecting the veins and arteries of the pelvis or lower extremities. It is not appropriate as a screening tool for asymptomatic patients without a previous diagnosis.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR PELVIS CTA:

For evaluation of known or suspected vascular disease:

- For pelvic extent of known large vessel diseases (abdominal aorta, inferior vena cava, superior/inferior mesenteric, celiac, splenic, renal or iliac arteries/veins), e.g., aneurysm, dissection, arteriovenous malformations (AVMs), and fistulas, intramural hematoma, and vasculitis.
- Evidence of vascular abnormality seen on prior imaging studies.
- For suspected pelvic extent of aortic dissection.
- Evaluation of known or suspected aneurysms limited to the pelvis or in evaluating pelvic extent of aortic aneurysm (Khosa, 2011; Uberoi, 2011)**.
  - Known or suspected iliac artery aneurysm >2.5 cm AND equivocal or indeterminate ultrasound results OR
  - Prior imaging (e.g. ultrasound) demonstrating iliac artery aneurysm >2.5 cm in diameter OR
  - Suspected complications of known aneurysm as evidenced by clinical findings such as new onset of pelvic pain.
  - Follow up of iliac artery aneurysm: Six months if between 3.0-3.5 cm and if stable, follow yearly. If >3.5 cm, <six month follow up (and consider intervention)
- Suspected retroperitoneal hematoma or hemorrhage (To determine vascular source of hemorrhage in setting of trauma, tumor invasion, fistula or vasculitis; otherwise CT (rather than CTA) is sufficient and the modality of choice for diagnosing hemorrhage).
- For evaluation of suspected pelvic vascular disease when findings on ultrasound are indeterminate (MR or CT venography may be used as the initial study for pelvic thrombosis or thrombophlebitis) (ACR, 2013).
- Venous thrombosis if previous studies have not resulted in a clear diagnosis (ACR, 2013).
- Vascular invasion or displacement by tumor (Conventional CT or MRI also appropriate) (Certik, 2015; Kaufman, 2005).
- Pelvic vein thrombosis or thrombophlebitis (ACR, 2013).
- For evaluation of suspected pelvic vascular disease when findings on ultrasound are indeterminate (MR or CT venography may be used as the initial study for evaluating pelvic thrombosis or thrombophlebitis) (ACR, 2013).
- Mesenteric ischemia/ ischemic colitis (CTA is usually the preferred study (ACR, 2012)).
- Lower gastrointestinal hemorrhage: Active bleeding in a hemodynamically stable patient or non localized intermittent bleeding as an alternative to Tc-99m RBC scan when colonoscopy did not localize the bleeding, is contraindicated or unavailable (ACR, 2014; Clerc, 2017).
Pre-operative evaluation (ACR, 2017):
- Evaluation of interventional vascular procedures prior to endovascular aneurysm repair (EVAR), or for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.

Post-operative or post-procedural evaluation:
- Evaluation of endovascular/interventional vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.
- Evaluation of post-operative complications e.g., pseudoaneurysms, related to surgical bypass grafts, vascular stents and stent-grafts in the peritoneal cavity.
- Follow-up for post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA) and iliac artery aneurysms. Routine, baseline study (post-op/intervention) is warranted within 1-3 months (Chaikof, 2018; Uberoi, 2011).
  - Asymptomatic at six (6) month intervals, for one (1) year, then annually.
  - Symptomatic/complications related to stent graft – more frequent imaging may be needed.
- Follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Chest CTA/Pelvis CTA combo:
- For evaluation of extensive vascular disease involving the chest and abdominal cavities such as aortic dissection, vasculitic diseases such as Takayasu’s arteritis, significant post-traumatic or post-procedural vascular complications, etc.
- For preoperative or preprocedural evaluation such as transcatheter aortic valve replacement (TAVR).

ADDITIONAL INFORMATION RELATED TO PELVIS CTA:

Abd/Pelvis CTA & Lower Extremity CTA Runoff Requests: Only one authorization request is required, using CPT Code 75635 Abdominal Arteries CTA. This study provides for imaging of the abdomen, pelvis and both legs. The CPT code description is CTA aorto-iliofemoral runoff; abdominal aorta and bilateral ilio-femoral lower extremity runoff.

Bruit: blowing vascular sounds heard over partially occluded blood vessels. Abdominal bruits may indicate partial obstruction of the aorta or other major arteries such as the renal, iliac, or femoral arteries. Associated risks include but are not limited to: renal artery stenosis, aortic aneurysm, atherosclerosis, AVM, or coarctation of aorta.

Peripheral Artery Disease (PAD) – Before the availability of computed tomography angiography (CTA), peripheral arterial disease was evaluated using CT and only a portion of the peripheral arterial tree could be imaged. Multi-detector row CT (MDCT) overcomes this limitation and provides an accurate alternative to CT and is a cost-effective diagnostic strategy in evaluating PAD.

*MRI/CT and acute hemorrhage: MRI is not indicated and MRA/MRV (MR Angiography/Venography) is rarely indicated for evaluation of intraperitoneal or retroperitoneal hemorrhage, particularly in the acute setting. CT is the study of choice due to its availability, speed of the study and less susceptibility to artifact from patient motion. Advances in technology have allowed conventional CT to not just detect hematomas but also the source of acute vascular extravasation. In special cases finer vascular detail to
assess the specific source vessel responsible for hemorrhage may require the use of CTA. CTA in diagnosis of lower gastrointestinal bleeding is such an example (Clerc, 2017).

MRA/MRV is often utilized in non acute situations to assess vascular structure involved in atherosclerotic disease and its complications, vasculitis, venous thrombosis, vascular congestion or tumor invasion. Although some of these conditions may be associated with hemorrhage, it is usually not the primary reason why MRI/MRA/MRV is selected for the evaluation. A special condition where MRI may be superior to CT for evaluating hemorrhage is to detect an underlying neoplasm as the cause of bleeding (Abe, 2010).

**Follow-up of asymptomatic incidentally-detected iliac artery aneurysms (Uberoi, 2011):**
- <3.0 cm: rarely rupture, grow slowly, follow-up not generally needed
- 3.0-3.5 cm: followed up initially at 6 months
  - if stable, then annual imaging
- >3.5 cm: greater likelihood of rupture
  - <6 month follow up
  - consider intervention
REFERENCES


CPT Codes: 72192, 72193, 72194

INTRODUCTION:

CT provides direct visualization of anatomic structures in the abdomen and pelvis and is a fast imaging tool used to detect and characterize disease involving the abdomen and pelvis. Pelvic imaging begins at the iliac crests through pubic symphysis. It has an ability to demonstrate abnormal calcifications or fluid/gas patterns in the viscera or peritoneal space.

In general, ionizing radiation from CT should be avoided during pregnancy. Ultrasound is clearly a safer imaging option and is the first imaging test of choice, although CT after equivocal ultrasound has been validated for diagnosis. Clinicians should exercise increased caution with CT imaging in children, pregnant women, and young adults due to the risks of exposure to ionizing radiation. Screening for pregnancy as part of a work-up is suggested to minimize the number of unexpected radiation exposures for women of childbearing age.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR PELVIS CT:

Initial staging of prostate cancer (NCCN, 2017):
PSA levels >20 ng/mL, biopsy, Gleason Score ≥8, or clinically advanced disease (T3, T4 or T1-T2 and nomogram (e.g. Partin, cancer of prostate risk assessment CAPRA) indicating probability of lymph node involvement >10%).

Known prostate cancer for workup of recurrence and response to treatment (NCCN, 2017):
- Initial treatment by radical prostatectomy:
  - Failure of PSA to fall to undetectable levels or PSA detectable and rising on at least 2 subsequent determinations.
- Initial treatment radiation therapy:
  - Post-RT rising PSA or positive digital exam and is candidate for local therapy.

Evaluation of suspicious known mass/tumors (unconfirmed diagnosis of cancer) for further evaluation of indeterminate or questionable findings:
- Initial evaluation of suspicious pelvic masses/tumors found only in the pelvis by physical exam and ultrasound has been performed or for further evaluation of abnormality seen on ultrasound (US) or when US would be inconclusive (ACR, 2013, 2014).
- Surveillance: One follow-up exam to ensure no suspicious change has occurred in a tumor in the pelvis. No further surveillance CT unless tumor(s) are specified as highly suspicious or change was found on exam or last follow-up imaging.

Evaluation of known cancer for further evaluation of indeterminate or questionable findings, identified by physical examination or imaging exams such as ultrasound (US):
- Initial staging of known cancer
  - All cancers, excluding the following:
• Basal Cell Carcinoma of the skin (NCCN, 2018).
• Melanoma without symptoms or signs of metastasis (NCCN, 2018; Trotter, 2013).
• Prostate cancer: unless PSA > 20 ng/ml, Gleason score on biopsy >= 8 or clinically advanced disease (T3, T4 or T1-T2 and nomogram (e.g. Partin, cancer of prostate risk assessment CAPRA) indicating probability of lymph node involvement >10%) (NCCN, 2017).

• Follow-up of Known Cancer (NCCN, 2018; Bourgioti, 2016):
  o Follow-up of known cancer of patient undergoing active treatment within the past year.
  o Known cancer with suspected pelvis metastasis based on a sign, symptom or an abnormal lab value.
  o Active monitoring for recurrence as clinically indicated.

For evaluation of enlargement of organ or abnormality seen on previous imaging:
• Evaluation of an organ enlargement such as uterus or ovaries as evidenced by physical examination or an abnormality on prior ultrasound.
• Further evaluation of organ enlargement or abnormality seen on previous imaging.

For evaluation of suspected infection or inflammatory disease (ACR, 2013; Cartwright 2015; McKay 2007):
• Suspected acute appendicitis (or severe acute diverticulitis) in and adult if pelvic pain and tenderness to palpation is present, with at LEAST one of the following:
  o WBC elevated
  o Fever
  o Anorexia or
  o Nausea and vomiting.
• Suspected appendicitis in a child after ultrasound has been obtained (Choose Wisely, ACR/AAP/ACS).
• Suspected complications of diverticulitis (known to be limited to the pelvis by prior imaging) with pelvic pain or severe tenderness, not responding to antibiotic treatment.
• Suspected infection (based on elevated WBC, fever, anorexia or nausea and vomiting) in the pelvis.
• Suspected inflammatory bowel disease (Crohn’s or ulcerative colitis) with abdominal pain, and persistent diarrhea, or bloody diarrhea.

For evaluation of known infection or inflammatory disease follow up (ACR, 2013, 2014):
• Complications of diverticulitis with severe pelvic pain or severe tenderness or mass, not responding to antibiotic treatment, (prior imaging study is not required for diverticulitis diagnosis).
• Known inflammatory bowel disease, (Crohn’s or ulcerative colitis) with recurrence or worsening signs/symptoms requiring re-evaluation.
• Any known infection that is clinically suspected to have created an abscess in the pelvis.
• Any history of fistula limited to the pelvis that requires re-evaluation, or is suspected to have recurred.
• Abnormal fluid collection seen on prior imaging that needs follow-up evaluation.
• Known infection in the pelvis.

For evaluation of known or suspected vascular disease (e.g., aneurysms, hematomas) (Khosa, 2011; Uberoi, 2011) **:
• Evidence of vascular abnormality identified on imaging studies.
• Evaluation of suspected or known aneurysms limited to the pelvis or in evaluating pelvic extent of aortic aneurysm
- Suspected or known iliac artery aneurysm >2.5 cm AND equivocal or indeterminate ultrasound results OR
- Prior imaging (e.g. ultrasound) demonstrating iliac artery aneurysm >2.5 cm in diameter OR
- Suspected complications of known aneurysm as evidenced by clinical findings such as new onset of pelvic pain.
- Follow up of iliac artery aneurysm: Six month if between 3.0-3.5 cm and if stable follow yearly. If >3.5cm, <six month follow up (and consider intervention)
  - Scheduled follow-up evaluation of aorto/iliac endograft or stent.
    - Asymptomatic at six (6) month intervals, for two (2) years
    - Symptomatic/complications related to stent graft – more frequent imaging may be needed.
- Suspected retroperitoneal hematoma or hemorrhage.

**For evaluation of trauma (ACR, 2012):**
- For evaluation of trauma with lab or physical findings of pelvic bleeding.
- For evaluation of physical or radiological evidence of pelvis fracture.

**Pre-operative evaluation:**
- For pelvic surgery or procedure.

**For post-operative/procedural evaluation:**
- Follow-up of known or suspected post-operative complication involving the hips or the pelvis (Davis, 2016; Yanny, 2012).
- A follow-up study to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases:**
- < 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.

**Other indications for Pelvic CT:**
- Persistent pelvic pain not explained by previous imaging/procedure.
- Unexplained pelvic pain in patients seventy-five (75) years or older.
- Hernia with suspected complications (e.g. bowel obstruction or strangulation) or prior to surgical repair or when physical exam or prior imaging (e.g. ultrasound) is non-diagnostic or equivocal (Lassandro, 2011; Miller, 2014; Robinson, 2013).
- Ischemic bowel (Dhatt, 2015).
- Known or suspected aseptic/avascular necrosis of hip(s) and MRI is contraindicated after completion of initial x-ray (ACR, 2015).
- Sacroiliitis (infectious or inflammatory) after completion of initial x-ray and MRI is contraindicated (ACR, 2016; Jans, 2014).
- Sacroiliac joint dysfunction and MRI contraindicated when there is:
  - Persistent back and/or sacral pain unresponsive to four (4) weeks of conservative treatment, received within the past six (6) months, including physical therapy or physician supervised home exercise plan (HEP).

**Combination of studies with Pelvis CT:**
- Abdomen CT/Pelvis CT/Chest CT/Neck MRI/Neck CT – known tumor/cancer for initial staging or evaluation before starting chemotherapy or radiation treatment.
If an Abdomen/Pelvis CT combo is indicated and the Abdomen CT has already been approved, then the Pelvis CT may be approved.

**ADDITIONAL INFORMATION RELATED TO PELVIS CT:**

Ultrasound should be considered prior to a request for Pelvis CT for the following evaluations:
- Evaluation or follow up of ovarian mass
- Repeat CT for aneurysm ordered by non-surgeon.

**CT for organ enlargement** - An Abd/pelvis combo is most appropriate because it will demonstrate the kidneys and the ureters. Other organs may require an Abdomen CT or Pelvis CT only.

**CT for suspected renal stones** - An initial CT study is done to identify the size of the stone and rule out obstruction. *(7 mm is the key size· less than that size the expectation is that it will pass)* After the initial CT study for kidney stone is done, the stone can be followed by x-ray or US (not CT). If a second exacerbation occurs/a new stone is suspected another CT would be indicated to access the size of stone and rule out obstruction.

**CT Imaging for Renal Colic and Hematuria** – Multidetector computed tomography (CT) is the modality of choice for the evaluation of the urinary tract. It is fast and it has good spatial resolution. It is superior to plain-film for imaging the renal parenchyma. CT protocols include: “stone protocol” for detecting urinary tract calculi, “renal mass protocol” for characterizing known renal masses and CT urography for evaluating hematuria. Non-contrast CT can be used for detecting most ureteral and renal stones but sometimes an intravenous contrast agent is needed to determine the relationship of the calculus to the opacified ureter. CT is an effective imaging examination for diagnosing hematuria caused by urinary tract calculi, renal tumors, and urothelial tumors.

**CT Imaging for Abdominal and Pelvic Aneurysms** – Abdominal and pelvic aneurysms are usually asymptomatic and most are discovered during imaging studies ordered for other indications or, particularly in the abdomen, on physical examination as a pulsatile mass. If a pulsatile abdominal mass is found, abdominal ultrasonography is an inexpensive and noninvasive technique for examination. For further examination, CT may be performed to better define the shape and extent of the aneurysm and the local anatomic relationships of the visceral and renal vessels. CT has high level of accuracy in sizing aneurysms.

**Follow-up of asymptomatic incidentally-detected iliac artery aneurysms (Uberoi, 2011):**
- <3.0 cm: rarely rupture, grow slowly, follow-up not generally needed
- 3.0-3.5 cm: followed up initially at 6 months
  o if stable, then annual imaging
- >3.5 cm: greater likelihood of rupture
  o <6 month follow up
  o consider intervention

**Combination request of Abdomen CT/Chest CT** - A Chest CT will produce images to the level of L3. Documentation for combo is required.
Hematuria and CT Imaging of Urinary Tract – Multidetector CT urography is a first line of investigation in patients with hematuria due to its ability to display the entire urinary tract, including renal parenchyma, pelvicaliceal systems, ureters and bladder with a single imaging test. To evaluate hematuria, the urinary tract is assessed for both calculi and neoplasms of the kidney and or urothelium.

Helical CT of Prostate Cancer – Conventional CT is not useful in detecting prostate cancer as it does not allow direct visualization. Contrast-enhanced MRI is more useful in detecting prostate cancer. MRI is recommended in patients with suspected cancer but prior negative biopsy because MRI alone can miss up to 26% of clinically significant cancers that would be detected on systemic biopsy (Borofsky, 2018). Helical CT of the prostate may be a useful alternative to MRI in patients with an increasing PSA level and negative findings on biopsy but is not the imaging study of choice.

Prostate Cancer – For symptomatic patients and/or those with a life expectancy of greater than 5 years, a bone scan is appropriate for patients with T1 to T2 disease who also have a PSA greater than 20ng/ml or a Gleason score of 8 or higher. Patients with a T3 to T4 disease or symptomatic disease should also receive a bone scan. Pelvic computed tomography (CT) or magnetic resonance imaging (MRI) scanning is recommended if there is T3 (tumor extent outside prostate with (T3b) or without (T3a) seminal vesicle invasion) or T4 (outside prostate but more extensive than seminal vesicle involvement) disease, or T1 (limited prostate volume involvement, typically <5%) or T2 (more extensive involvement confined to prostate) disease and a nomogram (combination of information, e.g. Gleason score, clinical stage and PSA) indicates that there is greater than 10% chance of lymph node involvement, although staging studies may not be cost effective until the chance of lymph node positively reaches 45%. Biopsy should be considered for further evaluation of suspicious nodal findings. For all other patients, no additional imaging is required for staging.

Pelvic Trauma and CT Imaging – Helical CT is useful in the evaluation of low or high flow vascular injuries in patient with blunt pelvic trauma. It provides detailing of fractures and position of fracture fragments along with the extent of diastasis of the sacroiliac joints and pubic symphysis. CT helps determine whether pelvic bleeding is present and can identify the source of bleeding. With CT, high flow hemorrhage can be distinguished from low flow hemorrhage aiding the proper treatment.

Bladder Cancer and CT Imaging – The diagnosis of upper tract transitional cell carcinoma is dependent on imaging. CT urography is increasingly being used in the imaging of the upper urinary tract in patients with bladder cancer. Multidetector CT scans are more accurate than the older ones and are used in the diagnosis, staging and surveillance of transitional cell carcinoma of the upper urinary tract.

Urinary Calculi and Reduced Radiation Dose – Studies have been performed to retrospectively determine the effect of 50% and 75% radiation dose reductions on sensitivity and specificity of CT for the detection of urinary calculi. Ciaschini, et al found no significant differences between the examinations at 100% radiation dose and those at the reduced dosage for the detection of calculi greater than 3 mm.

Imaging of hernias: Most hernias are diagnosed clinically with imaging recommended for the diagnosis of occult hernias or in the evaluation of hernia complications such as bowel obstruction or strangulation. To detect occult hernias, ultrasound is a first line study with a sensitivity of 86% and specificity of 77% compared to 80% sensitivity and 65% specificity for CT (Robinson, 2013). According to Miller et al “Magnetic resonance imaging is generally not considered a first- or even second-line evaluation modality for hernias...” (Miller, 2014). Based on this analysis MRI is recommended only when ultrasound and CT have been performed and fail to make a diagnosis.
REFERENCES


CPT Codes: 72195, 72196, 72197

INTRODUCTION:

Magnetic resonance imaging of the pelvis is a noninvasive technique for the evaluation, assessment of severity, and follow-up of diseases of the male and female pelvic organs. MRI provides excellent contrast of soft tissues and provides multiplanar and 3D depiction of pathology and anatomy. Patients undergoing MRI do not have exposure to ionizing radiation or iodinated contrast materials. MRI techniques utilize body coils to image the entire pelvis or endoluminal coils for evaluation of the rectum, prostate and genitourinary system.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR PELVIC MRI:

Initial pelvic imaging for staging of prostate cancer (NCCN, 2017):
- PSA levels >20 ng/mL, biopsy GS ≥8, or clinically advanced disease (T3, T4 or T1-T2 and nomogram (e.g., Partin, Cancer of Prostate Risk Assessment CAPRA) indicating probability of lymph node involvement >10%).

Known prostate cancer for workup of recurrence and response to treatment (NCCN, 2017):
- Initial treatment by radical prostatectomy:
  - Failure of PSA to fall to undetectable levels or PSA detectable and rising on at least 2 subsequent determinations.
- Initial treatment radiation therapy:
  - Post-RT rising PSA or positive digital exam and is candidate for local therapy.

Indication for (suspected prostate) diagnostic transrectal prostate MRI (ACR, 2016; AUA-SAR, 2016; Bjurlin; Borofsky, 2018)):
- In patients without confirmed diagnosis of prostate cancer (with persistently elevated (>= 4.0 ng/ml) or rising PSA and prior negative biopsy).

Evaluation of suspicious known mass/tumors (unconfirmed diagnosis of cancer) for further evaluation of indeterminate or questionable findings.
- Initial evaluation of suspicious pelvic masses/tumors found only in the pelvis by physical exam and ultrasound has been performed or for further evaluation of abnormality seen on ultrasound (US) or when US is inconclusive (ACR, 2013, 2014).
- Surveillance: One follow-up exam to ensure no suspicious change has occurred in a tumor in the pelvic. No further surveillance unless tumor(s) are specified as highly suspicious or change was found on exam or last follow-up imaging.

Evaluation of known cancer for further evaluation of indeterminate or questionable findings, identified by physical examination or imaging exams such as ultrasound (US) and CT:
- Initial staging of known cancer:
  - All cancers, excluding the following:
- Basal Cell Carcinoma of the skin (NCCN, 2018).
- Melanoma without symptoms or signs of metastasis (NCCN, 2018; Trotter, 2013).
- Prostate cancer: unless PSA > 20 ng/ml, Gleason score on biopsy >/= 8 or clinically advanced disease (T3, T4 or T1-T2 and nomogram (e.g., Partin, cancer of prostate risk assessment CAPRA) indicating probability of lymph node involvement >10%) (NCCN, 2017).

- Follow-up of Known Cancer (NCCN, 2018; Bourgioti, 2016):
  - Follow-up of known cancer of patient undergoing active treatment within the past year.
  - Known cancer with suspected pelvic metastasis based on a sign, symptom or an abnormal lab value.
  - Active monitoring for recurrence as clinically indicated.

**For evaluation of enlargement of organ or abnormality seen on previous imaging:**
- Evaluation of an organ enlargement such as uterus or ovaries as evidenced by physical examination or an abnormality on prior imaging (e.g. ultrasound or CT).
- Further evaluation of organ enlargement or abnormality seen on previous imaging.

**For evaluation of suspected infection or inflammatory disease and preliminary imaging has been performed or is contraindicated (ACR, 2013; Cartwright, 2015; McKay, 2007):**
- Suspected acute appendicitis (or severe acute diverticulitis) in an adult if pelvic pain and tenderness to palpation is present, with at LEAST one of the following:
  - WBC elevated
  - Fever
  - Anorexia or
  - Nausea and vomiting.
- Suspected appendicitis in a child after ultrasound has been obtained (Choosing Wisely®, ACR/AAP/ACS).
- Suspected complications of diverticulitis (known to be limited to the pelvis by prior imaging) with pelvic pain or severe tenderness, not responding to antibiotic treatment.
- Suspected infection (based on elevated WBC, fever, anorexia or nausea and vomiting) in the pelvis.
- Suspected inflammatory bowel disease (Crohn’s or ulcerative colitis) with abdominal pain, and persistent diarrhea, or bloody diarrhea (MRI may not be well tolerated in the acute setting of inflammatory bowel disease (ACR, 2014)).

**For evaluation of known infection or inflammatory disease follow up (ACR, 2013, 2014):**
- Complications of diverticulitis with severe abdominal pain or severe tenderness or mass, not responding to antibiotic treatment, (prior imaging study is not required for diverticulitis diagnosis).
- Known inflammatory bowel disease (Crohn’s or ulcerative colitis) with recurrence or worsening signs/symptoms requiring re-evaluation.
- Any known infection that is clinically suspected to have created an abscess in the pelvis and preliminary imaging has been performed or is contraindicated.
- Any history of fistula limited to the pelvis that requires re-evaluation, or is suspected to have recurred.
- Abnormal fluid collection seen on prior imaging that needs follow-up evaluation and preliminary imaging has been performed or is contraindicated.
- Known infection in the pelvis and preliminary imaging has been performed or is contraindicated.

**Pre-operative evaluation:**
For pelvic surgery or procedure.
For post-operative/procedural evaluation:
• Follow-up of known or suspected post-operative complication involving the hips or the pelvis (Davis, 2016; Yanny, 2012).
• A follow-up study to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed.

Indications for Musculoskeletal Pelvic MRI:
• Initial evaluation of suspicious mass/tumor of the bones, muscles or soft tissues of the pelvis found on an imaging study, and needing clarification, or found by physical exam and remains non-diagnostic after x-ray or ultrasound.
• Evaluation of suspected fracture and/or injury when initial imaging is inconclusive or needs further evaluation.
• For evaluation of known or suspected aseptic/avascular necrosis of hip(s) after completion of initial x-ray (ACR, 2015).
• Sacroiliitis (infectious or inflammatory) after completion of initial x-ray (ACR, 2016; Jans, 2014).
• Sacroiliac Joint Dysfunction when there is (Jans, 2014):
  o Persistent back and/or sacral pain unresponsive to four (4) weeks of conservative treatment, received within the past six (6) months, including physical therapy or physician supervised home exercise plan (HEP).
• Persistent Pain:
  o For evaluation of persistent pain unresponsive to four (4) weeks of conservative treatment received within the past six (6) months.
• Pelvic floor failure OR post operative complications after pelvic floor surgery (ACR, 2014):
  o For evaluation of incontinence and anatomical derangements including, but not limited to uterine prolapse, rectocele, cystocele.
• For further evaluation of congenital anomalies of the sacrum and pelvis and initial imaging has been performed.
• Athletic pubalgia (Koulouris, 2008; Omar, 2008):
  o For evaluation of persistent groin or symphysis pubis pain related to a suspected diagnosis of athletic pubalgia (sports hernia), when not responding to 4 weeks of conservative treatment*.

Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases:
• ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine

Other Indications for a Pelvic MRI:
• For location or evaluation of undescended testes in adults and in children, including determination of location of testes, where ultrasound has been done previously (Tasian, 2011).
• To provide an alternative to follow-up of an indeterminate pelvic CT when previous CT/Ultrasound was equivocal and needed to clarify a finding a CT could not.
• For evaluation and characterization of uterine and adnexal masses, (e.g., fibroids, ovaries, tubes and uterine ligaments), or congenital abnormality where ultrasound has been done previously (ACR, 2018).
• For evaluation of uterus prior to and after embolization (Deshmukh, 2012).
• For evaluation of endometriosis when preliminary imaging has been completed or to follow up known endometriosis (ACR, 2012; Siegelman, 2012)
• Prior to uterine surgery if there is abnormality suspected on prior ultrasound.
• For evaluation of known or suspected abnormality of the fetus noted on prior imaging and no prior pelvis MRI (ACR-SPR, 2015; Perrone, 2008).
• Occult hernia when physical exam or prior imaging (ultrasound AND CT) is non-diagnostic or equivocal (Lassandro, 2011; Miller, 2014; Robinson, 2013).

**ADDITIONAL INFORMATION RELATED TO PELVIC MRI:**

*Conservative Therapy - Sacroiliac Joint Dysfunction* should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (epidural, facet, bursal, and/or joint, not including trigger point, and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:

- Information provided on exercise prescription/plan AND
- Follow up with member with documentation provided regarding completion of HEP (after suitable 4 week period) or inability to complete HEP due to physical reasons i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

**MRI and Undescended Testes** – The most common genital malformation in boys is undescended testis. In one series 70% of undescended testes are palpable and despite the advances in ultrasound technology, ultrasound cannot reliably identify intra-abdominal testes, which comprise 20% of all undescended testes (Tasian, 2011). The timely management of undescended testes is important to potentially minimize the risk of infertility and lessen the risk of malignancy. MRI is used as a diagnostic tool in the detection of undescended testes and can reveal information for both anatomic and tissue characterization. It is noninvasive, non-ionizing, and can obtain multiplanar images.

**MRI and Adnexal Masses** – MRI is used in the evaluation of adnexal masses. It can identify and characterize different neoplastic and nonneoplastic abnormalities, e.g., exoophytic leiomyoma, endometrioma, dermoid cyst, and ovarian edema. It is a useful adjunct when sonography is inconclusive in the evaluation of adnexal masses.

**MRI and Endometriosis** – MRI manifestations of endometriosis vary including endometrioma, peritoneal endometrial implant, adhesion and other rare features. The data obtained from imaging must be combined with clinical data to perform preoperative assessment of endometriosis.

**MRI and Prostate Cancer** – Although prostate cancer is the second leading cause of cancer in men, the majority of cases do not lead to a prostate cancer related death. Aggressive treatment of prostate cancer can have side effects such as incontinence, rectal injury, and impotence. It is very important to do an evaluation which will assist in making decisions about therapy or treatment. MRI can non-invasively assess prostate tissue, functionally and morphologically. MRI evaluation may use a large array of techniques, e.g., T1-weighted images, T2-weighted images, and dynamic contrast enhanced T1-weighted images.

**Prostate Cancer** – In selected patients diagnosed with prostate cancer, MRI of the pelvis can be used for initial staging, evaluation of recurrence and response to radiation therapy. A separate technique, transrectal prostate MRI, is used in patients with persistent PSA elevation despite prior negative biopsies. MRI is recommended in patients with suspected cancer but prior negative biopsy because MRI alone can miss up to 26% of clinically significant cancers that would be detected on systemic biopsy
(Borofsky, 2018). Patients with suspected prostate cancer should first undergo a systematic biopsy and if that fails to demonstrate tumor, an MRI can then be obtained to guide future biopsy attempts (Bjurlin).

For symptomatic patients and/or those with a life expectancy of greater than 5 years, a bone scan is appropriate for patients with T1 to T2 disease who also have a PSA greater than 20ng/mL or a Gleason score of 8 or higher. Patients with a T3 to T4 disease or symptomatic disease should also receive a bone scan. Pelvic computed tomography (CT) or magnetic resonance imaging (MRI) scanning is recommended if there is T3 or T4 disease, or T1 or T2 disease and a nomogram indicates that there is greater than 20% chance of lymph node involvement, although staging studies may not be optimal until the chance of lymph node positively reaches 45%. Biopsy should be considered for further evaluation of suspicious nodal findings. For all other patients, no additional imaging is required for staging.

Men who suffer a biochemical recurrence following prostatectomy fall into two groups: (1) those whose PSA level fails to fall to undetectable levels after surgery, or (2) those who achieve an undetectable PSA after surgery with a subsequent detectable PSA level that increases on two or more laboratory determinations. Since PSA elevation alone does not necessary lead to clinical failure, the workup for both of these groups focuses on the assessment of distant metastasis. The specific tests depend on the clinical history, but potentially include a bone scan, biopsy, PSA doubling time assessment, CT/MRI or radioimmunologic scintigraphy (i.e., ProstaScint scan). Bone scans are appropriate when patients develop symptoms or when the PSA level is increasing rapidly. In one study, the probability of a positive bone scan for a patient not on ADT (androgen deprivation therapy) after radical prostatectomy was less then 5% unless the PSA increased to 40 to 45 ng/mL.

Further work up is indicated in patients who are considered candidates for local therapy. These patients include those with original clinical stage T1-2, a life expectancy of greater than 10 years, and a current PSA of less than 10ng/mL. Work up includes a prostate biopsy, bone scan and additional tests as clinically indicated such as abdominal/pelvic CT, MRI or radioimmunologic scintigraphy (i.e., ProstaScint scan).

A negative biopsy following post-radiation biochemical recurrence poses clinical uncertainties. Observation, ADT, or enrolling in clinical trials are viable options. Alternatively, the patients may undergo more aggressive workup, such as repeat biopsy, MR spectroscopy, and or endorectal MRI.

Fusion imaging of multi-parametric magnetic resonance imaging (MRI) and transrectal ultrasound (TRUS) to guide prostate biopsy is not covered.

**MRI and Rectal Cancer** – MRI is used in the evaluation of rectal cancer to visualize not only the intestinal wall but also the surrounding pelvic anatomy. MRI is an excellent imaging technique due to its high soft-tissue contrast, powerful gradient system, and high resolution. It provides accurate evaluation of the topographic relationship between lateral tumor extent and the mesorectal fascia.

**Imaging of hernias**: Most hernias are diagnosed clinically with imaging recommended for the diagnosis of occult hernias or in the evaluation of hernia complications such as bowel obstruction or strangulation. To detect occult hernias, ultrasound is a first line study with a sensitivity of 86% and specificity of 77%, compared to 80% sensitivity and 65% specificity for CT (Robinson, 2013). According to Miller et al “Magnetic resonance imaging is generally not considered a first- or even second-line evaluation modality for hernias...” (Miller, 2014). Based on this analysis, MRI is recommended only when ultrasound and CT have been performed and fail to make a diagnosis.
REFERENCES


CPT Codes: 72198

IMPORTANT NOTE:
Abdomen/Pelvis MRA & Lower Extremity MRA Runoff Requests: Two authorization requests are required, one Abd MRA, CPT code 74185 and one for Lower Extremity MRA, CPT code 73725. This will provide imaging of the abdomen, pelvis and both legs.

INTRODUCTION:

Magnetic resonance angiography (MRA) generates images of the arteries that can be evaluated for evidence of stenosis, occlusion, or aneurysms. It is used to evaluate the arteries of the abdominal aorta and the renal arteries. Contrast enhanced MRA requires the injection of a contrast agent which results in very high quality images. It does not use ionizing radiation, allowing MRA to be used for follow-up evaluations.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR PELVIS MRA:

For evaluation of known or suspected pelvic vascular disease:
- For pelvic extent of known large vessel diseases (abdominal aorta, inferior vena cava, superior/inferior mesenteric, celiac, splenic, renal or iliac arteries/veins), e.g., aneurysm, dissection, arteriovenous malformations (AVMs), and fistulas, intramural hematoma, and vasculitis.
- Evidence of vascular abnormality seen on prior imaging studies.
- For suspected pelvic extent of aortic dissection.
- Evaluation of known or suspected aneurysms limited to the pelvis or in evaluating pelvic extent of aortic aneurysm (Khosa, 2011; Uberoi, 2011) **
  - Known or suspected iliac artery aneurysm >2.5 cm AND equivocal or indeterminate ultrasound results OR
  - Prior imaging (e.g. ultrasound) demonstrating iliac artery aneurysm >2.5 cm in diameter OR
  - Suspected complications of known aneurysm as evidenced by clinical findings such as new onset of pelvic pain.
  - Follow up of iliac artery aneurysm: Six month if between 3.0-3.5 cm and if stable follow yearly. If >3.5 cm, <six month follow up (and consider intervention).
- Retroperitoneal hematoma or hemorrhage when an underlying neoplasm is suspected and prior imaging is inconclusive (Abe, 2010).*
- For evaluation of suspected pelvic vascular disease when findings on ultrasound are indeterminate (MR or CT venography may be used as the initial study for evaluating pelvic thrombosis or thrombophlebitis) (ACR, 2013).
- Venous thrombosis if previous studies have not resulted in a clear diagnosis (ACR, 2013).
- Vascular invasion or displacement by tumor (Conventional CT or MRI also appropriate) (Certik, 2015; Kaufman, 2005).
- Pelvic vein thrombosis or thrombophlebitis (ACR, 2013).
- Mesenteric ischemia (ACR, 2012).
Pre-operative evaluation (ACR, 2017):
- Evaluation of interventional vascular procedures prior to endovascular aneurysm repair (EVAR), or for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.

Post-operative or post-procedural evaluation:
- Evaluation of endovascular/interventional vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.
- Evaluation of post-operative complications, e.g. pseudoaneurysms, related to surgical bypass grafts, vascular stents and stent-grafts in the peritoneal cavity.
- Follow-up for post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA) and iliac artery aneurysms. Routine, baseline study (post-op/intervention) is warranted within 1-3 months (Chaikof, 2018; Uberoi, 2011).
  - Asymptomatic at six (6) month intervals, for one (1) year, then annually.
  - Symptomatic/complications related to stent graft – more frequent imaging may be needed.
- Follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

ADDITIONAL INFORMATION RELATED TO PELVIS MRA:

Abdomen/Pelvis MRA & Lower Extremity MRA Runoff Requests: Two authorization requests are required, one Abd MRA, CPT code 74185 and one for Lower Extremity MRA, CPT code 73725. This will provide imaging of the abdomen, pelvis and both legs.

Bruit: Blowing vascular sounds heard over partially occluded blood vessels. Abdominal bruits may indicate partial obstruction of the aorta or other major arteries such as the renal, iliac, or femoral arteries. Associated risks include but are not limited to: renal artery stenosis, aortic aneurysm, atherosclerosis, AVM, or coarctation of aorta.

MRA and Chronic Mesenteric Ischemia – Contrast-enhanced MRA is used for the evaluation of chronic mesenteric ischemia, including treatment follow-up. Chronic mesenteric ischemia is usually caused by severe atherosclerotic disease of the mesenteric arteries, e.g., celiac axis, superior mesenteric artery, inferior mesenteric artery. At least two of the arteries are usually affected before the occurrence of symptoms such as abdominal pain after meals and weight loss. MRA is the technique of choice for the evaluation of chronic mesenteric ischemia in patients with impaired renal function.

MRA and Abdominal Aortic Aneurysm Repair – MRA may be performed before endovascular repair of an abdominal aortic aneurysm. Endovascular repair of abdominal aortic aneurysm is a minimally invasive alternative to open surgical repair and its success depends on precise measurement of the dimensions of the aneurysm and vessels. This helps to determine selection of an appropriate stent-graft diameter and length to minimize complications such as endoleakage. MRA provides images of the aorta and branches in multiple 3D projections and may help to determine the dimensions needed for placement of an endovascular aortic stent graft. MRA is noninvasive and rapid and may be used in patients with renal impairment.

*MRI/CT and acute hemorrhage: MRI is not indicated and MRA/MRV (MR Angiography/Venography) is rarely indicated for evaluation of intraperitoneal or retroperitoneal hemorrhage, particularly in the acute setting. CT is the study of choice due to its availability, speed of the study, and less susceptibility to artifact from patient motion. Advances in technology have allowed conventional CT to not just detect
hematomas but also the source of acute vascular extravasation. In special cases, finer vascular detail to assess the specific source vessel responsible for hemorrhage may require the use of CTA. CTA in the diagnosis of lower gastrointestinal bleeding is such an example (Clerc, 2017).

MRA/MRV is often utilized in non acute situations to assess vascular structure involved in atherosclerotic disease and its complications, vasculitis, venous thrombosis, vascular congestion or tumor invasion. Although some of these conditions may be associated with hemorrhage, it is usually not the primary reason why MRI/MRA/MRV is selected for the evaluation. A special condition where MRI may be superior to CT for evaluating hemorrhage is to detect an underlying neoplasm as the cause of bleeding (Abe, 2010).

**Follow-up of asymptomatic incidentally-detected iliac artery aneurysms (Uberoi, 2011):**
- <3.0 cm: rarely rupture, grow slowly, follow-up not generally needed
- 3.0-3.5 cm: followed up initially at 6 months
  - if stable, then annual imaging
- >3.5 cm: greater likelihood of rupture
  - <6 month follow up
  - consider intervention
REFERENCES


CPT Codes: 73200, 73201, 73202

INTRODUCTION:

Computed tomography (CT) may be used for the diagnosis, evaluation, and management of conditions of the hand, wrist, elbow and shoulder. CT is not usually the initial imaging test, but is performed after standard radiographs. CT is used for preoperative evaluation or to evaluate specific abnormalities of the bones, joints, and soft tissues of the upper extremities.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR UPPER EXTREMITY CT (HAND, WRIST, ARM, ELBOW, OR SHOULDER) (plain radiographs must precede CT evaluation):

Evaluation of suspicious mass/tumor (unconfirmed cancer diagnosis) (Zoga, 2017):
- Initial evaluation of suspicious mass/tumor which remains non-diagnostic after x-ray or ultrasound is completed.
- Surveillance: One follow-up exam if initial evaluation is indeterminate and lesion remains suspicious for cancer. No further surveillance unless tumor is specified as highly suspicious or change was found on last imaging.

Evaluation of known cancer (Fitzgerald, 2015; Morrison, 2013):
- Initial staging of known cancer in the upper extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study, or abnormal lab value.
- Known cancer with suspected upper extremity metastasis based on a sign, symptom, imaging study, or abnormal lab value.
- Active monitoring for recurrence as clinically indicated.

For evaluation of known or suspected infection or inflammatory disease: (e.g. osteomyelitis, septic arthritis, soft tissue infection) and MRI is contraindicated or cannot be performed (Fayad, 2007; Beaman, 2017):
- Further evaluation of abnormal or non-diagnostic findings on prior imaging.
- With abnormal physical or laboratory findings.
- Known or suspected (based upon initial workup including x-ray) septic arthritis or osteomyelitis.

For evaluation of suspected (AVN) avascular necrosis (e.g., aseptic necrosis) and MRI is contraindicated or cannot be performed:
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
- High suspicion for AVN (e.g. corticosteroid use, transplant recipients) with negative plain films.
For evaluation of known or suspected autoimmune disease, (e.g. rheumatoid arthritis) and MRI is contraindicated or cannot be performed (Colebatch, 2013):
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
- Imaging of a single joint for diagnosis or response to therapy after plain films and appropriate lab tests (e.g., RF, ANA, CRP, ESR, CCP).

For evaluation of known or suspected fracture and/or injury:
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
- Suspected fracture when imaging is negative or equivocal.
- Determine position of known fracture fragments/dislocation.
- Evaluate for delayed union or non-union of fracture or joint fusion.

For evaluation of persistent pain and initial imaging has been performed and MRI is contraindicated or cannot be performed:
- Chronic (lasting 3 months or greater) pain and/or persistent tendonitis unresponsive to conservative treatment*, within the last 6 months which includes active medical therapy (physical therapy, chiropractic treatments, and/or physician supervised exercise**) of at least four (4) weeks, OR
- With progression or worsening of symptoms during the course of conservative treatment.

Pre-operative/procedural evaluation:
- Pre-operative evaluation for a planned surgery or procedure.

Post-operative/procedural evaluation:
- When imaging, physical, or laboratory findings indicate joint infection, delayed or non-healing, or other surgical/procedural complications.

Additional indications for an Upper Extremity (Hand, Wrist, Arm, Elbow, or Shoulder) CT:
- Bone scan, ultrasound, or x-ray is non-diagnostic or requires further evaluation.
- CT arthrogram and MRI is contraindicated or cannot be performed (Amini, 2017).
- To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, or treated osteochondral defects where physical or imaging findings suggest its presence and MRI is contraindicated or cannot be performed.
- Known or suspected partial or complete tendon rupture and MRI is contraindicated or cannot be performed.
- Suspected foreign body with negative or non-diagnostic x-ray AND ultrasound (Halaas, 2007; Horton, 2001; Beaman, 2017).

Additional indications for Shoulder CT (Burbank, 2008):
- For any evaluation of patient with shoulder prosthesis or other implanted metallic hardware where prosthetic loosening or dysfunction is suspected on physical examination or imaging (Buck, 2008).
- Evaluation of recurrent dislocation and MRI is contraindicated or cannot be performed (Ng, 2009).
- For evaluation of brachial plexus dysfunction (brachial plexopathy/thoracic outlet syndrome) and MRI is contraindicated or cannot be performed.
- For evaluation of known or suspected labral tear with instability on exam, abnormality on x-ray or history of prior known dislocation. (SLAP lesion, Bankart lesion) and MRI is contraindicated or cannot be performed.
- Impingement or rotator cuff tear indicated by positive Neer’s sign, Hawkion’s sign or drop sign and MRI is contraindicated or cannot be performed (Ardic, 2006; Nazarian, 2013).
• Status post prior rotator cuff repair with suspected re-tear and findings on prior imaging are indeterminate and MRI is contraindicated or cannot be performed (Buck, 2008).

Additional indications for Wrist CT when MRI is contraindicated or cannot be performed (Kaewlai, 2008):
• For evaluation of suspected ligament injury with evidence of wrist instability on examination or evidence of joint space widening on x-ray
• To differentiate between occult ganglion and synovitis in chronic dorsal wrist pain.
• For evaluation of suspected scaphoid fracture when 2 week follow up x-rays are negative or non-diagnostic (Phillips, 2004; Yin, 2010).

ADDITIONAL INFORMATION RELATED TO UPPER EXTREMITY CT:

*Conservative Therapy*: (musculoskeletal) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, injections (bursal, and/or joint, not including trigger point), and diathermy, can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program, and/or chiropractic care.

**Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:
• Information provided on exercise prescription/plan AND
• Follow up with member with information provided regarding completion of HEP (after suitable 4 week period), or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

CT to Evaluate Shoulder Pain – The initial work-up for chronic shoulder pain includes plain radiographs. When the diagnosis remains unclear, further testing including may include computed tomography. CT is the preferred imaging technique for evaluating bony disorders of the shoulders, e.g., arthritis, tumors, occult fractures, etc. CT may be useful in patients with suspected rotator cuff tears who cannot undergo magnetic resonance imaging (MRI).

Shoulder Dislocation – Glenoid bone loss occurs in anterior shoulder dislocation. Severe degrees of glenoid bone loss are shown on axial radiography, but it can be quantified more definitively using CT. This information is important as it helps to predict the likelihood of further dislocation and the need for bone augmentation surgery. The number of dislocations cannot reliably predict the degree of glenoid bone loss; it is important to quantify glenoid bone loss, initially by arthroscopy and later by CT. In the CT examination, both glenoids can be examined simultaneously resulting in a comparison of the width of the glenoid in the dislocating shoulder and in the non-dislocating shoulder.

Shoulder fractures – CT may be used to characterize shoulder fractures when more information is need preoperatively. CT can show the complexity of the fracture, and the displacement and angulation.

CT and Wrist Fractures – CT is indicated for wrist fractures where there is fracture comminution, displacement, or complex intraarticular extension. CT can provide a detailed evaluation of radiocarpal articular step-off and gap displacement which can predict the development of radiocarpal osteoarthritis. CT can be performed in several planes, providing soft-tissue and bone detail. CT is also useful in
determining the position of known fracture fragments and in assessing the union or status of fracture healing.

**CT for Preoperative Evaluation** – Where more information is needed preoperatively, CT is used to demonstrate fracture complexity, displacement and angulation.

**CT and Scaphoid Fractures** – CT is accurate in depicting occult cortical scaphoid fractures. It may be used as a second choice diagnostic method when patients are clinically suspected of having a scaphoid fracture but radiographs are negative or equivocal. Usually the diagnosis of a scaphoid fracture of the wrist is based upon clinical presentation and conventional radiographs. However, a large percentage of patients with a high clinical probability of a scaphoid fracture have unremarkable radiographs. Computed tomography (CT) is another diagnostic tool for patients who have symptoms of a scaphoid fracture but have negative findings on conventional radiographs. Multidetector CT allows coverage of the whole wrist with excellent spatial resolution. It has been proven to be superior to MRI in the detection of cortical involvement of occult scaphoid fractures.

**CT and Avascular Necrosis Complicating Chronic Scaphoid Nonunion** – Preoperative CT of a scaphoid nonunion may be helpful in identifying avascular necrosis and predicting subsequent fracture union. If the results of CT suggest avascular necrosis, treatment options may include vascularized bone grafts or limited wrist arthrodesis.

**CT and Posttraumatic Elbow Effusions** – Multidetector computed tomography (MDCT) may help to detect occult fractures of the elbow when posttraumatic elbow effusions are shown on radiographs without any findings of fracture. Effusions may be visualized on radiographs as fat pads, which can be elevated by the presence of fluid in the joint caused by an acute fracture. MDCT may be useful when effusions are shown on radiographs without a visualized fracture, but there is a clinical suspicion of a lateral condylar or radial head fracture.

**CT and Avascular Necrosis** – Sports such as racquetball and gymnastics may cause repeated microtrauma due to the compressive forces between the radial head and capitellum. Focal avascular necrosis and osteochondritis dissecans of the capitellum may result. CT may show the extent of subchondral necrosis and chondral abnormalities. The images may also help detect intraarticular loose bodies.

**CT and Acute Osseous Trauma** – Many elbow injuries result from repetitive microtrauma rather than acute trauma and the injuries are sometimes hard to diagnose. Non-displaced fractures are not always evident on plain radiographs. When fracture is suspected, CT may improve diagnostic specificity and accuracy.

**CT and Wrist Tumor** – Osteoma does not often occur in the wrist. Symptoms may resemble atypical tenosynovitis. Pain may seem to be related to an injury. CT may be used to evaluate a suspected tumor and may visualize a round lucency surrounded by a rim of sclerosis. CT can give details about the location of the tumor, relative to joints.

**Upper Extremity Osteomyelitis and Septic Arthritis** – CT helps to distinguish among the types of musculoskeletal infections. Its specific imaging features help identify the forms of infection in the bones and soft tissue. Osteomyelitis, a bone infection most commonly associated with an open fracture or direct trauma, is often not detected in the initial conventional radiographic evaluation because bone changes are not evident for 14-21 days after the onset of infection. CT is also used to help diagnose septic arthritis; CT features include joint effusion and bone erosions around the joint.
American Academy of Pediatrics “Choosing Wisely” Guidelines advise against ordering advanced imaging studies (MRI or CT) for most musculoskeletal conditions in a child until all appropriate clinical, laboratory and plain radiographic examinations have been completed. “History, physical examination, and appropriate radiographs remain the primary diagnostic modalities in pediatric orthopaedics, as they are both diagnostic and prognostic for the great majority of pediatric musculoskeletal conditions. Examples of such conditions would include, but not be limited to, the work up of injury or pain (spine, knees and ankles), possible infection, and deformity. MRI examinations and other advanced imaging studies frequently require sedation in the young child (5 years old or less) and may not result in appropriate interpretation if clinical correlations cannot be made. Many conditions require specific MRI sequences or protocols best ordered by the specialist who will be treating the patient… if you believe findings warrant additional advanced imaging, discuss with the consulting orthopaedic surgeon to make sure the optimal studies are ordered.
REFERENCES


INTRODUCTION:

Computed tomography angiography (CTA) can visualize blood flow in arterial and venous structures throughout the upper extremity using a computerized analysis of x-ray images. It is enhanced by contrast material that is injected into a peripheral vein to promote visualization. CTA is much less invasive than catheter angiography which involves injecting contrast material into an artery. CTA is less expensive and carries lower risks than catheter angiography.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR UPPER EXTREMITY CTA:

For assessment/evaluation of known or suspected vascular disease/condition:
- For evaluation of suspected vascular disease: aneurysm, arteriovenous malformation, fistula, vasculitis, or intramural hematoma (Bozlar, 2013).
- For evaluation of Raynaud's syndrome.
- For evaluation of vascular invasion or displacement by tumor (Kransdorf, 2017).
- For evaluation of suspected upper extremity embolism or thrombosis (Dill, 2014; Bozlar, 2013).
- For evaluation of traumatic injuries to the upper extremity with clinical findings suggestive of arterial injury (Peng, 2008).

Pre-operative/procedural evaluation:
- Pre-operative evaluation for a planned surgery or procedure (Ahmed, 2017; Hsu, 2008).

Post-operative/procedural evaluations:
- For evaluation of complications of interventional vascular procedures, e.g., pseudoaneurysms related to surgical bypass grafts, vascular stents, or stent-grafts.
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Other indications for Upper Extremity CTA:
- For evaluation of a dialysis graft (Neyman, 2006).

ADDITIONAL INFORMATION RELATED TO UPPER EXTREMITY CTA:

CTA and Raynaud's Syndrome – Raynaud’s syndrome is evidenced by episodic waxy pallor or cyanosis of the fingers caused by vasoconstriction of small arteries or arterioles in the fingers. It usually occurs due to a response to cold or to emotional stimuli. CTA may be used in the evaluation of Raynaud’s syndrome.
**CTA and Dialysis Graft** – The management of the hemodialysis access is important for patients undergoing dialysis. With evaluation and interventions, the patency of hemodialysis fistulas may be prolonged. In selected cases, CTA is useful in the evaluation of hemodialysis graft dysfunction due to its speed and high resolution. Rapid data acquisition during the arterial phase, improved visualization of small vessels and lengthened anatomic coverage increase the usefulness of CTA.

**CTA and Stenosis or Occlusion** – CTA of the central veins of the chest is used for the detection of central venous stenoses and occlusions. High-spatial resolution CTA characterizes the general morphology and degree of stenosis. Enlarged and well-developed collateral veins in combination with the non-visualization of a central vein may be indicative of chronic occlusion, whereas less-developed or absent collateral veins are suggestive of acute occlusions. A hemodynamically significant stenosis may be indicated by the presence of luminal narrowing with local collaterals.
REFERENCES


CPT Codes: 73218, 73219, 73220, 73221, 73222, 73223

INTRODUCTION:

Magnetic resonance imaging shows the soft tissues and bones. With its multiplanar capabilities, high contrast, and high spatial resolution, it is an accurate diagnostic tool for conditions affecting the joint and adjacent structures. MRI has the ability to positively influence clinicians’ diagnoses and management plans for patients with conditions such as primary bone cancer, fractures, abnormalities in ligaments/tendons/cartilage, septic arthritis, and infection/inflammation.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR UPPER EXTREMITY MRI (HAND, WRIST, ARM, ELBOW or SHOULDER) (plain radiographs must precede MRI evaluation):

Evaluation of suspicious mass/tumor (unconfirmed cancer diagnosis) (Zoga, 2017):
- Initial evaluation of suspicious mass/tumor which remains non-diagnostic after x-ray or ultrasound is completed.
- Surveillance: One follow-up exam if initial evaluation is indeterminate and lesion remains suspicious for cancer. No further surveillance unless tumor is specified as highly suspicious or change was found on last imaging.

Evaluation of known cancer (Fitzgerald, 2015; Morrison, 2013):
- Initial staging of known cancer in the upper extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study, or abnormal lab value.
- Known cancer with suspected upper extremity metastasis based on a sign, symptom, imaging study or abnormal lab value.
- Active monitoring for recurrence as clinically indicated

For evaluation of known or suspected infection or inflammatory disease (e.g. osteomyelitis, septic arthritis, soft tissue infection) (Beaman, 2017):
- Further evaluation of abnormal or non-diagnostic findings on prior imaging.
- With abnormal physical or laboratory findings.
- Known or suspected (based upon initial workup including x-ray) septic arthritis or osteomyelitis.

For evaluation of suspected (AVN) avascular necrosis (i.e. aseptic necrosis) (Kekatpure, 2014):
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
- High suspicion for AVN (e.g. corticosteroid use, transplant recipients) with negative plain films.

For evaluation of known or suspected autoimmune disease (e.g., rheumatoid arthritis) (Boutry, 2007; Colebatch, 2013):
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
• Imaging of a single joint for diagnosis or response to therapy after plain films and appropriate lab tests (e.g., RF, ANA, CRP, ESR).

For evaluation of known or suspected fracture and/or injury:
• Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
• Suspected fracture when imaging is negative or equivocal.
• Determine position of known fracture fragments/dislocation.

For evaluation of persistent pain and initial imaging (e.g. x-ray) has been performed:
• Chronic (lasting 3 months or greater) pain and/or persistent tendonitis unresponsive to conservative treatment*, within the last 6 months which includes active medical therapy (physical therapy, chiropractic treatments, and/or physician supervised exercise**) of at least four (4) weeks, OR
• With progression or worsening of symptoms during the course of conservative treatment.

Pre-operative/procedural evaluation.
• Pre-operative evaluation for a planned surgery or procedure.

Post-operative/procedural evaluation:
• When imaging, physical or laboratory findings indicate joint infection, delayed or non-healing or other surgical/procedural complications.

Additional indications for Upper Extremity (Hand, Wrist, Arm, Elbow, or Shoulder) MRI:
• Bone scan, ultrasound, or x-ray is non-diagnostic or requires further evaluation.
• MR arthrogram (Amini, 2017).
• To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, or treated osteochondral defects where physical or imaging findings suggest its presence.
• Known or suspected partial or complete tendon rupture.
• Suspected foreign body with negative or non-diagnostic x-ray AND ultrasound (Horton, 2001; Beaman, 2017).

Additional indications for Shoulder MRI (Burbank, 2008):
• For evaluation of known or suspected labral tear with instability on exam, abnormality on x-ray or history of prior known dislocation. (SLAP lesion, Bankart lesion)
• Impingement or rotator cuff tear indicated by positive Neer’s sign, Hawkin’s sign or drop sign (Nazarian, 2013; Ardic, 2006).
• Status post prior rotator cuff repair with suspected re-tear and findings on prior imaging are indeterminate (Buck, 2008).
• For evaluation of brachial plexus dysfunction (brachial plexopathy/thoracic outlet syndrome).
• For evaluation of recurrent dislocation (Ng, 2009).

Additional indications for Wrist MRI:
• For evaluation of suspected ligament injury with evidence of wrist instability on examination or evidence of joint space widening on x-ray
• For suspected TFCC (triangular fibrocartilage complex) injury (Ng, 2017).
• To differentiate between occult ganglion and synovitis in chronic dorsal wrist pain (Anderson, 2006).
• For evaluation of suspected scaphoid fracture when 2 week follow up x-rays are negative or non-diagnostic (Phillips, 2004; Yin, 2010).
ADDITIONAL INFORMATION RELATED TO UPPER EXTREMITY MRI:

*Conservative Therapy* (musculoskeletal) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, injections (bursal, and/or joint, not including trigger point), and diathermy, can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:

- Information provided on exercise prescription/plan AND
- Follow up with member with information provided regarding completion of HEP (after suitable 4 week period), or inability to complete HEP due to physical reason i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

**Rotator Cuff Tears** – 3.0 Tesla MRI has been found valuable for the detection of partial thickness rotator cuff tendon tears and small rotator cuff tendon tears. It is especially useful in detecting the partial tears due to increased spatial resolution. Increased spatial resolution results in precise measurements of rotator cuff tendon tears in all 3 planes and it also reduces acquisition time which reduces motion artifacts. 3.0 Tesla makes it possible to adequately evaluate tendon edges and avoid underestimation of tears. MRI is less invasive than MR arthrography and it is faster and less expensive. MRI may be useful in the selection of patients that may benefit from arthroscopy.

**MRI and Occult Fractures** – Magnetic resonance imaging may help to detect occult fractures of the elbow when posttraumatic elbow effusions are shown on radiographs without any findings of fracture. Effusions may be visualized on radiographs as fat pads, which can be elevated by the presence of fluid in the joint caused by an acute fracture. MRI may be useful when effusions are shown on radiographs without a visualized fracture, but there is a clinical suspicion of a lateral condylar or radial head fracture.

**MRI and Avascular Necrosis** – Sports such as racquetball and gymnastics may cause repeated microtrauma due to the compressive forces between the radial head and capitellum. Focal avascular necrosis and osteochondritis dissecans of the capitellum may result. MRI can be used to evaluate the extent of subchondral necrosis and chondral abnormalities. The images may also help detect intraarticular loose bodies.

**MRI and Acute Osseous Trauma** – Many elbow injuries result from repetitive microtrauma rather than acute trauma and the injuries are sometimes hard to diagnose. Non-displaced fractures are not always evident on plain radiographs. When fracture is suspected, MRI may improve diagnostic specificity and accuracy. T1-weighted images can delineate morphologic features of the fracture.

**MRI and Brachial Plexus** - MRI is the only diagnostic tool that accurately provides high resolution imaging of the brachial plexus. The brachial plexus is formed by the cervical ventral rami of the lower cervical and upper thoracic nerves which arise from the cervical spinal cord, exit the bony confines of the cervical spine, and traverse along the soft tissues of the neck, upper chest, and course into the arms.
The American Academy of Pediatrics “Choosing Wisely” Guidelines advise against ordering advanced imaging studies (MRI or CT) for most musculoskeletal conditions in a child until all appropriate clinical, laboratory and plain radiographic examinations have been completed. “History, physical examination, and appropriate radiographs remain the primary diagnostic modalities in pediatric orthopaedics, as they are both diagnostic and prognostic for the great majority of pediatric musculoskeletal conditions. Examples of such conditions would include, but not be limited to, the work up of injury or pain (spine, knees and ankles), possible infection, and deformity. MRI examinations and other advanced imaging studies frequently require sedation in the young child (5 years old or less) and may not result in appropriate interpretation if clinical correlations cannot be made. Many conditions require specific MRI sequences or protocols best ordered by the specialist who will be treating the patient. If you believe findings warrant additional advanced imaging, discuss with the consulting orthopaedic surgeon to make sure the optimal studies are ordered.
REFERENCES


CPT Codes: 73225

INTRODUCTION:

Magnetic resonance angiography (MRA) is a noninvasive alternative to catheter angiography for evaluation of vascular structures in the upper extremity. Magnetic resonance venography (MRV) is used to image veins instead of arteries. MRA and MRV are less invasive than conventional x-ray digital subtraction angiography.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR UPPER EXTREMITY MRA/MRV:

For assessment/evaluation of known or suspected vascular disease/condition:
- For evaluation of suspected vascular disease: aneurysm, arteriovenous malformation, fistula, vasculitis, or intramural hematoma (Connell, 2002).
- For evaluation of Raynaud's syndrome (Connell, 2002).
- For evaluation of vascular invasion or displacement by tumor (Kransdorf, 2017).
- For evaluation of suspected upper extremity embolism or thrombosis (Dill, 2014).
- For evaluation of traumatic injuries to the upper extremity with clinical findings suggestive of arterial injury (Connell, 2002).
- Suspected fibromuscular dysplasia of the brachial artery (Sharma, 2014).

Pre-operative/procedural evaluation:
- Pre-operative evaluation for a planned surgery or procedure (Ahmed, 2017).

Post-operative/procedural evaluations:
- Post-operative or interventional vascular procedure for luminal patency versus re-stenosis (due to atherosclerosis, thromboembolism, intimal hyperplasia and other causes), as well as complications such as pseudoaneurysms related to surgical bypass grafts and vascular stents and stent-grafts.
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

ADDITIONAL INFORMATION RELATED TO UPPER EXTREMITY MRA/MRV:

MRA/MRV and Raynaud's Syndrome – Raynaud’s syndrome is evidenced by episodic waxy pallor or cyanosis of the fingers caused by vasoconstriction of small arteries or arterioles in the fingers. It usually occurs due to a response to cold or to emotional stimuli. MRA may be used in the evaluation of Raynaud’s syndrome.

MRA/MRV and Stenosis or Occlusion – MRA of the central veins of the chest is used for the detection of central venous stenoses and occlusions. High-spatial resolution MRA characterizes the general
morphology and degree of stenosis. Enlarged and well-developed collateral veins in combination with the non-visualization of a central vein may be indicative of chronic occlusion, whereas less-developed or absent collateral veins are suggestive of acute occlusions. A hemodynamically significant stenosis may be indicated by the presence of luminal narrowing with local collaterals (Kim, 2008).
REFERENCES


INTRODUCTION:

Plain radiographs are typically used as the first-line modality for assessment of lower extremity conditions. Computed tomography (CT) is used for evaluation of tumors, metastatic lesions, infection, fractures and other problems. Magnetic resonance imaging (MRI) is the first-line choice for imaging of many conditions, but CT may be used in these cases if MRI is contraindicated or unable to be performed.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR LOWER EXTREMITY CT (FOOT, ANKLE, KNEE, LEG or HIP): (plain radiographs must precede CT evaluation):

Evaluation of suspicious mass/tumor (unconfirmed cancer diagnosis):
- Initial evaluation of suspicious mass/tumor which remains non-diagnostic after x-ray or ultrasound is completed.
- Surveillance: One follow-up exam if initial evaluation is indeterminate and lesion remains suspicious for cancer. No further surveillance unless tumor is specified as highly suspicious, or change was found on last imaging (Zoga, 2017).

Evaluation of known cancer:
- Initial staging of known cancer in the lower extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study or abnormal lab value.
- Known cancer with suspected lower extremity metastasis based on a sign, symptom, imaging study or abnormal lab value.
- Active monitoring for recurrence as clinically indicated (Fitzgerald, 2015; Morrison, 2013).

For evaluation of known or suspected infection or inflammatory disease (e.g. osteomyelitis, septic arthritis, soft tissue infection) and MRI is contraindicated or cannot be performed:
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
- With abnormal physical, laboratory, and/or imaging findings.
- Known or suspected (based upon initial workup including imaging) septic arthritis or osteomyelitis (Beaman, 2017).

For evaluation of suspected (AVN) avascular necrosis (e.g., aseptic necrosis, Legg-Calve-Perthes disease in children) and MRI is contraindicated or cannot be performed:
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
- High suspicion for AVN (e.g. corticosteroid use, transplant recipients) with negative plain films (Murphey, 2016).

For evaluation of known or suspected autoimmune disease, (e.g. rheumatoid arthritis) and MRI is contraindicated or cannot be performed:
• Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
• Imaging of a single joint for diagnosis or response to therapy after plain films and appropriate lab tests (e.g. RF, ANA, CRP, ESR) (Colebatch, 2013).

For evaluation of known or suspected fracture and/or injury:
• Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
• Suspected fracture when imaging is negative or equivocal.
• Determine position of known fracture fragments/dislocation.

For evaluation of persistent pain, initial imaging has been performed and MRI is contraindicated or cannot be performed:
• Chronic (lasting 3 months or greater) pain and/or persistent tendinitis unresponsive to conservative treatment*, within the last 6 months which includes active medical therapy (physical therapy, chiropractic treatments, and/or physician supervised exercise**) of at least four (4) weeks, OR
• With progression or worsening of symptoms during the course of conservative treatment.

Pre-operative/procedural evaluation:
• Pre-operative evaluation for a planned surgery or procedure.

Post-operative/procedural evaluation:
• When imaging, physical, or laboratory findings indicate joint infection, delayed or non-healing, or other surgical/procedural complications.

Additional indications for Lower Extremity (Foot, Ankle, Knee, Leg, or Hip) CT:
• Bone scan, ultrasound, or x-ray is non-diagnostic or requires further evaluation.
• For evaluation of leg length discrepancy when physical deformities of the lower extremities would prevent standard modalities such as x-rays or a Scanogram from being performed. (Scanogram (CPT code 77073); bone length study is available as an alternative to lower extremity CT evaluation for leg length discrepancy) (Sabharwal, 2008).
• CT arthrogram and MRI is contraindicated or cannot be performed.
• To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, or treated osteochondral defects where physical or imaging findings suggest its presence and MRI is contraindicated or cannot be performed.
• Suspected foreign body with negative or non-diagnostic x-ray AND ultrasound (Halaas, 2007; Horton, 2001; Beaman, 2017).

Additional indications specifically for FOOT or ANKLE CT:
• Chronic (lasting 3 months or greater) pain in a child or an adolescent with painful rigid flat foot where imaging is unremarkable or equivocal or to evaluate for known or suspected tarsal coalition (Harris, 2004).
• Physical findings of ligament damage such as an abnormal drawer test of the ankle or significant laxity on valgus or varus stress testing and/or joint space widening on x-ray, and MRI is contraindicated or cannot be performed.

Additional indications specifically for KNEE CT and MRI is contraindicated or cannot be performed:
• Blood in the joint (hemarthrosis) demonstrated by aspiration.
• For evaluation of suspected Baker’s cyst or posterior knee swelling with equivocal or non-diagnostic findings on ultrasound (Ward, 2001).
• Physical findings of a meniscal injury determined by physical examination tests (e.g. McMurray’s, Apley’s, Thessaly’s).
• Physical findings of anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) ligamentous injury determined by the drawer test, pivot shift test, or the Lachman test.
• Physical findings of medial cruciate ligament (MCL) or lateral cruciate ligament (LCL) ligamentous injury determined by significant laxity on varus or valgus stress tests. (Bennett, 2012; Mohankumar, 2014; Tuite, 2014).

Additional indications specifically for HIP CT:
• For evaluation of patient with hip prosthesis or other implanted metallic hardware where prosthetic loosening or dysfunction is suspected on physical examination or imaging (Fritz, 2014).
• For evaluation of suspected slipped capital femoral epiphysis with non-diagnostic or equivocal imaging and MRI is contraindicated or cannot be performed (Hesper, 2017).
• Suspected labral tear of the hip and MRI is contraindicated or cannot be performed.

ADDITIONAL INFORMATION RELATED TO LOWER EXTREMITY CT:

*Conservative Therapy*: (musculoskeletal) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, injections (bursal, and/or joint, not including trigger point), and diathermy, can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:
• Information provided on exercise prescription/plan AND
• Follow up with member with information provided regarding completion of HEP (after suitable 4 week period), or inability to complete HEP due to physical reasons i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

CT and Ankle Fractures – One of the most frequently injured areas of the skeleton is the ankle. These injuries may include ligament sprains, as well as fractures. A suspected fracture is first imaged with conventional radiographs in anteroposterior, internal oblique and lateral projections. CT is used in patients with complex ankle and foot fractures after radiography.

CT and Hip Trauma – Computed tomography is primarily used to evaluate acute trauma, e.g., acetabular fracture or hip dislocation. It can detect intraarticular fragments and associated articular surface fractures and it is useful in surgical planning.

CT and Knee Fractures – CT is used after plain films to evaluate fractures to the tibial plateau. These fractures occur just below the knee joint, involving the cartilage surface of the knee. Soft tissue injuries are usually associated with the fractures. The meniscus is a stabilizer of the knee and it is very important to detect meniscal injury in patients with tibial plateau fractures. CT of the knee with two-dimensional reconstruction in the sagittal and coronal planes may be performed for evaluation of injuries with multiple fragments and comminuted fractures. Spiral CT has an advantage of rapid acquisition and
reconstruction times and may improve the quality of images of bone. Soft tissue injuries are better demonstrated with MRI.

**CT and Knee Infections** – CT is used to depict early infection which may be evidenced by increased intraosseous density or the appearance of fragments of necrotic bone separated from living bone by soft tissue or fluid density. Contrast-enhanced CT may help in the visualization of abscesses and necrotic tissue.

**CT and Knee Tumors** – CT complements arthrography in diagnosing necrotic malignant soft-tissue tumors and other cysts and masses in the knee. Meniscal and ganglion cysts are palpable masses around the knee. CT is useful in evaluations of the vascular nature of lesions.

**CT and Legg-Calve-Perthes Disease (LPD)** – This childhood condition is associated with an insufficient blood supply to the femoral head which is then at risk for osteonecrosis. Clinical signs of LPD include a limp with groin, thigh or knee pain. Flexion and adduction contractures may develop as the disease progresses and eventually movement may only occur in the flexion-extension plane. This condition is staged based on plain radiographic findings. CT scans are used in the evaluation of LPD and can demonstrate changes in the bone trabecular pattern. They also allow diagnosis of bone collapse and sclerosis early in the disease where plain radiography is not as sensitive.

**CT and Osteolysis** – Since computed tomography scans show both the extent and the location of lytic lesions, they are useful to guide treatment decisions, as well as to assist in planning for surgical intervention when needed, in patients with suspected osteolysis after Total Hip Arthroplasty (THA).

**CT and Tarsal Coalition** – This is a congenital condition in which two or more bones in the mid-foot or hind-foot are joined. It usually presents during late childhood or late adolescence and is associated with repetitive ankle sprains. Mild pain, deep in the subtalar joint and limited range of motion are clinical symptoms. Tarsal coalition is detectable on oblique radiographs, but these are not routinely obtained at many institutions. Clinical diagnosis is not simple; it requires the expertise of skilled examiners. CT is valuable in diagnosing tarsal coalition because it allows differentiation of osseous from non-osseous coalitions and also depicts the extent of joint involvement as well as degenerative changes. It may also detect the overgrowth of the medial aspect of the talus that may be associated with talocalcaneal coalitions.

**American Academy of Pediatrics “Choosing Wisely” Guidelines** advise against ordering advanced imaging studies (MRI or CT) for most musculoskeletal conditions in a child until all appropriate clinical, laboratory and plain radiographic examinations have been completed. “History, physical examination, and appropriate radiographs remain the primary diagnostic modalities in pediatric orthopaedics, as they are both diagnostic and prognostic for the great majority of pediatric musculoskeletal conditions. Examples of such conditions would include, but not be limited to, the work up of injury or pain (spine, knees and ankles), possible infection, and deformity. MRI examinations and other advanced imaging studies frequently require sedation in the young child (5 years old or less), and may not result in appropriate interpretation if clinical correlations cannot be made. Many conditions require specific MRI sequences or protocols best ordered by the specialist who will be treating the patient... if you believe findings warrant additional advanced imaging, discuss with the consulting orthopaedic surgeon to make sure the optimal studies are ordered.
REFERENCES


CPT Codes: 73706

INTRODUCTION:

Lower extremity computed tomography angiography (CTA) is an effective, noninvasive and robust imaging modality that is used in the assessment of symptomatic lower extremity vascular disease. It has excellent spatial resolution and shows accurate details of peripheral vasculature. CTA is an effective alternative to catheter-based angiography and allows accurate planning of open surgical and endovascular interventions.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR LOWER EXTREMITY CTA:

For assessment/evaluation of suspected or known vascular disease/condition:
- Significant ischemia in the presence of ulcers/gangrene (Weiss, 2018)
- Large vessel diseases, e.g. aneurysm, dissection, arteriovenous malformations (AVMs), fistulas, intramural hematoma, and vasculitis.
- Arterial entrapment syndrome (Hai, 2008).
- Venous thrombosis after non-diagnostic ultrasound (Hanley, 2013)
- Vascular invasion or displacement by tumor (Kransdorf, 2017).
- Pelvic vein thrombosis or thrombophlebitis (Hanley, 2013; Karande, 2016).
- Abnormal preliminary testing (ankle/brachial index, ultrasound/doppler arterial evaluation) associated with significant symptoms of claudication with exercise (Ahmed, 2017; Met, 2009)
- For evaluation of traumatic injuries to the lower extremity with clinical findings suggestive of arterial injury (Tuite, 2018; Inaba, 2006; LeBus, 2008)

Pre-operative/procedural evaluation:
- Pre-operative evaluation for a planned surgery or procedure (Ahmed, 2017; Godshall, 2005).

Post-operative / procedural evaluation:
- Post-operative or interventional vascular procedure for luminal patency versus re-stenosis (due to atherosclerosis, thromboembolism, intimal hyperplasia and other causes) as well as complications such as pseudoaneurysms related to surgical bypass grafts and vascular stents and stent-grafts (Lopera, 2008; Toomay, 2006).
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

ADDITIONAL INFORMATION RELATED TO LOWER EXTREMITY CTA:

Abdominal Arteries CTA: For imaging of the abdomen, pelvis AND both legs (CTA aorto-iliofemoral runoff; abdominal aorta and bilateral iliofemoral lower extremity runoff) use CPT code 75635.
Peripheral Arterial Disease – Multi-detector CTA (MDCTA) is used in the evaluation of patients with peripheral arterial disease. It can be used to evaluate the patency after revascularization procedures. It is the modality of choice in patients with intermittent claudication. A drawback is its hampered vessel assessment caused by the depiction of arterial wall calcifications, resulting in a decreased accuracy in severely calcified arteries.

Chronic Limb Threatening Ischemia – Assessment and promotion of blood flow through the calf arteries is very important in patients with chronic limb threatening ischemia. MDCTA allows for visualization of pedal vessels.

Surgical or Percutaneous Revascularization – CTA is accurate in the detection of graft-related complications, including stenosis and aneurysmal changes. It can reveal both vascular and extravascular complications.

CTA and screening for peripheral vascular disease: The USPSTF (U.S. Preventative Services Task Force) does not recommend routine screening for peripheral vascular disease in asymptomatic patients. High risk patients (eg. diabetics) may be screened with ABI (ankle brachial index) and duplex ultrasound.
REFERENCES


INTRODUCTION:

Magnetic resonance imaging shows the soft tissues and bones. With its multiplanar capabilities, high contrast, and high spatial resolution, it is an accurate diagnostic tool for conditions affecting the joint and adjacent structures. MRI has the ability to positively influence clinicians’ diagnoses and management plans for patients with conditions such as primary bone cancer, fractures, abnormalities in ligaments/tendons/cartilage, septic arthritis, and infection/inflammation.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR LOWER EXTREMITY MRI (FOOT, ANKLE, KNEE, LEG or HIP) (plain radiographs must precede MRI evaluation):

**Evaluation of suspicious mass/tumor (unconfirmed cancer diagnosis) (Zoga, 2017):**
- Initial evaluation of suspicious mass/tumor which remains non-diagnostic after x-ray or ultrasound is completed.
- Surveillance: One follow-up exam if initial evaluation is indeterminate and lesion remains suspicious for cancer. No further surveillance unless tumor is specified as highly suspicious, or change was found on last imaging.

**Evaluation of known cancer (Fitzgerald, 2015; Morrison, 2013):**
- Initial staging of known cancer in the lower extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study or abnormal lab value.
- Known cancer with suspected lower extremity metastasis based on a sign, symptom, imaging study or abnormal lab value.
- Active monitoring for recurrence as clinically indicated.

**For evaluation of known or suspected infection or inflammatory disease (e.g. osteomyelitis, septic arthritis, soft tissue infection):**
- Further evaluation of abnormal or non-diagnostic findings on prior imaging.
- With abnormal physical or laboratory findings.
- Known or suspected (based upon initial workup including x-ray) septic arthritis or osteomyelitis (Bancroft, 2007; Beaman, 2017).

**For evaluation of suspected (AVN) avascular necrosis (i.e. aseptic necrosis, Legg-Calve-Perthes disease in children):**
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
- High suspicion for AVN (e.g. corticosteroid use, transplant recipients) with negative plain films (Murphey, 2016).

**For evaluation of known or suspected autoimmune disease (e.g. rheumatoid arthritis):**
• Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
• Imaging of a single joint for diagnosis or response to therapy after plain films and appropriate lab tests (e.g. RF, ANA, CRP, ESR) (Boutry, 2007; Colebatch, 2013).

For evaluation of known or suspected fracture and/or injury:
• Further evaluation of an abnormality or non-diagnostic findings on prior imaging.
• Suspected fracture when imaging is negative or equivocal.
• Determine position of known fracture fragments/dislocation.

For evaluation of persistent pain and initial imaging has been performed:
• Chronic (lasting 3 months or greater) pain and/or persistent tendonitis unresponsive to conservative treatment*, within the last 6 months which includes active medical therapy (physical therapy, chiropractic treatments, and/or physician supervised exercise**) of at least four (4) weeks, OR
• With progression or worsening of symptoms during the course of conservative treatment.

Pre-operative/procedural evaluation:
• Pre-operative evaluation for a planned surgery or procedure.

Post-operative/procedural evaluation:
• When imaging, physical or laboratory findings indicate joint infection, delayed or non-healing or other surgical/procedural complications.

Additional indications for a Lower Extremity (Foot, Ankle, Knee, Leg or Hip) MRI:
• Bone scan, ultrasound, or x-ray is non-diagnostic or requires further evaluation.
• MR arthrogram.
• To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, or treated osteochondral defects where physical or imaging findings suggest its presence.
• Known or suspected partial or complete tendon rupture.
• Suspected foreign body with negative or non-diagnostic x-ray AND ultrasound (Halaas, 2007; Horton, 2001; Beaman, 2017).

Additional indications specifically for FOOT or ANKLE MRI
• Chronic (lasting 3 months or greater) pain in a child or adolescent with painful rigid flat foot where imaging is unremarkable or equivocal or to evaluate for known or suspected tarsal coalition (Harris, 2004).
• Physical findings of ligament damage such as an abnormal drawer test of the ankle or significant laxity on valgus or varus stress testing and/or joint space widening on x-rays.
• Evaluation of tarsal tunnel syndrome after abnormal plain films or abnormal nerve conduction studies or a failure of 4 weeks of conservative treatment.

Additional indications specifically for KNEE MRI:
• Blood in the joint (hemarthrosis) demonstrated by aspiration.
• For evaluation of suspected Baker’s cyst or posterior knee swelling with equivocal or non-diagnostic findings on ultrasound (Ward, 2001).
• Physical findings of a meniscal injury determined by physical examination tests (e.g. McMurray’s, Apley’s, Thessaly’s).
• Physical findings of anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) ligamentous injury determined by the drawer test, pivot shift test, or the Lachman test.
• Physical findings of medial collateral ligament (MCL) or lateral collateral ligament (LCL) ligamentous injury determined by significant laxity on varus or valgus stress tests (Bennett, 2012; Mohankumar, 2014; Tuite, 2014).

Additional indications specifically for HIP MRI:
• For evaluation of suspected slipped capital femoral epiphysis with non-diagnostic imaging (Hesper, 2017).
• For evaluation of patient with hip prosthesis or other implanted metallic hardware where prosthetic loosening or dysfunction is suspected on physical examination or imaging (Fritz, 2014).
• Suspected labral tear of the hip (Naraghi, 2015; Ward, 2013).

ADDITIONAL INFORMATION RELATED TO A LOWER EXTREMITY MRI:

*Conservative Therapy: (musculoskeletal) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, injections (bursal, and/or joint, not including trigger point), and diathermy, can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care.

**Home Exercise Program - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
• Information provided on exercise prescription/plan AND
• Follow up with member with information provided regarding completion of HEP (after suitable 4 week period), or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

MRI and Knee Trauma - MRI is an effective means of evaluating internal derangements of the knee with a very high accuracy for detection of meniscal injury. On MRI of the knee, meniscal injury may appear “free-floating”, corresponding to a meniscal avulsion or detachment from the tibial plateau. The floating meniscus seen on MRI is a result of significant trauma. It may also be associated with significant ligamentous injury. The results of the MRI are valuable to the surgeon as he plans to reattach the meniscus to the tibial plateau.

MRI and Osteonecrosis – Osteonecrosis is a complication of knee surgery which may be accompanied by new or persistent pain after meniscal surgery. It can be detected by MRI with subcortical low signal intensity of T1-weighted images with or without central high signal intensity on T2-weighted images. Osteonecrosis can result in collapse of the articular surface.

MRI and Legg-Calve-Perthes Disease (LPD) –This childhood condition is associated with an insufficient blood supply to the femoral head which is then at risk for osteonecrosis. Clinical signs of LPD include a limp with groin, thigh or knee pain. Flexion and adduction contractures may develop as the disease progresses and eventually movement may only occur in the flexion-extension plane. This condition is staged based on plain radiographic findings. MRI is used in identifying the early stage of LPD when plain films are normal. It is also used in preoperative planning to diagnose “hinge abduction” (lateral side of the femoral head contacts the acetabular margin and femoral head does not slide as it should). However, MRI is not used as a standard diagnostic tool.
**MRI and Septic Arthritis** – Young children and older adults are the most likely to develop septic arthritis in the hip joint. Early symptoms include pain in the hip, groin, or thigh along with a limping gait and fever. It is sometimes hard to differentiate this condition from transient synovitis, a less serious condition with no known long-term sequelae. MRI may help in the differential diagnosis of these two conditions. Coronal T1-weighted MRI, performed immediately after contrast administration, can evaluate blood perfusion at the femoral epiphysis.

**MRI and Slipped Capital Femoral Epiphysis** – This condition, where the femoral head is displaced in relation to the femoral neck, is the most common hip disorder in adolescents and it is more common in obese children. Its symptoms include a limping gait, groin pain, thigh pain and knee pain. Most cases are stable and the prognosis is good with early diagnosis and treatment. Unstable slipped capital femoral epiphysis may lead to avascular necrosis. MRI is used for diagnosis of slipped capital femoral epiphysis. Its image can be oriented to a plane orthogonal to the plane of the physis to detect edema in the area of the physis.

**MRI and Tarsal Coalition** – This is a congenital condition in which two or more bones in the midfoot or hindfoot are joined. It usually presents during late childhood or late adolescence and is associated with repetitive ankle sprains. Mild pain, deep in the subtalar joint and limited range of motion are clinical symptoms. Tarsal coalition is detectable on oblique radiographs, but these are not routinely obtained at many institutions. Clinical diagnosis is not simple; it requires the expertise of skilled examiners. MRI is valuable in diagnosing tarsal coalition because it allows differentiation of osseous from non-osseous coalitions and also depicts the extent of joint involvement as well as degenerative changes. It may also detect overgrowth of the medial aspect of the talus that may be associated with talocalcaneal coalitions.

**MRI and Tarsal Tunnel** – Tarsal Tunnel Syndrome is due to compression of the posterior tibial nerve as it passes through the tarsal tunnel into the foot. Compression can cause a sensation of burning or numbness to the bottom of the foot. Common causes include flat foot, over-protonation, and arthritis. Nerve conduction studies can reveal damage to the posterior tibial nerve. MRI may be valuable in demonstrating other structures causing extrinsic compression on the nerve.

**The American Medical Society for Sports Medicine “Choosing Wisely” Guidelines** advise against ordering a knee MRI for a patient with anterior knee pain without mechanical symptoms or effusion unless the patient has not improved following completion of an appropriate functional rehabilitation program. “The most common cause of anterior knee pain is patellofemoral pain syndrome. Magnetic resonance imaging (MRI) is rarely helpful in managing this syndrome. Treatment should focus on a guided exercise program to correct lumbo pelvic and lower limb strength and flexibility imbalances. If pain persists, if there is recurrent swelling or if mechanical symptoms such as locking and painful clicking are present, and radiographs are non-diagnostic, an MRI may be useful.”

**The American Academy of Pediatrics “Choosing Wisely” Guidelines** advise against ordering advanced imaging studies (MRI or CT) for most musculoskeletal conditions in a child until all appropriate clinical, laboratory and plain radiographic examinations have been completed. “History, physical examination, and appropriate radiographs remain the primary diagnostic modalities in pediatric orthopaedics, as they are both diagnostic and prognostic for the great majority of pediatric musculoskeletal conditions. Examples of such conditions would include, but not be limited to, the work up of injury or pain (spine, knees and ankles), possible infection, and deformity. MRI examinations and other advanced imaging studies frequently require sedation in the young child (5 years old or less), and may not result in appropriate interpretation if clinical correlations cannot be made. Many conditions require specific MRI sequences or protocols best ordered by the specialist who will be treating the patient... if you
believe findings warrant additional advanced imaging, discuss with the consulting orthopaedic surgeon to make sure the optimal studies are ordered.
REFERENCES


CPT Code: 73725

**INTRODUCTION:**

Magnetic resonance angiography (MRA) is a noninvasive alternative to catheter angiography for evaluation of vascular structures in the lower extremity. Magnetic resonance venography (MRV) is used to image veins instead of arteries. MRA and MRV are less invasive than conventional x-ray digital subtraction angiography.

A request for MR Angiography includes standard MRI imaging. An authorization for MRI in addition to MRA is not required.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

**INDICATIONS FOR LOWER EXTREMITY MRA/MRV:**

For assessment/evaluation of suspected or known vascular disease/condition:
- Significant ischemia in the presence of ulcers/gangrene (Weiss, 2018).
- Large vessel diseases, e.g., aneurysm, dissection, arteriovenous malformations (AVMs), fistulas, intramural hematoma, and vasculitis.
- Arterial entrapment syndrome (Hai, 2008).
- Venous thrombosis after non-diagnostic ultrasound (Hanley, 2013).
- Vascular invasion or displacement by tumor (Kransdorf, 2017).
- Pelvic vein thrombosis or thrombophlebitis (Hanley, 2013; Karande, 2016).
- Abnormal preliminary testing (ankle/brachial index, ultrasound/doppler arterial evaluation) associated with significant symptoms of claudication with exercise (Ahmed, 2017).
- For evaluation of traumatic injuries to the lower extremity with clinical findings suggestive of arterial injury (Tuite, 2018).

Pre-operative/procedural evaluation:
- Pre-operative evaluation for a planned surgery or procedure (Ahmed, 2017).

Post-operative/procedural evaluation:
- Post-operative or interventional vascular procedure for luminal patency versus re-stenosis (due to atherosclerosis, thromboembolism, intimal hyperplasia and other causes), as well as complications such as pseudoaneurysms related to surgical bypass grafts and vascular stents and stent-grafts (Lopera, 2008).
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

**ADDITIONAL INFORMATION RELATED TO LOWER EXTREMITY MRA/MRV:**
MRA of Foot – Fast contrast-enhanced time-resolved 3D MR angiography is used in evaluating the arterial supply of the foot. It does not require the use of ionizing radiation and iodinated contrast medium and it is minimally invasive, safe, fast, and accurate. Dorsalis pedis bypass surgery is an option for preserving a foot in a patient with arterial occlusive disease and MRA may be used in the preoperative evaluation. It can discriminate arteries from veins and can provide other key information, e.g., patency of the pedal arch, presence of collateral pathways, and depiction of target vessel suitable for surgical bypass. Time-resolved gadolinium enhanced MRA can identify injured fat pads in the foot before they have become ulcerated.

MRA and arterial obstructive disease – Catheter angiography is the standard of reference for assessing arterial disease but MRA with contrast enhanced media has gained acceptance and can image the entire vascular system. Contrast agents such as high dose gadolinium have been associated with the development of nephrogenic systemic fibrosis in patients with chronic renal insufficiency. Gadolinium dosage may be decreased without compromising image quality in high-spatial-resolution contrast-enhanced MRA of the lower extremity.
REFERENCES


CPT Codes: 74150, 74160, 74170

INTRODUCTION:

CT provides direct visualization of anatomic structures in the abdomen and pelvis and is a fast imaging tool used to detect and characterize diseases involving the abdomen and pelvis. Abdominal imaging begins at the diaphragm and extends to the umbilicus or iliac crests. CT uses x-rays and multiple detectors to create cross sectional images of the normal anatomy, as well as demonstrate abnormal soft tissue densities, calcifications or fluid/gas patterns in the viscera or peritoneal space.

In general, ionizing radiation from CT should be avoided during pregnancy. Ultrasound is clearly a safer imaging option and is the first imaging test of choice, although CT after equivocal ultrasound has been validated for diagnosis. Clinicians should exercise increased caution with CT imaging in children, pregnant women, and young adults due to the risks of exposure to ionizing radiation. Screening for pregnancy as part of a work-up is suggested to minimize the number of unexpected radiation exposures for women of childbearing age.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ABDOMEN CT:

Evaluation of suspicious known mass/tumors (unconfirmed diagnosis of cancer) for further evaluation of indeterminate or questionable findings:

- Initial evaluation of suspicious masses/tumors found only in the abdomen by physical exam or imaging study, such as ultrasound (US) (ACR, 2014).
- Surveillance: One follow-up exam to ensure no suspicious change has occurred in a tumor in the abdomen. No further surveillance CT unless tumor(s) are specified as highly suspicious, or change was found on last follow-up CT, new/changing sign/symptoms or abnormal lab values.

Evaluation of known cancer for further evaluation of indeterminate or questionable findings, identified by physical examination or imaging exams such as ultrasound (US):

- Initial staging of known cancer
  - All cancers, excluding the following:
    - Basal cell carcinoma of the skin (NCCN, 2018).
    - Melanoma without symptoms or signs of metastasis (NCCN, 2018; Trotter, 2013).
- Follow-up of known cancer (NCCN, 2018):
  - Follow-up of known cancer of patient undergoing active treatment within the past year.
  - Known cancer with suspected abdominal metastasis based on a sign, symptom or an abnormal lab value.
  - Active monitoring for recurrence as clinically indicated.

For evaluation of an organ or abnormality seen on previous imaging:

- For the evaluation of an organ enlargement such as splenomegaly or hepatomegaly as evidenced by physical examination or confirmed on any previous imaging study.
For evaluation of suspected infection or inflammatory disease (ACR, 2013; Cartwright, 2015; McKay, 2007):

- Suspected acute appendicitis (or severe acute diverticulitis) in an adult if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  - WBC elevated
  - Fever
  - Anorexia or
  - Nausea and vomiting.
- Suspected appendicitis in a child after ultrasound has been obtained (Choosing Wisely, ACR/AAP/ACS).
- Suspected peritonitis (from any cause) if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  - Rebound, rigid abdomen, or
  - Severe tenderness to palpation present over entire abdomen.
- Suspected pancreatitis: can have pancreatitis without abnormally elevated amylase and lipase (Mathur, 2015).
- Suspected inflammatory bowel disease (Crohn’s or ulcerative colitis) with abdominal pain, and persistent diarrhea, or bloody diarrhea.
- Suspected cholecystitis or retained gallstones with recent equivocal ultrasound.
- Suspected infection in the abdomen (based on elevated WBC, fever, anorexia, or nausea and vomiting).

For evaluation of known infection or inflammatory disease follow up (ACR, 2013; Cartwright, 2015; McKay, 2007):

- Complications of diverticulitis with severe abdominal pain or severe tenderness or mass, not responding to antibiotic treatment. (prior imaging study is not required for diverticulitis diagnosis).
- Pancreatitis by history, (including pancreatic pseudocyst) with abdominal pain suspicious for worsening, or re-exacerbation.
- Known inflammatory bowel disease (Crohn’s or ulcerative colitis) with recurrence or worsening signs/symptoms requiring re-evaluation.
- Any known infection that is clinically suspected to have created an abscess in the abdomen.
- Any history of fistula limited to the abdomen that requires re-evaluation, or is suspected to have recurred.
- Abnormal fluid collection seen on prior imaging that needs follow-up evaluation.
- Follow up for peritonitis (from any cause) if abdominal/pelvic pain and tenderness to palpation is present, and at LEAST one of the following:
  - Rebound, rigid abdomen, or
  - Severe tenderness to palpation present over entire abdomen.
- Hepatitis/hepatoma screening after ultrasound is abnormal, equivocal, or non-diagnostic (Bruix, 2011; Marquardt, 2016). (No literature supports the use of AFP alone in the screening of HCC).
- Known infection in the abdomen.

For evaluation of known or suspected vascular disease (e.g., aneurysms or hematomas) (Khosa, 2011; Uberoi, 2011)**:

- Evidence of vascular abnormality seen on imaging studies.
- Evaluation of suspected or known aneurysm limited to abdomen or in evaluating abdominal extent of aortic aneurysm**
  - Suspected or known aneurysm > 2.5 cm AND equivocal or indeterminate ultrasound results
  OR
- Prior imaging (e.g. ultrasound) demonstrating aneurysm >2.5 cm in diameter OR
- Suspected complications of known aneurysm as evidenced by clinical findings such as new onset of abdominal pain.
- Scheduled follow-up evaluation of aorto/iliac endograft or stent (Abd/Pelvis CTA is preferred)
  - Asymptomatic at six (6) month intervals, for two (2) years
  - Symptomatic/complications related to stent graft – more frequent imaging may be needed
- Suspected retroperitoneal hematoma or hemorrhage.

**For evaluation of trauma (ACR, 2012):**
- For evaluation of trauma with lab or physical findings of intra-abdominal bleeding limited to the abdomen.
- Suspected retroperitoneal hematoma or hemorrhage.

**Pre-operative evaluation:**
- For abdominal surgery or procedure.

**Post-operative/procedural evaluation:**
- Follow-up of known or suspected post-operative complication involving only the abdomen.
- A follow-up study to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases:**
- ≤5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine or Lumbar Spine.

**Other Indications for an Abdomen CT:**
- Suspected adrenal mass based on diagnostic testing/imaging results, and/or a suspicious clinical presentation. (Biopsy or FDG PET is recommended when pheochromocytoma is not suspected, the mass is > 4 cm, AND there is a history of primary malignancy (ACR, 2012)).
- Persistent abdominal pain not explained by previous imaging/procedure
- Unexplained weight loss of 10% of body weight in two months (patient history is acceptable); with a second MD visit documenting some further decline in weight.
- Unexplained weight loss of 5% of body weight in six months confirmed by documentation to include the following (Bosch, 2017; Wong, 2014).
  - Related history and abdominal exam.
  - Chest x-ray
  - Abdominal Ultrasound
  - Lab tests, must include TSH
  - Colonoscopy if patient fifty plus (50+) years old
- Unexplained abdominal pain in patients seventy-five (75) years or older (USPSTF does not recommend screening colonoscopy in patients over 75).
- Suspected spigelian hernia (ventral hernia) or incisional hernia (evidenced by a surgical abdominal scar) when ordered as a pre-operative study OR when physical exam or prior imaging (e.g. ultrasound) is non-diagnostic or equivocal (Lassandro, 2011) OR ultrasound is contraindicated due to obesity.
- Hernia with suspected complications (e.g. bowel obstruction or strangulation) or prior to surgical repair OR when physical exam or prior imaging (e.g. ultrasound) is non-diagnostic or equivocal (Lassandro, 2011) OR ultrasound is contraindicated due to obesity.
- Ischemic bowel.
• Suspected complete or high-grade partial small bowel obstruction limited to the abdomen.

Combination of studies with Abdomen CT:
• Abdomen CT/Pelvis CT/Chest CT/Neck MRI/Neck CT with MUGA – known tumor/cancer for initial staging or evaluation before starting chemotherapy or radiation treatment.

If an Abdomen/Pelvis CT combo is indicated and the Abdomen CT has already been approved, then the Pelvis CT may be approved.

ADDITIONAL INFORMATION RELATED TO ABDOMEN CT:

Combination studies for suspected appendicitis, peritonitis, diverticulitis, or inflammatory bowel disease (IBD):
• Combined Abdomen CT and Pelvis CT is usually ordered
• There are situations that a combo Abd/Pelvis CT was not ordered such as Pelvis CT previously approved and separate subsequent request for Abdomen CT, etc.

Ultrasound should be considered prior to a request for Abdomen CT for the following evaluations:
• Possible gallstones or abnormal liver function tests with gall bladder present.
• Evaluation of cholecystitis.
• Repeat CT studies of renal mass.
• Repeat CT Hepatic mass follow-up.
• Repeat CT for aortic aneurysm.

Screening for Hepatocellular carcinoma (HCC): AASLD (American Association for the Study of Liver Diseases) recommends screening for HCC with ultrasound every 6 months for patients with hepatitis C and B (Bruix, 2011). The literature differs on the role of AFP (alpha fetoprotein) in the screening of HCC. Some authors argue against its use altogether due to its lack of sensitivity and specificity in detecting HCC (Bruix, 2011; Marquardt, 2016) and instead recommend ultrasound alone for screening. According to Marquardt the AASLD and EASLD (European Association for the Study of the Liver) “do not endorse its [AFP] use in clinical routine, neither alone nor in combination with ultrasound”. This approach is supported by reports of patients with chronic viral hepatitis and elevated AFP but normal livers on imaging. AFP elevation in these cases is due to hepatic inflammation and viral replication (Patil, 2013), not neoplasm. Others advocate for combined ultrasound and AFP for screening (Tzartzeva, 2018; Tan, 2011) citing increased sensitivity compared to ultrasound alone in detecting early stage HCC particularly in cirrhotic patients. In a meta-analysis by Tzartzeva, et al of thirty-two studies (13,367 patients with cirrhosis), ultrasound with AFP had a 63% sensitivity of detecting early stage HCC, compared to 45% for ultrasound alone. In the final analysis, no literature supports the use of AFP alone in the screening of HCC.

CT for organ enlargement - An abd/pelvis combo is most appropriate because it will demonstrate the kidneys and the ureters. Other organs may require an Abdomen CT or Pelvis CT only.

CT for suspected renal stones - An initial CT study is done to identify the size of the stone and rule out obstruction. (7 mm is the key size: less than that size the expectation is that it will pass). After the initial CT study for kidney stone is done, the stone can be followed by x-ray or US (not CT). If a second exacerbation occurs/a new stone is suspected another CT would be indicated to access the size of stone and rule out obstruction.
CT Imaging for renal colic and hematuria: CT protocols include: “stone protocol” for detecting urinary tract calculi, “renal mass protocol” for characterizing known renal masses, and CT urography for evaluating hematuria. Non-contrast CT can be used for detecting most ureteral and renal stones, but sometimes an intravenous contrast agent is needed to determine the relationship of the calculus to the opacified ureter. CT is an effective imaging examination for diagnosing hematuria caused by urinary tract calculi, renal tumors, and urothelial tumors.

CT Imaging for abdominal aortic aneurysms (AAA): If a pulsatile abdominal mass is found in an asymptomatic patient, abdominal ultrasonography is an inexpensive and noninvasive technique for initial evaluation. For further examination, CT may be performed to better define the shape and extent of the aneurysm and the local anatomic relationships of the visceral and renal vessels. CT has high level of accuracy in sizing aneurysms. CT angiography is not routinely required to assess abdominal aortic aneurysms and the decision to utilize conventional CT or CT angiography is based on factors unique to the individual case.

Risk of rupture in 6 years for an AAA < 4 cm is 1%. For a 4-5 cm AAA the risk of rupture increases to 1-3% per year and becomes 6-11% per year for AAA 5-7 cm in cross sectional diameter. >7 cm the risk of rupture goes to 7% per year.

**Abdominal aneurysms and general guidelines for follow-up:**
The normal diameter of the suprarenal abdominal aorta is 3.0 cm and that of the infrarenal is 2.0 cm. Aneurysmal dilatation of the infrarenal aorta is defined as diameter >/= 3.0 cm or dilatation of the aorta >/= 1.5x the normal diameter. - Initial evaluation of AAA is accurately made by ultrasound. Ultrasound can detect and size AAA, with the advantage of being relatively inexpensive, noninvasive, and not require iodinate contrast. The limitations are that overlying bowel gas can obscure findings and the technique is operator dependent.

Recommended intervals for initial follow-up imaging (any modality) of ectatic aortas and abdominal aortas (follow up intervals may vary depending on comorbidities and the growth rate of the aneurysm):
2.5-2.9 cm: ............5yr
3.0-3.4 cm: ............3yr
3.5-3.9 cm: ............2yr
4.0-4.4 cm: ............1yr
4.5-4.9 cm: ............6 mo
5.0-5.5 cm: ............3-6 mo

The Society of Vascular Surgery has different follow up intervals for AAA (SVS, 2018):
>2.5 cm - <3 cm........10 yr
3.0 - 3.9 cm.............3 yr
4.0 - 4.9 cm.............12 mo
5.0 - 5.4 cm.............6 mo.

The Society of Vascular Surgery recommends elective repair of AAA >/= 5.5 cm in patients at low or acceptable surgical risk (Chaikof, 2018).

CTA is not always the study of choice to following an aneurysm. Clinicians interested in documenting size in asymptomatic patient without the concern for complications or branch vessel patency may chose a non-contrast CT.
Combination request of Abdomen CT/Chest CT - A Chest CT will produce images to the level of L3. Documentation for combo is required.

REDUCING RADIATION EXPOSURE:

CT urography - Utilization of appropriate imaging techniques can reduce radiation exposure in performance of CT urography. Some protocols may result in 15-35 mSv of exposure. In the article by Chow, et al. a technique involving administration of IV contrast in two boluses separated by a suitable time delay, allows nephrographic and excretory phases to be acquired in a single imaging pass. This allows for full non-contrast and contrast imaging to be obtained with two imaging passes.

Evaluation for appendicitis following clinical and laboratory evaluation - Sonography of the right upper quadrant and pelvis followed by graded compression and color Doppler sonography of the right lower quadrant was used by Gaitini and colleagues as the initial imaging study in 420 consecutive patients referred for emergency evaluation of acute appendicitis. This method correctly diagnosed acute appendicitis in 66 of 75 patients (88%) and excluded it correctly in 312 of 326 patients (96%). It was inconclusive in 19 patient (<5%). Sensitivity, specificity, positive predictive value, negative predictive value and accuracy were 74.2%, 97%, 88%, 93%, and 92%, respectively and comparable to CT. Appropriate and timely diagnosis of acute appendicitis is needed. Negative laparotomy rates can range from 16% to 47% when based on clinical and laboratory data alone, while perforation rate can reach 35% when surgery is delayed. Appropriate initial imaging can lower the negative laparotomy rate to 6-10%. Ultrasound has a higher non-diagnostic rate, 4% vs. 0.8% for MDCT. In a prospective study operator experience and patient BMI did not affect diagnostic accuracy.

Consider the role of barium contrast studies - Effective doses for fluoroscopic SBFT (small bowel follow through) imaging ranged between 1.37-3.83 mSv for the right lower quadrant, central abdomen and pelvis, respectively. The findings by Jaffe, et al suggest a modified examination for Crohn’s disease indications would have lower effective doses than these. For MDCT the effective dose was 16.1 mSv. This indicates a 5 fold increase in the use of MDCT over SBFT. For patients with Crohn’s disease, efforts should be made to minimize the number of CT examinations, decrease the CT dose or consider MR Enterography. Limitations of SBFT include partial evaluation of extramucosal and extraluminal disease, impaired evaluation of small-bowel loops, especially those inaccessible in the deep pelvis.

Consider the role of capsule endoscopy - Retrospective comparison of capsule endoscopy (CE) to CT in patients with no evidence of a small-bowel stricture at barium examination was the focus of the article by Hara, et al. Studies were done for bleeding of unknown origin after colonoscopy and/or Gastroenterologist, inflammatory bowel disease or chronic abdominal pain. CE was found to be more sensitive than CT examination in the 19 patients that underwent both. CE provides a complimentary and sensitive approach to the evaluation of the small bowel without radiation exposure. A negative examination does not completely rule out pathology.

Work up for distant metastasis in the initial evaluation of melanoma - Multiple studies, including the two authored by Miranda and Yancovitz, indicate that imaging studies including Chest x-ray, Chest CT, Abdomen/Pelvis CT, Brain CT or Brain MRI in the absence of symptoms or findings of metastatic disease have extremely low yields (< 1%) in the survey evaluation of newly diagnosed melanoma, even in the presence of a positive sentinel node biopsy. The further work-up of the more common benign incidental finding (5-7%) on these studies lead to many more diagnostic tests, including surgery, which are seldom warranted.
Initial evaluation of abdominal aortic aneurysm (AAA) - Initial evaluation of AAA is accurately made by ultrasound. Risk of rupture in 6 years for an AAA < 4 cm is 1%. For a 4-5 cm AAA the risk of rupture increases to 1-3% per year and becomes 6-11% per year for AAA 5-7 cm in cross sectional diameter. >7 cm the risk of rupture goes to 7% per year.

Chronic contained ruptures should meet the following criteria: known abdominal aortic aneurysm, previous pain symptoms that may have resolved; stable hemodynamic status with a normal HCT, CT scans showing retroperitoneal hemorrhage, and pathologic confirmation of organized hematoma.

Initial evaluation of adnexal masses - MRI is a sensitive and specific modality for evaluation of adnexal masses in comparison to CT. While improved diagnostic accuracy of MRI was not shown to be statistically significant in the study there was a trend to more accurate results with MRI over multi-detector (16-row) CT.

Evaluation for recurrence of ovarian cancer metastases - MRI was noted to be superior to PET/CT (with non-contrast CT) in the detection of recurrence of ovarian cancer in a small study (36 patients).

Pre-operative evaluation of primary rectal cancer - Abdomen CT may detect hepatic and extra-hepatic disease relevant to decision making and prognosis in rectal cancer but complete imaging through the pelvis does not add useful information. The area of the pelvis in pre-operative evaluation of rectal cancer is better defined by Pelvis MRI.

Imaging of hernias: Most hernias are diagnosed clinically with imaging recommended for the diagnosis of occult hernias or in the evaluation of hernia complications such as bowel obstruction or strangulation. To detect occult hernias, ultrasound is a first line study with a sensitivity of 86% and specificity of 77% compared to 80% sensitivity and 65% specificity for CT (Robinson, 2013). According to Miller, et al “Magnetic resonance imaging is generally not considered a first- or even second-line evaluation modality for hernias...” (Miller, 2014). Based on this analysis MRI is recommended only when ultrasound and CT have been performed and fail to make a diagnosis.
REFERENCES


CPT Codes: 74174

INTRODUCTION:

Computed tomographic angiography (CTA) is used in the evaluation of many conditions affecting the veins and arteries of the abdomen and pelvis or lower extremities. This study (Abdomen/Pelvis CTA) is useful for evaluation of the arteries/veins in the peritoneal cavity (abdominal aorta, iliac arteries) while the Abdominal Arteries CTA is more useful for the evaluation of the abdominal aorta and the vascular supply to the legs. It is not appropriate as a screening tool for asymptomatic patients without a previous diagnosis.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ABDOMEN/PELVIS CTA:

For evaluation of known or suspected abdominal vascular disease:
- For known large vessel diseases (abdominal aorta, inferior vena cava, superior/inferior mesenteric, celiac, splenic, renal or iliac arteries/veins), e.g., aneurysm, dissection, arteriovenous malformations (AVMs), and fistulas, intramural hematoma, and vasculitis.
- Evidence of vascular abnormality seen on prior imaging studies.
- For suspected aortic dissection.
- Evaluation of known or suspected aortic aneurysm (Khosa, 2013; Chaikof, 2018)**:
  - Known or suspected aneurysm > 2.5 cm AND equivocal or indeterminate ultrasound results OR
  - Prior imaging (e.g. ultrasound) demonstrating aneurysm >2.5 cm in diameter OR
  - Suspected complications of known aneurysm as evidenced by signs/symptoms such as new onset of abdominal or pelvic pain.
- Suspected retroperitoneal hematoma or hemorrhage (To determine vascular source of hemorrhage in setting of trauma, tumor invasion, fistula or vasculitis; otherwise CT (rather than CTA) is sufficient and the modality of choice for diagnosing hemorrhage).
- Lower gastrointestinal hemorrhage: Active bleeding in a hemodynamically stable patient or non localized intermittent bleeding as an alternative to Tc-99m RBC scan when colonoscopy did not localize the bleeding, is contraindicated or unavailable (ACR, 2014; Clerc, 2017).
- Venous thrombosis if previous studies have not resulted in a clear diagnosis.
- For evaluation of suspected mesenteric ischemia (ACR, 2012).
- Vascular invasion or displacement by tumor (Conventional CT or MRI also appropriate) (Certik, 2015; Kaufman, 2005).
- For evaluation of known or suspected renal artery stenosis or resistant hypertension in the setting of normal renal function or impaired renal function unrelated to recent medication (ACR, 2017) demonstrated by any of the following (Hartman, 2009; Tullus, 2010):
  - Unsuccessful control after treatment with 3 or more (>2) anti-hypertensive medication at optimal dosing.
  - Acute elevation of creatinine after initiation of an angiotensin converting enzyme inhibitor, (ACE inhibitor) or angiotensin receptor blocker, (ARB).
  - Asymmetric kidney size noted on ultrasound.
Onset of hypertension in a person younger than age 30 without any other risk factors or family history of hypertension.
Significant hypertension (diastolic blood pressure > 110 mm Hg) in a young adult (i.e., younger than 35 years) suggestive of fibromuscular dysplasia
Diagnosis of a syndrome with a higher risk of vascular disease, such as neurofibromatosis, tuberous sclerosis and Williams’ syndrome
New onset of hypertension after age 50
Acute rise in blood pressure in a person with previously stable blood pressures.
Flash pulmonary edema without identifiable causes.
Malignant hypertension.
Bruit heard over renal artery and hypertension.

Pre-operative evaluation:
- Evaluation of interventional vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.

Post-operative or post-procedural evaluation:
- Evaluation of endovascular/interventional abdominal vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism and intimal hyperplasia.
- Evaluation of post-operative complications, e.g. pseudoaneurysms, related to surgical bypass grafts, vascular stents and stent-grafts in the peritoneal cavity.
- Follow-up for post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA) or abdominal extent of iliac artery aneurysms. Routine, baseline study (post-op/intervention) is warranted within 1-3 months (Chaikof, 2018; Uberoi, 2011).
  - Asymptomatic at six (6) month intervals, for one (1) year, then annually.
  - Symptomatic/complications related to stent graft – more frequent imaging may be needed.
- Follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Chest CTA/Abdomen/Pelvis CTA combo:
- For evaluation of extensive vascular disease involving the chest and abdominal cavities such as aortic dissection, vasculitic diseases such as Takayasu’s arteritis, significant post-traumatic or post-procedural vascular complications, etc.
- For preoperative or preprocedural evaluation such as transcatheter aortic valve replacement (TAVR).

ADDITIONAL INFORMATION RELATED TO ABDOMEN/PELVIS CTA:

Abd/Pelvis CTA & Lower Extremity CTA Runoff Requests: Only one authorization request is required, using CPT Code 75635 Abdominal Arteries CTA. This study provides for imaging of the abdomen, pelvis, and both legs. The CPT code description is CTA aorto-iliofemoral runoff: abdominal aorta and bilateral ilio-femoral lower extremity runoff.

Bruit: blowing vascular sounds heard over partially occluded blood vessels. Abdominal bruits may indicate partial obstruction of the aorta or other major arteries such as the renal, iliac, or femoral arteries. Associated risks include but are not limited to: renal artery stenosis, aortic aneurysm, atherosclerosis, AVM, or coarctation of aorta.
Peripheral Artery Disease (PAD) – Before the availability of computed tomography angiography (CTA), peripheral arterial disease was evaluated using CT and only a portion of the peripheral arterial tree could be imaged. Multi-detector row CT (MDCT) overcomes this limitation and provides an accurate alternative to CT and is a cost-effective diagnostic strategy in evaluating PAD. **Abdominal Arteries CTA (including runoff to the lower extremities) is the preferred study when evaluation of arterial sufficiency to the legs is part of the evaluation**

CTA and Abdominal Aortic Aneurysm – Endovascular repair is an alternative to open surgical repair of an abdominal aortic aneurysm. It has lower morbidity and mortality rates and is minimally invasive. In order to be successful, it depends on precise measurement of the aneurysm and involved vessels. CTA with 3D reconstruction is useful in obtaining exact morphologic information on abdominal aortic aneurysms. CTA is also used for the detection of postoperative complications of endovascular repair.

CTA and Abdominal Aortic Aneurysm **–** The normal diameter of the suprarenal abdominal aorta is 3.0 cm and that of the infrarenal is 2.0 cm. Aneurysmal dilatation of the infrarenal aorta is defined as diameter >/= 3.0 cm or dilatation of the aorta >/= 1.5x the normal diameter.

**Recommended intervals for initial follow-up imaging of ectatic aortas and abdominal aortas (follow up intervals may vary depending on comorbidities and the growth rate of the aneurysm)** from the white paper of the ACR Incidental Findings Committee II on vascular findings (Khosa, 2013):
- 2.5-2.9 cm: .........5yr
- 3.0-3.4 cm:.............3yr
- 3.5-3.9 cm:.............2yr
- 4.0-4.4 cm:.............1yr
- 4.5-4.9 cm:.............6 mo
- 5.0-5.5 cm:.............3-6 mo

The Society of Vascular Surgery has different follow up intervals for AAA (SVS 2018):
- >2.5 cm - <3 cm:.......10 yr
- 3.0 - 3.9 cm:.............3 yr
- 4.0 - 4.9 cm:.............12 mo
- 5.0 - 5.4 cm:.............6 mo.

The Society of Vascular Surgery recommends elective repair of AAA >/= 5.5 cm in patients at low or acceptable surgical risk (Chaikof, 2018).

**CTA and Renal Artery Stenosis** – Renal artery stenosis is the major cause of secondary hypertension. It may also cause renal insufficiency and end-stage renal disease. **Abdomen CTA (limiting evaluation to the aorta above the bifurcation and including the abdominal arteries) is the preferred study.** Atherosclerosis is one of the common causes of this condition, especially in older patients with multiple cardiovascular risk factors and worsening hypertension or deterioration of renal function. CTA is used to evaluate the renal arteries and detect renal artery stenosis.

**CTA and Thoracic Aorta Endovascular Stent-Grafts** – CTA is an effective alternative to conventional angiography for postoperative follow-up of aortic stent grafts. It is used to review complications after thoracic endovascular aortic repair. CTA can detect luminal and extraluminal changes to the thoracic aortic after stent-grafting and can be performed efficiently with fast scanning speed and high spatial and temporal resolution.
**MRI/CT and acute hemorrhage:** MRI is not indicated and MRA/MRV (MR Angiography/Venography) is rarely indicated for evaluation of intraperitoneal or retroperitoneal hemorrhage, particularly in the acute setting. CT is the study of choice due to its availability, speed of the study and less susceptibility to artifact from patient motion. Advances in technology have allowed conventional CT to not just detect hematomas but also the source of acute vascular extravasation. In special cases finer vascular detail to assess the specific source vessel responsible for hemorrhage may require the use of CTA. CTA in diagnosis of lower gastrointestinal bleeding is such an example (Clerc, 2017).

MRA/MRV is often utilized in non acute situations to assess vascular structure involved in atherosclerotic disease and its complications, vasculitis, venous thrombosis, vascular congestion or tumor invasion. Although some of these conditions may be associated with hemorrhage, it is usually not the primary reason why MRI/MRA/MRV is selected for the evaluation. A special condition where MRI may be superior to CT for evaluating hemorrhage is to detect an underlying neoplasm as the cause of bleeding (Abe, 2010).
REFERENCES


CPT Codes: 74175

INTRODUCTION:

Computed tomography angiography (CTA) generates images of the arteries that can be evaluated for evidence of stenosis, occlusion, or aneurysms. It is used to evaluate the arteries of the abdominal aorta and the renal arteries. CTA uses ionizing radiation and requires the administration of iodinated contrast agent which is a potential hazard in patients with impaired renal function. Abdominal CTA is not used as a screening tool, e.g. evaluation of asymptomatic patients without a previous diagnosis.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ABDOMEN CTA:

For evaluation of known or suspected abdominal vascular disease:
- For known large vessel diseases (abdominal aorta, inferior vena cava, superior/inferior mesenteric, celiac, splenic, renal, or iliac arteries/veins), e.g., aneurysm, dissection, arteriovenous malformations (AVMs), and fistulas, intramural hematoma, and vasculitis.
- Evidence of vascular abnormality seen on prior imaging studies.
- For suspected aortic dissection.
- Evaluation of known or suspected aortic aneurysm (Khosa, 2013; Chaikof, 2018)**:
  - Known or suspected aneurysm > 2.5 cm AND equivocal or indeterminate ultrasound results OR
  - Prior imaging (e.g. ultrasound) demonstrating aneurysm >2.5 cm in diameter OR
  - Suspected complications of known aneurysm as evidenced by signs/symptoms such as new onset of abdominal or pelvic pain.
- Suspected retroperitoneal hematoma or hemorrhage (To determine vascular source of hemorrhage in setting of trauma, tumor invasion, fistula or vasculitis; otherwise CT (rather than CTA) is sufficient and the modality of choice for diagnosing hemorrhage).
- Suspected renal vein thrombosis in patient with known renal mass.
- For evaluation of suspected mesenteric ischemia (ACR, 2012).
- Venous thrombosis if previous studies have not resulted in a clear diagnosis.
- Vascular invasion or displacement by tumor.
- For evaluation of portal venous system (hepatic portal system) after doppler ultrasound has been performed.
- For evaluation of known or suspected renal artery stenosis or resistant hypertension in the setting of normal renal function or impaired renal function unrelated to recent medication (ACR, 2017) demonstrated by any of the following (Hartman, 2009; Tullus, 2010):
  - Unsuccessful control after treatment with 3 or more (>2) anti-hypertensive medication at optimal dosing.
  - Acute elevation of creatinine after initiation of an angiotension converting enzyme inhibitor (ACE inhibitor) or angiotension receptor blocker (ARB).
  - Asymmetric kidney size noted on ultrasound.
o Onset of hypertension in a person younger than age 30 without any other risk factors or family history of hypertension.
o Significant hypertension (diastolic blood pressure > 110 mm Hg) in a young adult (i.e., younger than 35 years) suggestive of fibromuscular dysplasia
o Diagnosis of a syndrome with a higher risk of vascular disease, such as neurofibromatosis, tuberous sclerosis and Williams’ syndrome
o New onset of hypertension after age 50.
o Acute rise in blood pressure in a person with previously stable blood pressures.
o Flash pulmonary edema without identifiable causes.
o Malignant hypertension.
o Bruit heard over renal artery and hypertension.

Pre-operative evaluation:
• Evaluation prior to interventional vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.

Post-operative or post-procedural evaluation:
• Evaluation of endovascular/interventional abdominal vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.
• Evaluation of post-operative complications, e.g. pseudoaneurysms related to surgical bypass grafts, vascular stents, and stent-grafts in the peritoneal cavity.
• Follow-up for post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA) or abdominal extent of iliac artery aneurysms. Routine, baseline study (post-op/intervention) is warranted within 1-3 months (Chaikof, 2018; Uberoi, 2011).
  o Asymptomatic at six (6) month intervals for one (1) year, then annually.
  o Symptomatic/complications related to stent graft – more frequent imaging may be needed.
• Follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Chest CTA/Abdomen CTA combo:
• For evaluation of extensive vascular disease involving the chest and abdominal cavities such as aortic dissection, vasculitic diseases such as Takayasu’s arteritis, significant post-traumatic or post-procedural vascular complications, etc.
• For preoperative or preprocedural evaluation such as transcatheter aortic valve replacement (TAVR).

ADDITIONAL INFORMATION RELATED TO ABDOMEN CTA:

Abd/Pelvis CTA & Lower Extremity CTA Runoff Requests: Only one authorization request is required, using CPT Code 75635 Abdominal Arteries CTA. This study provides for imaging of the abdomen, pelvis, and both legs. The CPT code description is CTA aorto-iliofemoral runoff; abdominal aorta and bilateral ilio-femoral lower extremity runoff.

CTA and Abdominal Aortic Aneurysm (AAA):
Endovascular repair is an alternative to open surgical repair of an abdominal aortic aneurysm. It has lower morbidity and mortality rates and is minimally invasive. In order to be successful, it depends on precise measurement of the aneurysm and involved vessels. CTA with 3D reconstruction is useful in obtaining exact morphologic information on abdominal aortic aneurysms. CTA is also used for the detection of postoperative complications of endovascular repair.
**Abdominal Aneurysms and general Guidelines for follow-up:**
The normal diameter of the suprarenal abdominal aorta is 3.0 cm and that of the infrarenal is 2.0 cm. Aneurysmal dilatation of the infrarenal aorta is defined as diameter \( \geq 3.0 \) cm or dilatation of the aorta \( \geq 1.5 \times \) the normal diameter. Initial evaluation of AAA is accurately made by ultrasound. Ultrasound can detect and size AAA, with the advantage of being relatively inexpensive, noninvasive and not require iodinate contrast. The limitations are that overlying bowel gas can obscure findings and the technique is operator dependent.

**Recommended intervals for initial follow-up imaging of ectatic aortas and abdominal aortas** (follow up intervals may vary depending on comorbidities and the growth rate of the aneurysm) from the white paper of the ACR Incidental Findings Committee II on vascular findings (Khosa, 2013):

- 2.5 - 2.9 cm: \((\leq 5 \text{yr})\)
- 3.0 - 3.4 cm: \((\leq 3 \text{yr})\)
- 3.5 - 3.9 cm: \((\leq 2 \text{yr})\)
- 4.0 - 4.4 cm: \((\leq 1 \text{yr})\)
- 4.5 - 4.9 cm: \((6 \text{ mo})\)
- 5.0 - 5.5 cm: \((3 - 6 \text{ mo})\)

The Society of Vascular Surgery has different follow up intervals for AAA (SVS, 2018):

- \(> 2.5 \text{ cm} - < 3 \text{ cm}\): \((10 \text{ yr})\)
- 3.0 - 3.9 cm: \((\leq 3 \text{ yr})\)
- 4.0 - 4.9 cm: \((12 \text{ mo})\)
- 5.0 - 5.4 cm: \((6 \text{ mo})\)

The Society of Vascular Surgery recommends elective repair of AAA \(\geq 5.5 \text{ cm}\) in patients at low or acceptable surgical risk (Chaikof, 2018).

**CTA and Renal Artery Stenosis** – Renal artery stenosis is the major cause of secondary hypertension. It may also cause renal insufficiency and end-stage renal disease. Atherosclerosis is one of the common causes of this condition, especially in older patients with multiple cardiovascular risk factors and worsening hypertension or deterioration of renal function. CTA is used to evaluate the renal arteries and detect renal artery stenosis.
REFERENCES


CPT Codes: 74176, 74177, 74178

INTRODUCTION:

CT provides direct visualization of anatomic structures in the abdomen and pelvis and is a fast imaging tool used to detect and characterize disease involving the abdomen and pelvis. Abdomen/pelvis imaging begins at the diaphragmatic dome through pubic symphysis. CT uses x-rays and multiple detectors to create cross sectional images of the normal anatomy as well as demonstrate abnormal soft tissue densities, calcifications or fluid/gas patterns in the viscera or peritoneal space.

In general, ionizing radiation from CT should be avoided during pregnancy. Ultrasound is clearly a safer imaging option and is the first imaging test of choice, although CT after equivocal ultrasound has been validated for diagnosis. Clinicians should exercise increased caution with CT imaging in children, pregnant women, and young adults due to the risks of exposure to ionizing radiation. Screening for pregnancy as part of a work-up is suggested to minimize the number of unexpected radiation exposures for women of childbearing age.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ABDOMEN/PELVIS CT:

For evaluation of hematuria (Davis, 2012; Sharp, 2013):
- Hematuria (All hematuria should be documented by greater than 3 RBC per high-power field on urinalysis):
- Hematuria (non-infectious)
- Hematuria (infectious) persisting six weeks after the completion of antibiotic therapy.

For evaluation of known or suspected kidney or ureteral stones (ACEP, 2014):
- Delineation of suspected renal calculi or ureteral calculi.
- Known calculi in patients >50 years of age.
- Known renal calculi in patients <50 years of age after ultrasound has been obtained and is non-diagnostic, inconclusive, or shows an abnormality needing further evaluation.

Evaluation of suspicious known mass/tumors (unconfirmed diagnosis of cancer) for further evaluation of indeterminate or questionable findings:
- Initial evaluation of suspicious masses/tumors found by physical exam or imaging study, such as ultrasound (US) and both the abdomen and pelvis are likely affected (ACR, 2013, 2014).
- Surveillance: One follow-up exam to ensure no suspicious change has occurred in a tumor in the abdomen and pelvis. No further surveillance CT unless tumor(s) are specified as highly suspicious or change was found on last follow-up CT, new/changing sign/symptoms or abnormal lab values.

Evaluation of known cancer for further evaluation of indeterminate or questionable findings, identified by physical examination or imaging exams such as ultrasound (US):
- Initial staging of known cancer
All cancers, excluding the following:
- Basal Cell Carcinoma of the skin (NCCN, 2018).
- Melanoma without symptoms or signs of metastasis (NCCN, 2018; Trotter, 2013).
- Prostate cancer unless Gleason score seven plus (7+) or PSA over twenty (20) (NCCN, 2017).

Follow-up of known cancer (NCCN, 2018; Bourgioti, 2016):
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Known cancer with suspected abdominal/pelvic metastasis based on a sign, symptom or an abnormal lab value.
- Active monitoring for recurrence as clinically indicated.

For evaluation of an organ enlargement:
- For the evaluation of an organ enlargement such as splenomegaly, hepatomegaly, uterus or ovaries as evidenced by physical examination or confirmed on any previous imaging study.

For evaluation of suspected infection or inflammatory disease (ACR, 2013; Cartwright, 2015; McKay, 2007):
- Suspected acute appendicitis (or severe acute diverticulitis) in an adult if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  - WBC elevated
  - Fever
  - Anorexia or
  - Nausea and vomiting.
- Suspected appendicitis in a child after ultrasound has been obtained (Choosing Wisely, ACR/AAP/ACS).
- Suspected peritonitis (from any cause) if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  - Rebound, rigid abdomen, or
  - Severe tenderness to palpation present over entire abdomen.
- Suspected pancreatitis; can have pancreatitis without abnormally elevated amylase and lipase (Mathur, 2015).
- Suspected complications of diverticulitis (known to be limited to the abdomen/pelvis by prior imaging) with abdominal/pelvic pain or severe tenderness, not responding to antibiotics treatment.
- Suspected inflammatory bowel disease (Crohn’s or ulcerative colitis) with abdominal pain, and persistent diarrhea, or bloody diarrhea.
- Suspected cholecystitis or retained gallstones with recent equivocal ultrasound.
- Suspected infection in abdomen/pelvis (based on elevated WBC, fever, anorexia, or nausea and vomiting).

For evaluation of known infection or inflammatory disease follow up (ACR, 2013; Cartwright, 2015; McKay, 2007):
- Complications of diverticulitis with severe abdominal/pelvic pain or severe tenderness or mass not responding to antibiotic treatment (prior imaging study is not required for diverticulitis diagnosis).
- Pancreatitis by history (including pancreatic pseudocyst) with abdominal pain suspicious for worsening, or re-exacerbation.
- Known inflammatory bowel disease, (Crohn’s or Ulcerative colitis) with recurrence or worsening signs/symptoms requiring re-evaluation.
- Any known infection that is clinically suspected to have created an abscess in the abdomen or pelvis.
- Any history of fistula that requires re-evaluation, or is suspected to have recurred in the abdomen or pelvis.
- Abnormal fluid collection seen on prior imaging that needs follow-up evaluation.
• Follow up for peritonitis (from any cause) if abdominal/pelvic pain and tenderness to palpation is present, and at LEAST one of the following:
  o Rebound, rigid abdomen, or
  o Severe tenderness to palpation present over entire abdomen.
• Hepatitis/hepatoma screening after ultrasound has been obtained and is abnormal, equivocal or non-diagnostic (Bruix, 2011; Marquardt, 2016). (No literature supports the use of AFP alone in the screening of HCC).
• Known infection in the abdomen/pelvis region.

**For evaluation of known or suspected vascular disease (e.g., aneurysms or hematomas) (Khosa, 2011; Uberoi, 2011)**:
• Evidence of vascular abnormality seen on imaging studies.
  o Evaluation of suspected or known aortic aneurysm limited to the abdomen/pelvis or in evaluating abdominal/pelvic extent of aortic aneurysm**:
    o Suspected or known aneurysm > 2.5 cm AND equivocal or indeterminate ultrasound results OR
    o Prior imaging (e.g. ultrasound) demonstrating aneurysm > 2.5 cm in diameter OR
    o Suspected complications of known aneurysm as evidenced by clinical findings such as new onset of abdominal or pelvic pain
• Scheduled follow-up evaluation of aorto/iliac endograft or stent. (Abd/Pelvis CTA is preferred)
  o Asymptomatic at six (6) month intervals, for two (2) years
  o Symptomatic/complications related to stent graft – more frequent imaging may be needed.
• Suspected retroperitoneal hematoma or hemorrhage

**For evaluation of trauma (ACR, 2012)**:
• For evaluation of trauma with lab or physical findings of intra-abdominal/pelvic bleeding.
• Suspected retroperitoneal hematoma or hemorrhage.

**Pre-operative evaluation**:
• For abdominal/pelvic surgery or procedure.

**Post-operative/procedural evaluation**:
• Follow-up of known or suspected post-operative complication.
• A follow-up study to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases**:
• ≤5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on the cancer: Neck, Abdomen, Pelvis, Chest, Brain, Cervical Spine, Thoracic Spine, or Lumbar Spine.

**Other indications for Abdomen/Pelvic CT Combo**:
• Suspected adrenal mass or pheochromocytoma based on diagnostic testing/imaging results, and/or a suspicious clinical presentation. (Biopsy or FDG PET is recommended when pheochromocytoma is not suspected, the mass is > 4 cm, AND there is a history of primary malignancy (ACR, 2012)).
• Persistent abdomen/pelvic pain not explained by previous imaging/procedure.
• Unexplained weight loss of 10% of body weight in two months (patient history is acceptable); with a second MD visit documenting some further decline in weight.
• Unexplained weight loss of 5% of body weight in six months confirmed by documentation to include the following (Bosch, 2017; Wong, 2014).
  o Related history and abdominal exam.
  o Chest x-ray
  o Abdominal ultrasound
  o Lab tests, must include TSH
  o Colonoscopy if patient fifty plus (50+) years old

• Unexplained abdominal pain in patients seventy-five (75) years or older (USPSTF does not recommend screening colonoscopy in patients over 75).

• Suspected spigelian hernia (ventral hernia) or incisional hernia (evidenced by a surgical abdominal scar) when ordered as a pre-operative study OR when physical exam or prior imaging (e.g. ultrasound) is non-diagnostic or equivocal (Lassandro, 2011) OR ultrasound is contraindicated due to obesity.

• Hernia with suspected complications. (e.g. bowel obstruction or strangulation) or prior to surgical repair OR when physical exam or prior imaging (e.g. ultrasound) is non-diagnostic or equivocal (Lassandro, 2011; Miller, 2014; Robinson, 2013).

• Ischemic bowel.

• Suspected complete or high-grade partial small bowel obstruction.

ADDITIONAL INFORMATION RELATED TO ABDOMEN/PELVIS CT:

Ultrasound should be considered prior to a request for Abdomen or Pelvis CT for the following evaluations:
  o Possible gallstones or abnormal liver function tests with gall bladder present.
  o Evaluation of cholecystitis.
  o Repeat CT studies of renal mass.
  o Repeat CT Hepatic mass follow-up.
  o Repeat CT for aortic aneurysm ordered by non-surgeon.

CT for suspected renal stones: An initial CT study is done to identify the size of the stone and rule out obstruction. (7 mm is the key size, less than that size the expectation is that it will pass) After the initial CT study for kidney stone is done, the stone can be followed by x-ray or US (not CT). If a second exacerbation occurs/a new stone is suspected another CT would be indicated to access the size of stone and rule out obstruction.

CT Imaging for renal colic and hematuria: CT protocols include: “stone protocol” for detecting urinary tract calculi, “renal mass protocol” for characterizing known renal masses, and CT urography for evaluating hematuria. Non-contrast CT can be used for detecting most ureteral and renal stones but sometimes an intravenous contrast agent is needed to determine the relationship of the calculus to the opacified ureter. CT is an effective imaging examination for diagnosing hematuria caused by urinary tract calculi, renal tumors and urothelial tumors.

Screening for Hepatocellular carcinoma (HCC): AASLD (American Association for the Study of Liver Diseases) recommends screening for HCC with ultrasound every 6 months for patients with hepatitis C and B (Bruix, 2011). The literature differs on the role of AFP (alpha fetoprotein) in the screening of HCC. Some authors argue against its use altogether due to its lack of sensitivity and specificity in detecting HCC (Bruix, 2011; Marquardt, 2016) and instead recommend ultrasound alone for screening. According to Marquardt the AASLD and EASLD (European Association for the Study of the Liver) “do not endorse its [AFP] use in clinical routine, neither alone nor in combination with ultrasound”. This approach is
supported by reports of patients with chronic viral hepatitis and elevated AFP but normal livers on imaging. AFP elevation in these cases is due to hepatic inflammation and viral replication (Patil, 2013), not neoplasm. Others advocate for combined ultrasound and AFP for screening (Tzartzeva, 2018; Tan, 2011) citing increased sensitivity compared to ultrasound alone in detecting early stage HCC particularly in cirrhotic patients. In a meta-analysis by Tzartzeva, et al of thirty-two studies (13,367 patients with cirrhosis), ultrasound with AFP had a 63% sensitivity of detecting early stage HCC compared to 45% for ultrasound alone. In the final analysis, no literature supports the use of AFP alone in the screening of HCC.

CT Imaging for abdominal aortic aneurysms: If a pulsatile abdominal mass is found in an asymptomatic patient, abdominal ultrasonography is an inexpensive and noninvasive technique for initial evaluation. For further examination, CT may be performed to better define the shape and extent of the aneurysm and the local anatomic relationships of the visceral and renal vessels. CT has high level of accuracy in sizing aneurysms. CT angiography is not routinely required to assess abdominal aortic aneurysms and the decision to utilize conventional CT or CT angiography is based on factors unique to the individual case.

Risk of rupture in 6 years for an AAA < 4 cm is 1%. For a 4-5 cm AAA the risk of rupture increases to 1-3% per year and becomes 6-11% per year for AAA 5-7 cm in cross sectional diameter. >7 cm the risk of rupture goes to 7% per year.

**Abdominal aneurysms and general guidelines for follow-up:**
The normal diameter of the suprarenal abdominal aorta is 3.0 cm and that of the infrarenal is 2.0 cm. Aneurysmal dilatation of the infrarenal aorta is defined as diameter >/= 3.0 cm or dilatation of the aorta >/= 1.5x the normal diameter. Initial evaluation of AAA is accurately made by ultrasound. Ultrasound can detect and size AAA, with the advantage of being relatively inexpensive, noninvasive and not require iodinate contrast. The limitations are that overlying bowel gas can obscure findings and the technique is operator dependent.

**Recommended intervals for initial follow-up imaging (any modality) of ectatic aortas and abdominal aortas (follow up intervals may vary depending on comorbidities and the growth rate of the aneurysm):**

- 2.5-2.9 cm: ..........5yr
- 3.0-3.4 cm: ...........3yr
- 3.5-3.9 cm: ..........2yr
- 4.0-4.4 cm: ..........1yr
- 4.5-4.9 cm: ............6 mo
- 5.0-5.5 cm: ............3-6 mo

The Society of Vascular Surgery has different follow up intervals for AAA (SVS, 2018):

- >2.5 cm - <3 cm:.......10 yr
- 3.0 - 3.9 cm:..........3 yr
- 4.0 - 4.9 cm:..........12 mo
- 5.0 - 5.4 cm:.........6 mo.

The Society of Vascular Surgery recommends elective repair of AAA >/= 5.5 cm in patients at low or acceptable surgical risk (Chaikof, 2018).

**Combination request of Abdomen CT/Chest CT** - A Chest CT will produce images to the level of L3. Documentation for combo is required.

REDUCING RADIATION EXPOSURE:
Evaluation for appendicitis following clinical and laboratory evaluation -
Sonography of the right upper quadrant and pelvis followed by graded compression and color Doppler sonography of the right lower quadrant was used by Gaitini and colleagues as the initial imaging study in 420 consecutive patients referred for emergency evaluation of acute appendicitis. This method correctly diagnosed acute appendicitis in 66 of 75 patients (88%) and excluded it correctly in 312 of 326 patients (96%). It was inconclusive in 19 patient (<5%). Sensitivity, specificity, positive predictive value, negative predictive value and accuracy were 74.2%, 97%, 88%, 93%, and 92%, respectively and comparable to CT. Appropriate and timely diagnosis of acute appendicitis is needed. Negative laparotomy rates can range from 16% to 47% when based on clinical and laboratory data alone, while perforation rate can reach 35% when surgery is delayed. Appropriate initial imaging can lower the negative laparotomy rate to 6-10%. Ultrasound has a higher non-diagnostic rate (4%) vs. 0.8% for MDCT. In a prospective study operator experience and patient BMI did not affect diagnostic accuracy.

Consider alternatives to CT imaging in patients with Crohn disease: In facilities where the technical and clinical expertise exists, MR enterography is emerging as the study of choice (replacing CT) for patients requiring frequent follow up examinations to determine disease extent or progression. The technique also has advantage over small bowel follow through (SBFT) in that it avoids ionizing radiation completely, yet allows evaluation of extramucosal and extraluminal disease.

Consider the role of capsule endoscopy - Retrospective comparison of capsule endoscopy (CE) to CT in patients with no evidence of a small-bowel stricture at barium examination was the focus of the article by Hara, et al. Studies were done for bleeding of unknown origin after colonoscopy and/or Gastroenterologist, inflammatory bowel disease or chronic abdominal pain. CE was found to be more sensitive than CT examination in the 19 patients that underwent both. CE provides a complimentary and sensitive approach to the evaluation of the small bowel without radiation exposure. A negative examination does not completely rule out pathology.

Initial evaluation of abdominal aortic aneurysm (AAA) - Initial evaluation of AAA is accurately made by ultrasound.

Imaging of hernias: Most hernias are diagnosed clinically with imaging recommended for the diagnosis of occult hernias or in the evaluation of hernia complications, such as bowel obstruction or strangulation. To detect occult hernias, ultrasound is a first line study with a sensitivity of 86% and specificity of 77%, compared to 80% sensitivity and 65% specificity for CT (Robinson, 2013). According to Miller, et al “Magnetic resonance imaging is generally not considered a first- or even second-line evaluation modality for hernias...” (Miller, 2014). Based on this analysis, MRI is recommended only when ultrasound and CT have been performed and fail to make a diagnosis.
REFERENCES


INTRODUCTION:

Abdominal magnetic resonance imaging (MRI) is a proven and useful tool for the diagnosis, evaluation, assessment of severity and follow-up of diseases of the abdomen. It is more expensive than computed tomography (CT) but it avoids exposing the patient to ionizing radiation. MRI may be the best imaging procedure for patients with allergy to radiographic contrast material or renal failure. It may also be the procedure of choice for suspected lesions that require a technique to detect subtle soft-tissue contrast and provide a three dimensional depiction of a lesion. Abdominal MRI studies are usually targeted for further evaluation of indeterminate or questionable findings, identified on more standard imaging exams such as Ultrasound (US) and CT.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ABDOMEN MRI:

Evaluation of suspicious known mass/tumors (unconfirmed diagnosis of cancer) for further evaluation of indeterminate or questionable findings:
- Initial evaluation of suspicious abdomen masses/tumors found only in the abdomen by physical exam or imaging study, such as ultrasound (US) (ACR, 2014).
- Surveillance: One follow-up exam to ensure no suspicious change has occurred in a tumor in the abdomen. No further surveillance unless tumor(s) are specified as highly suspicious, or change was found on exam or last follow-up imaging.

Evaluation of known cancer for further evaluation of indeterminate or questionable findings, identified by physical examination or imaging exams such as ultrasound (US) and CT:
- Initial staging of known cancer
  - All cancers, excluding the following:
    - Basal Cell Carcinoma of the skin (NCCN, 2018).
    - Melanoma without symptoms or signs of metastasis (NCCN, 2018; Trotter, 2013).
- Follow-up of known cancer (NCCN, 2018; Bourgioti, 2016):
  - Follow-up of known cancer of patient undergoing active treatment within the past year.
  - Known cancer with suspected abdominal metastasis based on a sign, symptom or an abnormal lab value.
  - Cancer surveillance: Active monitoring for recurrence as clinically indicated.

For evaluation of suspected infection or inflammatory disease (ACR, 2013; Cartwright, 2015; McKay, 2007):
- Suspected acute appendicitis (or severe acute diverticulitis) in an adult if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  - WBC elevated
  - Fever
  - Anorexia or
  - Nausea and vomiting.
• Suspected appendicitis in a child after ultrasound has been obtained (Choosing Wisely, ACR/AAP/ACS).
• Suspected peritonitis (from any cause) if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  o Rebound, rigid abdomen, or
  o Severe tenderness to palpation present over entire abdomen.
• Suspected pancreatitis; can have pancreatitis without abnormally elevated amylase and lipase (Mathur, 2015).
• Suspected inflammatory bowel disease (Crohn’s or ulcerative colitis) with abdominal pain, and persistent diarrhea, or bloody diarrhea.
• Suspected cholecystitis or retained gallstones with recent equivocal ultrasound.
• Suspected infection in the abdomen (based on elevated WBC, fever, anorexia, or nausea and vomiting).

For evaluation of known infection or inflammatory disease follow up (ACR, 2013; Cartwright, 2015; McKay, 2007):
• Complications of diverticulitis with severe abdominal pain or severe tenderness or mass, not responding to antibiotic treatment, (prior imaging study is not required for diverticulitis diagnosis).
• Pancreatitis by history, (including pancreatic pseudocyst) with abdominal pain suspicious for worsening, or re-exacerbation.
• Known inflammatory bowel disease, (Crohn’s or ulcerative colitis) with recurrence or worsening signs/symptoms requiring re-evaluation.
• Any known infection that is clinically suspected to have created an abscess in the abdomen.
• Any history of fistula limited to the abdomen that requires re-evaluation, or is suspected to have recurred.
• Abnormal fluid collection seen on prior imaging that needs follow-up evaluation.
• Follow up of known peritonitis (from any cause) if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  o Rebound, rigid abdomen, or
  o Severe tenderness to palpation present over entire abdomen.
• Hepatitis/hepatoma screening after ultrasound has been obtained and is abnormal, equivocal or non-diagnostic (Bruix, 2011; Marquardt, 2016). (No literature supports the use of AFP alone in the screening of HCC).
• Known infection in the abdomen.

Pre-operative evaluation:
• For abdominal surgery or procedure.

Post-operative/procedural evaluation:
• Follow-up of known or suspected post-operative complication involving only the abdomen.
• A follow-up study to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed.

Indication for combination studies for the initial pre-therapy staging of cancer, OR active monitoring for recurrence as clinically indicated OR evaluation of suspected metastases:
• ≤ 5 concurrent studies to include CT or MRI of any of the following areas as appropriate depending on

Other Indications for an Abdominal MRI:
• To provide an alternative to abdominal CT when CT would be limited due to allergy to radiographic
  contrast material.
• To provide an alternative to follow-up of an indeterminate abdomen CT when previous CT/Ultrasound
  was equivocal.
• Suspected adrenal mass or pheochromocytoma based on diagnostic testing/imaging results, and/or a
  suspicious clinical presentation. (Biopsy or FDG PET is recommended when pheochromocytoma is not
  suspected, the mass is > 4 cm, AND there is a history of primary malignancy (ACR, 2012)).
• Occult hernia when physical exam or prior imaging (ultrasound AND CT) is non-diagnostic or
equivocal (Lassandro, 2011; Miller, 2014; Robinson, 2013).

Evaluation of iron overload in the following settings:
• Initial evaluation of liver iron in Hemochromatosis diagnosed on ferritin, iron saturation and/or
  genetic markers, in lieu of liver biopsy. (Gandon, 2004)
• Annual evaluation for high risk patients: transfusion-dependent thalassemia major, sickle cell
disease and other congenital anemias. (Wood, 2014)

ADDITIONAL INFORMATION RELATED TO ABDOMINAL MRI:

MRI of the liver – The liver is a common site of metastatic spread. Patients with a history of known or
suspected malignancy, especially tumors from the colon, lung, pancreas and stomach, are at risk for
developing hepatocellular carcinoma. Patients with chronic liver disease are also at risk for developing
liver cancer and undergo periodic liver screening for focal liver lesion detection, usually with
ultrasonography (US). Extra-cellular gadolinium chelate contrast-enhanced MRI is used for evaluating
patients with an abnormal US. Patients with hepatic metastases being considered for metastasectomy
undergo contrast-enhanced MRI using tissue-specific contrast agents.

Screening for Hepatocellular carcinoma (HCC): AASLD (American Association for the Study of Liver
Diseases) recommends screening for HCC with ultrasound every 6 months for patients with hepatitis C
and B (Bruix, 2011). The literature differs on the role of AFP (alpha fetoprotein) in the screening of HCC.
Some authors argue against its use altogether due to its lack of sensitivity and specificity in detecting
HCC (Bruix, 2011; Marquardt, 2016) and instead recommend ultrasound alone for screening. According to
Marquardt the AASLD and EASLD (European Association for the Study of the Liver) “do not endorse its
[AFP] use in clinical routine, neither alone nor in combination with ultrasound”. This approach is
supported by reports of patients with chronic viral hepatitis and elevated AFP but normal livers on
imaging. AFP elevation in these cases is due to hepatic inflammation and viral replication (Patil, 2013),
not neoplasm. Others advocate for combined ultrasound and AFP for screening (Tzartzeva, 2018; Tan,
2011) citing increased sensitivity compared to ultrasound alone in detecting early stage HCC particularly
in cirrhotic patients. In a meta-analysis by Tzartzeva, et al of thirty-two studies (13,367 patients with
cirrhosis) ultrasound with AFP had a 63% sensitivity of detecting early stage HCC compared to 45% for
ultrasound alone. In the final analysis, no literature supports the use of AFP alone in the screening of
HCC.

MRI of the adrenal glands – The adrenal glands are susceptible for metastases from various tumors,
especially of lung or breast. Adrenal lesions may also represent primary tumors of the adrenal cortex of
medulla, both benign and malignant. MRI may be done to distinguish between benign and malignant
lesions. Metastases are predominantly hypointense on T1-weighted images and hyperintense on T2-weighted images. Benign lesions, which have high lipid content, exhibit a drop in signal intensity on apposed phase chemical shift imaging.

**MRI of the pancreas** – The most common pancreatic endocrine tumors, accounting for up to 50% of all cases, are insulinomas, which are usually benign. The next most common is gastrinomas. Patients with gastrinomas generally present with recurrent, multiple or ‘ectopic’ peptic ulceration, the Zollinger-Ellison syndrome. After a diagnosis of gastrinomas has been confirmed, imaging should be done to localize and stage the disease. Other pancreatic endocrine tumors are rare and often associated with genetic disorders such as the multiple endocrine neoplasia type 1 (MEN 1). MRI is the preferred imaging for follow-up in patients with MEN 1 where repeated imaging may be required to assess the response to therapy.

**MRI of the kidney** – MRI in renal imaging has been used to differentiate benign lesions versus malignant lesions in patients unable to undergo CT scanning with contrast media or in cases where the CT findings were questionable. Initial evaluation of renal lesions is often undertaken with ultrasound. MRI can have additional diagnostic value in the evaluation of lesions with minimal amounts of fat or with intracellular fat. MRI may have a higher accuracy than CT in the evaluation of early lymph node spread. Although MRI of the kidney has not yet found broad clinical application, it may have an increasing role in the management of patients with renal disease.

**MRI of the spleen** – Among some radiologists, the spleen is considered a ‘forgotten organ’ although it is included and demonstrated on every abdominal CT and MRI. Malignant tumors of the spleen are rare; malignant lymphomas are the most common and are usually a manifestation of generalized lymphoma. Splenic metastases are predominantly hypointense on T1-weighted images and hyperintense on T2-weighted images and MRI is used for the detection of necrotic or hemorrhagic metastases.

**MRI to diagnose abdominal aortic aneurysm** – MRI can be useful in the diagnosis of aortic aneurysms in patients with chronic aortic disease. The advantages include: safety, noninvasive nature (except for intravenous contrast), wide field of view, multi-planar imaging and 3D relationship viewing. MRI, unlike CT, does not require large volumes of iodinated contrast. ECG-gated spin-echo MRI is the basis for many MRI imaging algorithms for diagnosing abdominal aortic disease. A rapid breath holds MRI, allows more comprehensive examination of the aorta and defines many types of aortic pathology.

**MRI for the evaluation of vascular abnormalities such as renal artery stenosis and celiac/superior mesenteric artery stenosis (in chronic mesenteric ischemia)** – Doppler Ultrasound, MRA or CTA should be considered as the preferred imaging modalities.

**Imaging of hernias** – Most hernias are diagnosed clinically with imaging recommended for the diagnosis of occult hernias or in the evaluation of hernia complications such as bowel obstruction or strangulation. To detect occult hernias, ultrasound is a first line study with a sensitivity of 86% and specificity of 77%, compared to 80% sensitivity and 65% specificity for CT (Robinson, 2013). According to Miller, et al “Magnetic resonance imaging is generally not considered a first- or even second-line evaluation modality for hernias...” (Miller, 2014). Based on this analysis MRI is recommended only when ultrasound and CT have been performed and fail to make a diagnosis.
REFERENCES


CPT Codes: 74185

INTRODUCTION:

Magnetic resonance angiography (MRA) generates images of the arteries that can be evaluated for evidence of stenosis, occlusion or aneurysms. It is used to evaluate the arteries of the abdominal aorta and the renal arteries. Contrast enhanced MRA requires the injection of a contrast agent which results in very high quality images. MRA does not use ionizing radiation, allowing MRA to be used for follow-up evaluations. Abdominal MRA is not used as a screening tool, e.g. evaluation of asymptomatic patients without a previous diagnosis.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ABDOMEN MRA:

For evaluation of known or suspected abdominal vascular disease:

- For known large vessel diseases (abdominal aorta, inferior vena cava, superior/inferior mesenteric, celiac, splenic, renal or iliac arteries/veins), e.g., aneurysm, dissection, arteriovenous malformations (AVMs), and fistulas, intramural hematoma, and vasculitis.
- Evidence of vascular abnormality seen on prior imaging studies.
  - Evaluation of known or suspected aortic aneurysm (Khosa, 2013; Chaikof, 2018) **:
    - Known or suspected aneurysm > 2.5 cm AND equivocal or indeterminate ultrasound results OR
    - Prior imaging (e.g. ultrasound) demonstrating aneurysm >2.5 cm in diameter OR
    - Suspected complications of known aneurysm as evidenced by signs/symptoms such as new onset of abdominal or pelvic pain.
- To determine the vascular source of retroperitoneal hematoma or hemorrhage when CTA is contraindicated
- Suspected renal vein thrombosis in patient with known renal mass.
- For evaluation of suspected mesenteric ischemia/ischemic colitis when CTA is contraindicated (ACR, 2012).
- Venous thrombosis if previous studies have not resulted in a clear diagnosis.
- Vascular invasion or displacement by tumor.
- For evaluation of hepatic blood vessel abnormalities (aneurysm, hepatic vein thrombosis, stenosis post transplant) after doppler ultrasound has been performed: to clarify or further evaluate ultrasound findings.
- For evaluation of splenic artery aneurysm.
- Kidney failure or renal insufficiency if initial evaluation performed with Ultrasound is inconclusive.
- For evaluation of known or suspected renal artery stenosis or resistant hypertension in the setting of normal renal function or impaired renal function unrelated to recent medication (ACR, 2017) demonstrated by any of the following (Hartman, 2009; Tullus, 2010):
  - Unsuccessful control after treatment with 3 or more (>2) anti-hypertensive medication at optimal dosing.
  - Acute elevation of creatinine after initiation of an angiotension converting enzyme inhibitor (ACE inhibitor) or angiotension receptor blocker (ARB).
- Asymmetric kidney size noted on ultrasound.
- Onset of hypertension in a person younger than age 30 without any other risk factors or family history of hypertension.
- Significant hypertension (diastolic blood pressure > 110 mm Hg) in a young adult (i.e., younger than 35 years) suggestive of fibromuscular dysplasia
- Diagnosis of a syndrome with a higher risk of vascular disease, such as neurofibromatosis, tuberous sclerosis and Williams’ syndrome
- New onset of hypertension after age 50.
- Acute rise in blood pressure in a person with previously stable blood pressures.
- Flash pulmonary edema without identifiable causes.
- Malignant hypertension.
- Bruit heard over renal artery and hypertension.

Pre-operative evaluation:
- Evaluation prior to interventional vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.
- For pretransplant evaluation of either liver or kidney.

Post-operative or post-procedural evaluation:
- Evaluation of endovascular/interventional abdominal vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.
- Evaluation of post-operative complications, e.g. pseudoaneurysms, related to surgical bypass grafts, vascular stents, and stent-grafts in the peritoneal cavity.
- Follow-up for post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA) or abdominal extent of iliac artery aneurysms. Routine, baseline study (post-op/intervention) is warranted within 1-3 months (Chaikof, 2018; Uberoi, 2011).
  - Asymptomatic at six (6) month intervals for one (1) year, then annually.
  - Symptomatic/complications related to stent graft – more frequent imaging may be needed.
- Follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

ADDITIONAL INFORMATION RELATED TO ABDOMEN MRA:

MRI Follow-up for post-endovascular repair (EVAR) – Although studies have shown that MRA is as sensitive as CT in detecting endoleaks, CT is generally the study of choice in this evaluation due to convenience, improved spatial resolution and less artifact from components of the stent graft. MRA is most helpful in the postoperative evaluation of patients with impaired renal function, but not severe enough to have contraindication to gadolinium administration.

Abd/Pelvis MRA & Lower Extremity MRA Runoff Requests: Two (2) authorization requests are required, one Abd MRA, CPT code 74185 and one for Lower Extremity MRA, CPT code 73725. This will provide imaging of the abdomen, pelvis, and both legs.
MRA and Abdominal Aortic Aneurysm – Endovascular repair is an alternative to open surgical repair of an abdominal aortic aneurysm. It has lower morbidity and mortality rates and is minimally invasive. In order to be successful, it depends on precise measurement of the aneurysm and involved vessels. MRA with gadolinium allows visualization of the aorta and major branches and is effective and reliable for use in planning the placement of the endovascular aortic stent graft. MRA is also used for the detection of postoperative complications of endovascular repair.

**Abdominal Aneurysms and general Guidelines for follow-up:**
The normal diameter of the suprarenal abdominal aorta is 3.0 cm and that of the infrarenal is 2.0 cm. Aneurysmal dilatation of the infrarenal aorta is defined as diameter >/= 3.0 cm or dilatation of the aorta >/= 1.5x the normal diameter (Khosa, et al). Initial evaluation of AAA is accurately made by ultrasound. Ultrasound can detect and size AAA, with the advantage of being relatively inexpensive, noninvasive and not require iodinate contrast. The limitations are that overlying bowel gas can obscure findings and the technique is operator dependent.

Recommended intervals for initial follow-up imaging of ectatic aortas and abdominal aortas (follow up intervals may vary depending on comorbidities and the growth rate of the aneurysm) from the white paper of the ACR Incidental Findings Committee II on vascular findings (Khosa, 2013):

<table>
<thead>
<tr>
<th>Diameter Range</th>
<th>Follow-up Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5-2.9 cm</td>
<td>5 yr</td>
</tr>
<tr>
<td>3.0-3.4 cm</td>
<td>3 yr</td>
</tr>
<tr>
<td>3.5-3.9 cm</td>
<td>2 yr</td>
</tr>
<tr>
<td>4.0-4.4 cm</td>
<td>1 yr</td>
</tr>
<tr>
<td>4.5-4.9 cm</td>
<td>6 mo</td>
</tr>
<tr>
<td>5.0-5.5 cm</td>
<td>3-6 mo</td>
</tr>
</tbody>
</table>

The Society of Vascular Surgery has different follow up intervals for AAA (SVS, 2018):

- >2.5 cm - <3 cm------10 yr
- 3.0 - 3.9 cm----------3 yr
- 4.0 - 4.9 cm----------12 mo
- 5.0 - 5.4 cm----------6 mo.

The Society of Vascular Surgery recommends elective repair of AAA >/= 5.5 cm in patients at low or acceptable surgical risk (Chaikof, 2018).

MRA and Renal Artery Stenosis – Renal artery stenosis is the major cause of secondary hypertension. It may also cause renal insufficiency and end-stage renal disease. Atherosclerosis is one of the common causes of this condition, especially in older patients with multiple cardiovascular risk factors and worsening hypertension or deterioration of renal function. Navigator-gated MR angiography is used to evaluate the renal arteries and detect renal artery stenosis.

MRA and Renal Vein Thrombosis – Renal vein thrombosis is a common complication of nephritic syndrome and often occurs with membranous glomerulonephritis. Gadolinium-enhanced MRA can demonstrate both the venous anatomy and the arterial anatomy and find filling defects within renal veins. The test can be used for follow-up purposes as it does not use ionizing radiation.

*MRI/CT and acute hemorrhage:* MRI is not indicated and MRA/MRV (MR Angiography/Venography) is rarely indicated for evaluation of intraperitoneal or retroperitoneal hemorrhage, particularly in the acute setting. CT is the study of choice due to its availability, speed of the study, and less susceptibility to artifact from patient motion. Advances in technology have allowed conventional CT to not just detect
hematomas but also the source of acute vascular extravasation. In special cases finer vascular detail to assess the specific source vessel responsible for hemorrhage may require the use of CTA. CTA in diagnosis of lower gastrointestinal bleeding is such an example (Clerc, 2017).

MRA/MRV is often utilized in non acute situations to assess vascular structure involved in atherosclerotic disease and its complications, vasculitis, venous thrombosis, vascular congestion or tumor invasion. Although some of these conditions may be associated with hemorrhage, it is usually not the primary reason why MRI/MRA/MRV is selected for the evaluation. A special condition where MRI may be superior to CT for evaluating hemorrhage is to detect an underlying neoplasm as the cause of bleeding (Abe, 2010).
REFERENCES


CPT Codes: 74261, 74262

INTRODUCTION:

Computed tomographic (CT) colonography, also referred to virtual colonoscopy, is used to examine the colon and rectum to detect abnormalities such as polyps and cancer. Polyps may be adenomatous (which have the potential to become malignant) or completely benign.

Colorectal cancer (CRC) is the third most common cancer and the second most common cause of cancer death in the United States. Symptoms include blood in the stool, change in bowel habit, abdominal pain, and unexplained weight loss.

In addition to its use as a diagnostic test in symptomatic patients, CT colonography may be used in asymptomatic patients with a high risk of developing colorectal cancer. Conventional colonoscopy and double-contrast barium enema are the main methods currently used for examining the colon.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCR) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CT COLONOSCOPY (VIRTUAL COLONOSCOPY):

For diagnostic (symptomatic patient) evaluation when conventional colonoscopy is contraindicated or could not be completed (AGA, 2015):

- Patient had failed colonoscopy due to conditions such as hypotension secondary to the sedation; adhesions from prior surgery; excessive colonic tortuosity.
- Patient has obstructive colorectal cancer.
- Patient is unable to undergo sedation or has medical conditions, e.g., recent myocardial infarction, recent colonic surgery, bleeding disorders, severe lung and/or heart disease.

ADDITIONAL INFORMATION RELATED TO CT COLONOSCOPY (VIRTUAL COLONOSCOPY):

Request for a follow-up study - A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
REFERENCES


CPT Codes: 74263

INTRODUCTION:

The goal of CT (computer tomographic) colonography (CTC), sometimes referred to as CT colonoscopy or virtual colonoscopy screening is to reduce colorectal cancer mortality through cancer prevention and early detection. Virtual colonoscopy is an American Cancer Society-recommended screening exam that has been shown in studies in the United States and abroad to increase screening rates where offered. Virtual colonoscopy has been proven comparably accurate to colonoscopy in most people of screening age. Mandatory insurance coverage of CT colonography and the other USPSTF-recognized exams is a major step forward in the battle against colorectal cancer (USPSTF, 2016).

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CT COLONOSCOPY (VIRTUAL COLONOSCOPY) SCREENING:

CTC is considered medically appropriate as an alternative to colonoscopy for screening an “average risk” and “moderate risk” member, every 5 (five) years, who is (ACR, 2013; USPSTF, 2016):

**Average, Moderate, or High risk (ACR, 2013):**
After incomplete colonoscopy
Unable to undergo sedation or has medical conditions, e.g., recent myocardial infarction, recent colonic surgery, bleeding disorders, severe lung and/or heart disease.

Average Risk Individuals:
- 50 – 75 years of age (See list of other weak evidence rec below).
- asymptomatic
- and without any of the following:
  - a family history of known genetic disorders that predispose them to a high lifetime risk of colorectal cancer (such as Lynch syndrome (Hereditary Nonpolyposis Colorectal Cancer))
  - a personal history of inflammatory bowel disease

Moderate Risk Individuals:
- Patient with history of carcinoma or adenoma (ACR, 2013)
- First degree family member with history of cancer or adenoma (ACR, 2013): in these instances the MSTF recommends screening be initiated earlier (Rex, 2017)**

Additional Information:

“While Virtual Colonoscopy is an alternative, ACG notes its limitations: CT Colonoscopy every 5 years (Also known as “virtual” colonoscopy) is endorsed in the updated MSTF guideline as a “tier 2” alternative
to colonoscopy every 10 years for patients who decline colonoscopy. The College includes CRC as an alternative in light of recent studies which reveal that CTC has a sensitivity of 82 to 92% for adenomas ≥1 cm. Although the benefits of CTC include low risk of perforation compared to colonoscopy, the College does not consider CTC as an equivalent to colonoscopy as a screening strategy for several reasons:
- its inability to detect polyps 5 millimeters and smaller, which constitute 80 percent of colorectal neoplasms;
- false positives are common with CTC; and concerns about the radiation risk associated with one or repeated CT colonography studies, although the exact risk associated with radiation is unclear.”

Screening Recommendations, the USPSTF, ACG, ACR, and ACS:

The United States Preventative Services Task Force (USPSTF) and The U.S. Multi-Society Task Force on Colorectal Cancer (MSTF) and American College of Radiology (ACR) recommend colorectal screening of asymptomatic adults starting at the age of 50 for the general population. The MSTF, but not the USPSTF or ACR, indicates “limited evidence” supports screening for African Americans starting at age 45 (Rex, 2017). Screening is recommended until the age of 75. The USPSTF gives screening a grade of “A”. This means “the USPSTF recommends the service and there is high certainty that the net benefit is substantial”. For adults older than 76 years, and younger than 85, the USPSTF recommendation grade is a “C” indicating “there is at least moderate certainty that the net benefit is small and the service should be offered “….for selected patients depending on individual circumstances”. All three organizations’ guidelines exclude from these general screening criteria some groups with an increased risk of developing cancer compared to the general population based on “genetic disorders that predispose them to a high lifetime risk of colorectal cancer (such as Lynch syndrome or familial adenomatous polyposis), or a personal history of inflammatory bowel disease…. (ACR, 2013). These patients are screened more frequently with colonoscopy and are not candidates for CTC except in the ACR appropriateness criteria where CTC is given a grade of “9” for patients with “a personal history of adenoma or carcinoma or first-degree family history of cancer or adenoma”.

According to the MSTF “The advantages of colonoscopy include high sensitivity for cancer and all classes of precancerous lesions, single-session diagnosis and treatment, and long intervals between examinations (10 years) in subjects with normal examinations”. The ACR appropriateness criteria gives CTC a grade of 9 out of 10, or “usually appropriate”, as the preferred imaging study for screening. Double contrast barium enema has been replaced by CTC as the preferred imaging study by both the MSTF and ACR (receiving a 6 out of 10 grade in the ACR appropriateness criteria “may be appropriate”). The ACR appropriateness criteria does not measure the relative merits of no radiologic tests for colorectal screening such as colonoscopy, flexible sigmoidoscopy, fecal occult blood test, fecal immunochemical test, or serum testing (Septin9 assay is the first FDA approved test) but comments in the appropriates criteria text: “….of the structural tests available, colonoscopy is currently considered to be the most sensitive and specific for detecting colorectal polyps and cancers”. The ACR indicates in its recommendation charts for high risk individuals with hereditary non-polyposis colorectal cancer, or inflammatory bowel disease, that colonoscopy is the preferred procedure giving CTC a grade of “3’ (usually not appropriate).

The American Cancer Society follows the screening intervals described by the organizations above but does not provide recommendations on the preferred exam. They recommend screening every 10 years for CT colonoscopy and every 5 years for CTC, flexible sigmoidoscopy, and double contrast barium enema.

U.S. Multi-Society Task Force on Colorectal Cancer (USMSTF) and the ACR has divided colorectal cancer risk levels into three categories (ACR, 2013).
1) Average (individuals ≥50 years of age),
2) Moderate (individuals with a personal history of a large adenoma or carcinoma or a first-degree relative with a history of adenoma or carcinoma), and
3) High (individuals with hereditary syndromes, such as hereditary nonpolyposis colorectal cancer and familial polyposis, or a personal history of ulcerative colitis or Crohn colitis).

*The U.S. Multi-Society Task Force on Colorectal Cancer: The American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy


**Recommendations

1. We suggest that persons with 1 first-degree relative with CRC or a documented advanced adenoma diagnosed at age <60 years or with 2 first-degree relatives with CRC and/or documented advanced adenomas undergo colonoscopy every 5 years beginning 10 years younger than the age at which the youngest first-degree relative was diagnosed or age 40, whichever is earlier (weak recommendation, low-quality evidence).

2. We suggest that persons with 1 first-degree relative diagnosed with CRC or a documented advanced adenoma at age ≥60 years begin screening at age 40. The options for screening and the recommended intervals are the same as those for average-risk persons (weak recommendation, very-low-quality evidence).

3. We suggest that persons with 1 or more first-degree relatives with a documented advanced serrated lesion (SSP or traditional serrated adenoma ≥10 mm in size or an SSP with cytologic dysplasia) should be screened according to above recommendations for persons with a family history of a documented advanced adenoma (weak recommendation, very-low-quality evidence).

4. We recommend that persons with 1 or more first-degree relatives with CRC or documented advanced adenomas, for whom we recommend colonoscopy, should be offered annual FIT if they decline colonoscopy (strong recommendation, moderate-quality evidence).
REFERENCES


CPT Codes: 74712, +74713

INTRODUCTION:

MRI not only contributes to diagnosis, but also serves as an important guide to treatment, delivery planning, and counseling. However, sonography is the screening modality of choice in the fetus. Fetal MRI should be performed only for a valid medical reason and only after careful consideration of sonographic findings or family history of an abnormality for which screening with MRI might be beneficial.

Indications:

- To better define or confirm a known or suspected abnormality of the fetus after ultrasound has been performed or when fetal surgery is planned (ACR-SPR, 2015; Perrone, 2008).

Safety guidelines and possible contraindications:

There are no documented fetal indications for the use of MRI contrast, but there may be rare instances where contrast is considered potentially helpful in assessing the pregnant patient’s anatomy or pathology.

The decision to administer contrast must be made on a case-by-case basis by the covering level 2 MR personnel-designated attending radiologist who will assess the risk-benefit ratio for that particular patient. The decision to administer a gadolinium-based MR contrast agent to pregnant patients should be accompanied by a well-documented and thoughtful risk-benefit analysis.
REFERENCES


CPT Codes: 75557, 75559, 75561, 75563 +75565

INTRODUCTION  
(Pennell 2010)

➢ Cardiac magnetic resonance imaging (MRI or CMR) provides high quality cardiovascular imaging without exposure to radiation. Quality imaging process requires patient ability to perform breath holding or regular free breathing, a regular rhythm, and absence of local implants that interfere with image or any implants that interfere with safety (Gerber 2018).

➢ Cardiac magnetic imaging (CMR) is often required when transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) elicit inadequate imaging data.

➢ Stress CMR for assessment of coronary artery disease (CAD) is performed pharmacologically either as:
  o Vasodilator perfusion imaging with gadolinium contrast
  OR
  o Dobutamine inotropic wall motion (ventriculography)

➢ CMR is frequently competitive with Cardiac CT (Cardiac Computed Tomography) with respect to structural imaging (Warnes 2008; Baumgartner 2010; Pennell 2010).

<table>
<thead>
<tr>
<th>Modality</th>
<th>Cardiac CT</th>
<th>Cardiac MR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrast</td>
<td>Often required</td>
<td>Required for some tissue characterization studies, often unnecessary</td>
</tr>
<tr>
<td>Radiation*</td>
<td>Yes</td>
<td>None, advantage for young patients and those requiring frequent exams</td>
</tr>
<tr>
<td>Resolution</td>
<td>Higher spatial</td>
<td>Higher temporal</td>
</tr>
<tr>
<td>Flow</td>
<td>Not standard</td>
<td>Standard</td>
</tr>
<tr>
<td>Patient comfort</td>
<td>Easy</td>
<td>Claustrophobia issues</td>
</tr>
<tr>
<td>Ferromagnetic implants</td>
<td>No issue</td>
<td>Relative contraindication</td>
</tr>
<tr>
<td>Cost</td>
<td>Moderate to High</td>
<td>High</td>
</tr>
</tbody>
</table>

* (Hirshfeld 2018)
Some scenarios might provide more detail with low dose CT than with CMR, thereby overriding the radiation risk (Ohana 2015).

➢ With respect to CAD evaluation, since CMR is only pharmacologic (non-exercise stress), and stress echocardiography (SE) or myocardial perfusion imaging (MPI) provide similar information about CAD, with SE performed at lower cost:
Requests for stress CMR require diversion to exercise SE first, to exercise MPI second.

**Exemptions** for the diversion to SE or exercise MPI:
- If body habitus or marked obesity (e.g. BMI ≥ 40) would interfere significantly with imaging with SE and MPI (Shah 2014)
- Evaluation of young (< 55 years old) patients with documented complex CAD, who are likely to need frequent non-invasive coronary ischemia evaluation and/or frequent radiation exposure from other testing (Hirshfeld 2018).

CMR can be used as an **alternative to required pharmacologic** MPI (Fihn 2012).

Pharmacologic *perfusion* imaging is indicated over exercise *perfusion* imaging in the following (Askew 2018):
- Inability to exercise safely (e.g. prohibitive comorbidity, severe valvular disease, provocation of serious arrhythmia with exercise, uncontrolled hypertension, with systolic BP > 180 or diastolic BP > 120)
- Complete left bundle branch block (LBBB) or a V-paced rhythm (due to perfusion artifacts)

CMR can also be performed as a dobutamine stress test when vasodilator MPI would be **contraindicated**: (Chareonthaitawee 2018; Henzlova 2016)
- Pulmonary or allergic intolerance to adenosine and analogues, documented or anticipated
- Dipyridamole within < 48 hours
- Relative unsuitability due to:
  - Hypotension or bradyarrhythmia
  - Interfering medications: Theophylline/aminophylline, caffeine, or theobromine within the past 12-24 hours
  - Seizure disorder with potential for adenosine provocation

CAD stenosis ≥ 50% is considered clinically significant or obstructive CAD. CAD and ischemic heart disease (IHD) mean the same thing. Hemodynamically or functionally significant CAD means the degree of stenosis is severe enough to cause ischemia. This is discussed in more detail in the Additional Information section (Fihn 2012; Wolk 2013; Montalescot 2013; Gerber 2018; Tobis 2007).

**Indications for CMR**
(Hendel 2006; Hundley 2010)

**CMR in CAD**
(Fihn 2012; Wolk 2013; Montalescot 2013)

- **Stable patients without known CAD** fall into 2 categories (Fihn 2012; Wolk 2013; Montalescot 2013):
  - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see part III in the Additional Information section).
Symptomatic, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant (≥ 50%) CAD (below):

The 3 Types of Chest Pain or Discomfort

- **Typical Angina (Definite)** is defined as including all 3 characteristics:
  1) Substernal chest pain or discomfort with characteristic quality and duration
  2) Provoked by exertion or emotional stress
  3) Relieved by rest and/or nitroglycerine

- **Atypical Angina (Probable)** has only 2 of the above characteristics

- **Nonanginal Chest Pain/Discomfort** has only 0-1 of the above characteristics

Once the type of chest pain has been established from the medical record, the Pretest Probability of CAD (meaning obstructive CAD defined as coronary arterial narrowing ≥ 50%) is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability (Wolk 2013):

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Gender</th>
<th>Typical/Definite Angina Pectoris</th>
<th>Atypical/Probable Angina Pectoris</th>
<th>Nonanginal Chest Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>40–49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td>≥60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
</tbody>
</table>

- **Very low**: < 5% pretest probability of CAD, usually not requiring stress evaluation (Fihn 2012)
- **Low**: 5-10% pretest probability of CAD
- **Intermediate**: 10% - 90% pretest probability of CAD
- **High**: > 90% pretest probability of CAD

Indications for Cardiac Magnetic Resonance (CMR)
(Hendel 2006; Fuisz 2018)

<table>
<thead>
<tr>
<th>Use of CMR in CAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Fihn 2012; Wolk 2013; Montalescot 2013; Askew 2018; Hendel 2006 )</td>
</tr>
</tbody>
</table>

**Suspected CAD**
(Without known history of CAD)
CMR available as an alternative to appropriate vasodilator MPI

1. Symptomatic patients without known CAD
- Low pretest probability who are unable to exercise
- Intermediate pretest probability
- High pre-test probability
- Repeat testing in patient with recurrent symptomatic presentation and negative result over 2 years ago
- Repeat testing in patient with new or worse symptoms and negative result at least one year ago

### 2. Asymptomatic patients without known CAD:

- Previously unevaluated electrocardiography (ECG) evidence of possible myocardial ischemia such as substantial ischemic ST segment or T wave abnormalities
- Previously unevaluated pathologic Q waves or wall motion abnormality (evidence of prior myocardial infarction)
- Unevaluated complete left bundle branch block in patients at intermediate to high global risk
- Following radiation therapy to the anterior or left chest, at 5 years post inception of radiation and every 5 years thereafter (Lancellotti 2013)

### 3. Incomplete or inconclusive CAD evaluation, within the past 2 years without known CAD

- Exercise stress ECG with low risk Duke treadmill score, but patient’s current symptoms indicate an intermediate or high pretest probability, which should include stress imaging
- Exercise stress ECG with intermediate Duke treadmill score
- Inconclusive/borderline CCTA (e.g. 40-70% lesions)
- An indeterminate (equivocal, borderline, or discordant) evaluation by prior stress imaging (SE or MPI) within the past 2 years, for whom a noninvasive approach is preferable to proceeding to invasive coronary arteriography (e.g. unclear symptoms, ECG and imaging discordant, etc., but patient has severe contrast allergy, CKD, etc.)

#### Known Major Vessel CAD
CMR available as an alternative to appropriate vasodilator MPI
(Patel 2017)

- Validated concern for a previous acute coronary syndrome without subsequent invasive or non-invasive coronary evaluation
- Follow up MPI at 2-year intervals is approvable, if it will affect consideration of coronary revascularization (initial or additional), in patients with one of the following:
  - History of silent ischemia with severe unrevascularized CAD, and revascularization could be feasible (Deedwania 2018)
  - History of severe unrevascularized major multivessel CAD, and revascularization could be feasible
  - Ejection fraction <= 40% with severe unrevascularized CAD, and revascularization could be feasible
- Ischemia assessment following inconclusive findings of invasive coronary arteriography or CCTA, for the purpose of assessing extent of ischemia and need for additional medical, interventional, or surgical therapy.
- For myocardial viability assessment with reduced LVEF <= 50% to assist with decisions regarding coronary revascularization, even when MPI or SE have been inconclusive in that regard (Patel 2013; Yancy 2013)
- New or worsening symptoms of ischemia in the absence of an acute coronary syndrome, unless the most current stress imaging study would warrant invasive coronary arteriography instead (e.g. History of high risk stress test without subsequent invasive coronary arteriography might warrant invasive coronary angiography) (Patel 2012)
• De novo HF, who have known CAD, even without angina, unless the patient is not eligible for revascularization of any kind, or unless invasive coronary arteriography is immediately planned (Yancy 2013)

<table>
<thead>
<tr>
<th>Special Diagnostic Conditions, Requiring Coronary Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CMR available as an alternative to appropriate vasodilator MPI</strong></td>
</tr>
<tr>
<td>• Newly diagnosed systolic or diastolic heart failure, especially with symptoms or signs of ischemia AND without invasive coronary angiography immediately planned (Yancy 2013; Patel 2013; Fihn 2012)</td>
</tr>
<tr>
<td>• Newly found wall motion abnormality (Colucci 2018a)</td>
</tr>
<tr>
<td>• Ventricular arrhythmias</td>
</tr>
<tr>
<td>o Sustained VT &gt;100 bpm, VF, or exercise induced VT, when invasive coronary arteriography is not the initially required test (Al-Khatib 2018 in press)</td>
</tr>
<tr>
<td>o Nonsustained VT, multiple episodes, each ≥3 beats at ≥100 bpm, without known cause or associated cardiac pathology, when an exercise ECG has shown an intermediate risk Duke Score or exercise ECG could not be performed (Zimetbaum 2018)</td>
</tr>
<tr>
<td>o Frequent PVCs ≥30/hour, or any PVC on a 12 lead ECG, without known cause or associated cardiac pathology, when an exercise ECG has shown an intermediate risk Duke Score OR an exercise ECG is not feasible due to inability to exercise or due to an uninterpretable ECG (Cha 2012; Manolis 2018)</td>
</tr>
<tr>
<td>• Prior to Class IC antiarrhythmic drug initiation in intermediate and high global risk patients (see global risk calculators in Additional Information Section) (Kumar 2018)</td>
</tr>
<tr>
<td>• Assessment of hemodynamic significance of one of the following previously documented conditions (also see Congenital Heart section below) (Anagnostopoulos 2004):</td>
</tr>
<tr>
<td>o Anomalous coronary arteries (Grani 2017; Kilner 2010)</td>
</tr>
<tr>
<td>o Muscle bridging of coronary artery (perform with exercise stress) (Sorajja 2018)</td>
</tr>
<tr>
<td>o Coronary aneurysms in Kawasaki’s disease (Newburger 2018)</td>
</tr>
</tbody>
</table>
| Congenital Heart Disease  
<table>
<thead>
<tr>
<th>(Warnes 2008; Baumgartner 2010; Kilner 2010; Orwat 2014; Wiant 2009)</th>
</tr>
</thead>
<tbody>
<tr>
<td>For evaluation of anomalous thoracic arteriovenous vessels, such as TGA (Cohen 2016). Further assessment of complex adult congenital heart disease after confirmation by initial echocardiography (TTE and/or TEE), to answer remaining clinically relevant questions with the exception that:</td>
</tr>
<tr>
<td>o Echocardiography is preferable to CMR for the identification of patent foramen ovale, structural abnormalities of valve leaflets, and their suspensory apparatus, and CMR should generally not be required (Douglas 2011)</td>
</tr>
<tr>
<td>• When TTE and/or TEE has been or would be insufficient for clinical management, for the choice between CMR and CT, several aspects must be considered including radiation exposure, resolution required, summary of information required, its impact upon management, the presence of a pacemaker/ICD, or other implants and patient claustrophobia. Sample indications include:</td>
</tr>
<tr>
<td>o Quantification of right ventricular (RV) volumes and ejection fraction (tetralogy of Fallot, systemic RV, and tricuspid regurgitation) CMR is preferred over CT (Haddad 2008; Dupont 200; Benza 2008).</td>
</tr>
<tr>
<td>o Evaluation of the RV outflow tract and RV-PA conduits (CMR or CT).</td>
</tr>
<tr>
<td>o Quantification of pulmonic regurgitation (PR) (CMR, not CT).</td>
</tr>
<tr>
<td>o Quantification of shunts by measurements of flow in the ascending aorta and pulmonary trunk (CMR, not CT).</td>
</tr>
<tr>
<td>o Evaluation of the entire aorta (aneurysm, dissection, intramural hematoma, Loeys-Dietz, Ehlers-Danlos, or confirmed genetic mutation known to predispose to aortic aneurysm and dissection). (CMR or CT initially, with annual CMR (MRI) for Loeys-Dietz, Ehlers Danlos; multiple options for Marfan’s, Turner’s; see Aortic Pathology section below) (Hiratzka 2010).</td>
</tr>
<tr>
<td>o Evaluation of pulmonary arteries (stenosis and aneurysms) and the aorta (coarctation) (CMR or CT).</td>
</tr>
<tr>
<td>o Evaluation of systemic and pulmonary veins (anomalous connection, obstruction, etc.) (CMR or CT).</td>
</tr>
<tr>
<td>o Aorto-pulmonary collaterals and arteriovenous malformations (either, but CT is superior to CMR for spatial resolution).</td>
</tr>
<tr>
<td>o Identification of coronary anomalies and CAD (CCTA better than CMR, if no other CMR data required) (also see coronary section above - Special Diagnostic Conditions).</td>
</tr>
<tr>
<td>o Evaluation of intra- and extra-cardiac masses (CMR or CT).</td>
</tr>
<tr>
<td>o Quantification of myocardial (muscle) mass (CMR or CT].</td>
</tr>
<tr>
<td>o Detection and quantification of myocardial fibrosis/scar (gadolinium late enhancement) [CMR, not CT].</td>
</tr>
<tr>
<td>• Tissue characterization (fibrosis, fat, iron etc.) (CMR, not CT).</td>
</tr>
<tr>
<td>• Assessment of right ventricular morphology in arrhythmogenic right ventricular dysplasia cardiomyopathy, based upon reason for suspicion, of which examples are:</td>
</tr>
<tr>
<td>o Nonsustained VT</td>
</tr>
<tr>
<td>o Syncope</td>
</tr>
<tr>
<td>o ECG abnormality: Prolonged S wave upstroke, epsilon waves, or right precordial T wave inversions (&gt; 14 yr old) in the absence of complete right bundle branch block</td>
</tr>
<tr>
<td>o First degree relative with phenotype or genotype of ARVD/C (either, but CMR is superior to CT) (Marcus 2010; McKenna 2018; te Riele 2015).</td>
</tr>
</tbody>
</table>
Valvular (Doherty 2017; Baumgartner 2017; Nishimura 2014; Ordovas 2008)

- Both TTE and TTE images are inadequate or not feasible for evaluation of possible valvular heart disease due to patient characteristics.
- Severe tricuspid regurgitation and suboptimal TTE images, for assessment of RV systolic function and systolic and diastolic volumes
- In patients with MR, when TTE and TEE (if able) show:
  - Moderate or severe MR, but images are suboptimal for assessment of MR severity, left ventricular function, and/or systolic and diastolic volumes
  - OR
  - Severity of the MR that is discordant with the clinical assessment
- In patients with AR, when TTE shows:
  - Moderate or severe AR, but images are suboptimal for assessment of AR severity, left ventricular function, and/or systolic and diastolic volumes
  - OR
  - Severity of the AR that is discordant with the clinical assessment
- Pre TAVR assessment of aortic annular size and shape and/or the aortic dimensions, when the patient cannot undergo cardiac CT (Otto 2017)
- Prior to transcatheter mitral valve interventions, when TTE and TEE result in uncertain assessment of the severity of mitral regurgitation (Wunderlich 2018)
- Patients with bicuspid aortic valve and aortic dilation > 4.0 cm require annual imaging with CT, MRI, or echo. (Echo is required when is can evaluate the full extent of pathology under surveillance.)
  This would increase to biannual (twice-yearly) imaging in the event of any one of the additional conditions: diameter > 4.5 cm, rapid rate of change 0.5 cm/yr, or a family history of a first degree relative with aortic dissection. Initial imaging with first 6 month re-evaluation for rate of expansion is appropriate.
- Characterization of bioprosthetic valve if suspected clinically significant valvular dysfunction and inadequate images from TTE and TEE.

Myocardial & Heart Failure
(Patel 2013, Yancy 2013)

- Evaluation of LV function following myocardial infarction OR in heart failure patients, when TTE (even with contrast agents) or MUGA, have been inadequate or discordant with prior information. (Montalescot 2013)
  For management of patients requiring cardiotoxic chemotherapy, with any **ONE** of the following: (Plana 2014) (See Cardio-Oncology section under Additional Information.)
  - TTE has been inadequate, unreliable, or discordant with prior information.
  - Candidacy for cardiotoxic chemotherapy is questionable due to borderline left ventricular dysfunction on other imaging
  - Discontinuation of cardiotoxic chemotherapy on the basis of a decline in left ventricular dysfunction is being considered
  Left ventricular function assessment at baseline prior to initiation of radiation to the anterior or left chest, at 5 years post initiation, and every 5 years thereafter, when TTE has been inadequate. (Lancellotti 2013)
  Diagnosis and monitoring of specific infiltrative cardiomyopathies, amyloidosis, sarcoidosis, hemochromatosis, endomyocardial fibrosis (Pereira 2018, Ordovas 2008)
- Assisting with assessment of sudden cardiac arrest/death in patients with non ischemic cardiomyopathy, if it will affect decision making with respect to management of the risk for
sudden cardiac arrest/death (e.g. ICD implantation) (Al-Khatib 2017, Kuruvilla 2014, Halliday 2017)

- In a patient suspected of cardiac sarcoid, evaluation of possible diffuse inflammation noted on 18-FDG PET, in order to guide therapy (Vita 2018)
- Diagnosis of acute myocarditis, with suspicion based upon new, unexplained findings such as any one of:
  - Rise in troponin not clearly due to acute myocardial infarction
  - Change in ECG suggesting acute myocardial injury or pericarditis, without evident myocardial infarction, often with arrhythmia
  - Abnormal systolic function when the results could alter management (Friedrich 2013, Kinderman 2012, Cooper 2018, Ordovas 2008)
- In cardiomyopathy (Ordovas 2008)
  - For detailed assessment of hypertrophic cardiomyopathy, when TTE is inadequate for diagnosis, management or operative planning, or when tissue characterization (fibrosis quantitation) will impact indications for ICD (Maron 2012, Maron 2014, Al-Khatib 2017)
  - For confirming a diagnosis of ischemic cardiomyopathy when it will make a difference in clinical management (Fuisz 2016, bColucci 2018)
- Evaluation of first degree relatives with strong family history of cardiomyopathy, when TTE (even with contrast) was inadequate.

**Evaluation of Intra- and Extra-Cardiac Structures**

Suspected cardiac mass, paravalvular abscess, suspected tumor or non-valvular thrombus (CT for valvular thrombus), or potential cardiac source of emboli, when TTE and TEE images are inadequate (Doherty 2017, Pennell 2010, Baumgartner 2017, Nishimura 2014, Kassop 2014, Ordovas 2008, Sexton 2018)

- In suspected infective endocarditis with moderate to high pretest probability (i.e. staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE is inadequate and TEE cannot be performed (Doherty 2017)
- Detailed evaluation of a known cardiac mass (tumor), non-valvular thrombus (CT for valvular thrombus), paravalvular abscess (most often previously noted on echocardiography) (Doherty 2017, Pennell 2010, Baumgartner 2017, Nishimura 2014, Kassop 2014, Ordovas 2008)
- When TTE and/or TEE are inadequate, evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, constriction versus restrictive cardiomyopathy) (CT superior for calcium assessment) (Klein 2013, Pennell 2010, Ordovas 2008)

Evaluation of left atrium and pulmonary veins prior to radiofrequency ablation for atrial fibrillation, including dimensions of veins for mapping purposes. (Ohana 2015, Figtree 2011)

- Assessment of left ventricular pseudoaneurysm, when TTE was inadequate and/or left ventriculography was not performed with cardiac catheterization or was inadequate. (Shapira 2018)

**Aortic Pathology:**


Echo is required when is can evaluate the full extent of pathology under surveillance.

- CT, MR, or echo can be used for screening and follow up, with CT and MR preferred for imaging beyond the proximal ascending thoracic aorta (see table below for top normal sizes).
Screening first degree relatives of individuals with a history of thoracic aortic aneurysm (defined as $\geq 50\%$ above top normal) or dissection or an associated high risk mutation for thoracic aneurysm in common.

Screening second degree relative of a patient with thoracic aortic aneurysm (defined as $\geq 50\%$ above top normal), when the first degree relative has aortic dilation, aneurysm, or dissection.

Six month follow up after initial finding of a dilated thoracic aorta, for assessment of rate of change.

Annual follow up of enlarged thoracic aorta that is above top normal for age, gender, and size up to 4.4 cm.

Biannual (twice/yr) follow up of enlarged aortic root $\geq 4.5$ (> 4.5 cm with bicuspid aortic valve) cm or showing growth rate $\geq 0.5$ cm/year.

### Aortic diameters: Upper limits of normal

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>BSA (m$^2$)</th>
<th>Ascending aorta (mm)</th>
<th>Descending aorta (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Women (n = 1,147)</td>
<td>Men (n = 1,805)</td>
<td>Women (n = 736)</td>
</tr>
<tr>
<td>$&lt; 45$</td>
<td>&lt; 1.70</td>
<td>33.8</td>
<td>33.0</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>34.4</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>35.0</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>$&gt; 2.1$</td>
<td>NA</td>
<td>38.3</td>
</tr>
<tr>
<td>45–54</td>
<td>&lt; 1.70</td>
<td>35.2</td>
<td>38.6</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>37.2</td>
<td>38.1</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>38.9</td>
<td>39.7</td>
</tr>
<tr>
<td></td>
<td>$&gt; 2.1$</td>
<td>40.6</td>
<td>40.6</td>
</tr>
<tr>
<td>55–64</td>
<td>&lt; 1.70</td>
<td>36.9</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>37.0</td>
<td>39.7</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>39.0</td>
<td>41.2</td>
</tr>
<tr>
<td></td>
<td>$&gt; 2.1$</td>
<td>42.0</td>
<td>43.1</td>
</tr>
<tr>
<td>$\geq 65$</td>
<td>&lt; 1.70</td>
<td>37.5</td>
<td>38.5</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>39.2</td>
<td>41.0</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>42.7</td>
<td>42.2</td>
</tr>
<tr>
<td></td>
<td>$&gt; 2.1$</td>
<td>NA</td>
<td>42.4</td>
</tr>
</tbody>
</table>

$^a$Upper limits of normal are $2$ standard deviations above the mean. Not calculated if there were fewer than $6$ patients in a group. BSA = body surface area; NA = not available.

An aneurysm is defined as $\geq 50\%$ greater than top normal. (Cikach 2018; Hiratzka 2010)

- Marfan’s patients require annual imaging with CT, MRI (avoids radiation, especially when frequent evaluation required), or echo when it can evaluate the full extent of pathology, with increase to biannual (twice-yearly) when diameter reaches 4.5 cm or when expansions is $> 0.5$ cm/year.
cm /yr. (Complete aortic annual CMR is recommended for annual evaluation Loeys-Dietz, Ehlers-Danlos, and certain other noted genetic mutations, wherein surgical intervention is recommended at 4.2 cm.)

- Turner’s syndrome patients should undergo imaging (CT, MRI - avoids radiation, especially when frequent evaluation required, or echo (when it can evaluate the full extent of pathology), of the heart and aorta for evidence of dilatation of the ascending thoracic aorta, and with normal imaging and no risk factors for aortic dissection, repeat imaging should be performed every 5-10 years or if otherwise indicated. If the aorta is enlarged, appropriate follow up imaging should be done according to size, as noted above. With a bicuspid aortic valve, the recommendation below applies.

- Patients with bicuspid aortic valve and aortic dilation > 4.0 cm require annual imaging with CT, MRI, or echo. (Echo is required when it can evaluate the full extent of pathology under surveillance.) This would increase to biannual (twice-yearly) imaging in the event of any one of the additional conditions: diameter > 4.5 cm, rapid rate of change 0.5 cm/yr, or a family history of a first degree relative with aortic dissection. Initial imaging with first 6 month re-evaluation for rate of expansion is appropriate.

- CMR can be used for the diagnosis and surveillance of aortitis (Bhave 2018).

- Any interval increase > 3 mm on echo should be validated by CT or CMR. (Baumgartner 2014).

- When higher resolution measurement is required for determining an indication or surgery, CT appear slightly better (Baumgartner 2014).

- Computed tomographic imaging or magnetic resonance imaging of the thoracic aorta is reasonable after a Type A or B aortic dissection or after prophylactic repair of the aortic root/ascending aorta.

- Computed tomographic imaging or magnetic resonance imaging of the aorta is reasonable at 1, 3, 6, and 12 months post un-operated dissection or intramural hematoma, penetrating atherosclerotic aortic ulcer, and if stable, annually thereafter so that any threatening enlargement can be detected in a timely fashion.

- Postoperative surveillance recommendations are taken from the 2010 ACC Thoracic Aortic Disease Guideline: See Table below (Hiratzka 2010).
CT and MR preferred for imaging beyond the proximal ascending thoracic aorta.

(Table above from Hiratzka 2010)
ADDITIONAL INFORMATION
I. General

Scenarios for which approval CMR is generally not approvable:

• For any combination imaging study
• For same imaging tests less than six weeks part unless specific guideline criteria states otherwise, e.g. evaluation of cardiac sarcoid with MR subsequent to PET (Vita 2018)
• For different imaging tests, such as CTA and CMR, of same anatomical structure less than six weeks apart without high level review to evaluate for medical necessity.
• For re-imaging of repeat or poor quality study

Request for a follow-up study - A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

Cardiac Tumors (Kassop 2014; Ordovas 2008)
MRI is the modality of choice to evaluate cardiac tumors due to its high contrast resolution and multiplanar capability which allows for optimal evaluation of myocardial infiltration, pericardial involvement and extra-cardiac vascular structures within and beyond the thorax. It is also useful in the differentiation of benign and malignant cardiac tumors and in differentiating thrombi from cardiac tumors.

CMR Safety (Chernoff 2018; Russo 2017; Nazarian 2017; Indik 2017; Brignole 2013)
Since many cardiac patients have cardiac implanted electrical devices (CIEDSs), the risk of CMR to the patient and the device must be weighed against the benefit to the patient, in terms of clinical value in optimal management.

Many newer CIEDs are ‘MR conditional’ for thoracic scanning, some only for non-thoracic scanning, and some for both. With adherence to manufacturer’s recommendations and precautions with respect to programming and patient/device monitoring, MR conditional CIEDs do permit safe MR scanning, with a limited amount of data available specific to cardiac MR.

The older ‘non MR conditional’ devices are often amendable to MR scanning at field strength ≤ 1.5 Tesla. However, the presence of a CIED is still generally considered a strong relative contraindication to routine MR examination, and therefore, MR imaging in patients with non-MRI-conditional permanent pacemakers or ICD should be undertaken only if no alternative diagnostic test is available and the potential benefit to the patient clearly outweighs the potential risks. Such an approach warrants informed patient consent, and the scanning protocol requires on site imaging and device management expertise.

Additional non-conditional device materials include combinations of components (even if individually conditional) from various manufacturers that have not been specifically tested together for conditional labeling. Other examples of non-conditional components include epicardial leads, abandoned leads, fractured leads, or an active non cardiac device.
II. ECG Stress Test Alone versus Stress Testing with Imaging

Prominent scenarios suitable for an ECG stress test WITHOUT imaging (i.e. exercise treadmill ECG test) are inferred from the guidelines presented above, often (but not always) requiring that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate AND has an interpretable ECG for ischemia during exercise (Wolk 2013):

- The (symptomatic) low pretest probability patient who is able to exercise and has an interpretable ECG
- The (asymptomatic) high global risk patient who is able to exercise and has an interpretable ECG

The patient who is under evaluation for exercise induced arrhythmia (or long QT interval evaluation when the resting QTc is normal), and coronary artery disease is not suspected (Al-Khatib 2017)

The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription.

Duke Exercise ECG Treadmill Score calculates risk from ECG treadmill alone:

- The equation for calculating the Duke treadmill score (DTS) is: \( \text{DTS} = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or 0.1 mV increments}) - (4 \times \text{exercise angina score}) \), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.
- The score typically ranges from -25 to +15. These values correspond to low-risk (with a score of ≥ +5), intermediate risk (with scores ranging from -10 to +4), and high-risk (with a score of ≤ -11) categories.

An uninterpretable baseline ECG includes (Fihn 2012):

- Abnormalities of ST segment depression of 0.1 mV (1 mm with conventional calibration) or more
- Ischemic looking T wave inversions of at least 0.25 mV (2.5 mm with conventional calibration)
- ECG findings of probable or definite LVH, WPW, a ventricular paced rhythm, or left bundle branch block
- Digitalis use or hypokalemia
- Resting HR under 50 bpm on a beta blocker and an anticipated suboptimal workload (e.g. rate-pressure product less than 20-25K) could render inconclusive result
- Prior false positive stress ECG

III. Global Risk of Cardiovascular Disease

Global risk of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to asymptomatic patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging (Douglas 2018). There are rare exemptions, such as patients requiring a I-C antiarrhythmic drug, who might require coronary risk stratification prior to initiation of the drug, when global risk is moderate or high.

- CAD Risk—Low
  10-year absolute coronary or cardiovascular risk less than 10%.
- CAD Risk—Moderate
  10-year absolute coronary or cardiovascular risk between 10% and 20%.
- CAD Risk—High
  10-year absolute coronary or cardiovascular risk of greater than 20%.
Links to Global Cardiovascular Risk Calculators*

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

(D’Agostino 2008; Ridker 2007; McClelland 2015; Goff 2014)

<table>
<thead>
<tr>
<th>Risk Calculator</th>
<th>Link to Online Calculator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reynolds Risk Score</td>
<td><a href="http://www.reynoldsriskscore.org/">http://www.reynoldsriskscore.org/</a></td>
</tr>
<tr>
<td>Can use if no diabetes</td>
<td></td>
</tr>
<tr>
<td>Unique for use of family history</td>
<td></td>
</tr>
<tr>
<td>Pooled Cohort Equation</td>
<td><a href="http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example">http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example</a></td>
</tr>
<tr>
<td>MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk</td>
<td><a href="https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx">https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx</a></td>
</tr>
</tbody>
</table>

IV. Definitions of Coronary Artery Disease
(Fihn 2012; Montalescot 2013; Patel 2017; Mintz 2016; Tobis 2007)

1. Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and refers to cross sectional narrowing when IVUS (intravascular ultrasound) is the method of determination.

2. Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a risk stratification tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.

3. Stenoses ≥ 50% are considered obstructive coronary artery disease (also referred to as clinically significant), while stenoses ≤ 50% are considered nonobstructive coronary artery disease (Gerber 2018).

4. Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
   i. Suggested by percentage diameter stenosis ≥ 70% by angiography; borderline lesions are 40-70% (Fihn 2012; Tobis 2007)
   ii. For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross sectional area on IVUS ≤ 6 square mm (Fihn 2012; Mintz 2016)
   iii. FFR (fractional flow reserve) ≤ 0.80 for a major vessel (Mintz 2016)
   iv. Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree

5. A major vessel would be a coronary vessel that would typically be substantial enough for revascularization, if it were indicated. Lesser forms of coronary artery disease would be labeled
as “limited” and not major (i.e. A 50% lesion in a tiny septal or modest size mid PDA would be limited obstructive coronary artery disease.)

6. Microvascular ischemic coronary artery disease, as might be described by a normal FFR (fractional flow reserve) above 0.80 with a reduced CFR (coronary flow reserve less than 2.5), has not otherwise been addressed in this manuscript, because it is very rarely an issue in compliance determinations. However, it would constitute a form of ischemic heart disease.

7. FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow. Newer iterations such as iFR (instantaneous wave free ratio) might supersede basic FFR technology in the near future.

8. New technology is evolving that estimates FFR from CCTA images. This is covered under the separate NIA Guideline for FFR-CT.

V. Anginal Equivalent

Development of an anginal equivalent (e.g. shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g. dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam, (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent (Moya 2009; Shen 2017; Fihn 2012).

VI. Peripheral Arterial Disease/Cerebrovascular Disease

Arterial vascular disease below the renal arteries is generally referred to as peripheral arterial disease, when the ankle brachial index is <0.9 or there is at least 50% vessel diameter narrowing on ultrasound or angiography (Hussain 2018).

Cerebrovascular disease generally refers to a history of TIA (transient ischemic attack) or stroke, or cerebrovascular lesions that put the patient at considerable risk for stroke (Caplan 2018).

There is no evidence to demonstrate that screening all patients with peripheral arterial disease for asymptomatic atherosclerosis in other arterial beds improves clinical outcome. Intensive treatment of risk factors through guideline directed medical therapy is the principal method for preventing adverse cardiovascular ischemic events secondary to atherosclerotic disease in other arterial beds (Gerhard-Herman 2016).

VII. Imaging Surveillance for Cardiotoxic Chemotherapy

(Plana 2014; Zamorano 2016; Maleszewski 2018; Herrmann 2014)

**TTE is the method of choice** for the evaluation of patients before, during, and after cancer therapy. Ideally accuracy prefers that 3D and global longitudinal strain (GLS) are part of the exam, and serum troponin (Tn) should also be measured. However, GLS and Tn might not have been performed, in which case determinations might need to be made with LVEF only. *Serum troponin (Tn) and GLS abnormalities constitute an abnormal assessment of LV function, because their abnormalities frequently herald an imminent fall in LVEF*(Plana 2014; Zamorano 2016).
**CMR** is recommended when TTE has been unreliable and/or candidacy for cardiotoxic chemotherapy based upon LVEF is questionable. MUGA can also be considered when TTE is inadequate and CMR is not available (Plana 2014).

**MUGA** is accurate and reproducible, but lacks information about pericardium and valves, incurs repeated radiation exposure, and is inaccurate during an irregular cardiac rhythm (Plana 2014).

**Surveillance guidelines** are somewhat complex, possibly beyond the scope of this guideline, especially in patients with additional risk factors for LV dysfunction (Herrmann 2014). As with all guidelines, adequate information for complex decisions might be impractical to acquire. However, if the reader requires more rigorous recommendations, they are summarized concisely in the table below. **Necessity determinations might not require strict adherence to this table at this time, but it is here to serve as a helpful reference for the reader, if desired.**

### TTE Surveillance Strategy for Cardiotoxic Chemotherapy (Optional Information)
(Plana 2014; Herrmann 2014; Zamorano 2016; Maleszewski 2018)

<table>
<thead>
<tr>
<th>Suspected/Detected LV Status at Baseline, During, or After Completion of Therapy (LVEF is minimum information, GLS and Tn can reveal early LV dysfunction prior to LVEF)</th>
<th>Type I Anthracyclines: Doxorubicin, Epirubicin, Idarubicin Mitoxantrone (Asnani 2018)</th>
<th>Type II Trastuzumab, Labatinib, Pertuzumab, Sorafenib, Sunitinib, Bevacizumab, Bortezomib **</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Normal:</strong> EF is ≥ 55%, troponin is negative, and global longitudinal strain (GLS) &gt; lower limit of normal*</td>
<td><strong>Normal assessment:</strong> Assess after a cumulative dose &gt; 200mg/M² (or its anthracycline equivalent) and prior to each additional 50 mg/M², and at completion of therapy, and 6 months later, and for cumulative dose &gt; 300 mg/M² include assessment at 1 year and at 5 years post completion of therapy. (Zamorano 2016)</td>
<td><strong>Normal assessment:</strong> Assess every 3 months during therapy and at 6 months post completion of therapy</td>
</tr>
<tr>
<td><strong>Abnormal:</strong> any one of:</td>
<td><strong>Abnormal assessment:</strong> Assess after every cycle, and reassess for verification 2-3 weeks later if a drop in LV function has been detected/suspected; assess 6 months post completion of therapy, followed by reassessment every 6 months until stable, and for cumulative dose &gt; 300 mg/M² include assessment at 1 year and 5 years post completion of therapy. (Zamorano 2016)</td>
<td><strong>Abnormal assessment:</strong> Assess after every cycle, and reassess for verification 2-3 weeks later if a drop in LV function has been detected /suspected; assess 6 months post completion of therapy, and if still not stable re-assess every 6 months until stable.</td>
</tr>
<tr>
<td>- GLS reduced &gt; 10-15% below normal (about 20 is normal*, labs vary)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Troponin positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- LVEF started &lt; 55%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- During therapy LVEF drops below 55% AND ≥ 5 points for a symptomatic/≥10 points for an asymptomatic patient. (Maleszewski 2018)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* GLS of (negative) 20 is generally normal, but individual labs vary (Collier 2017).
** Imatinib, rarely cardiotoxic, does not require surveillance of LV function (Floyd 2018).
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARVD/C</td>
<td>Arrhythmogenic right ventricular dysplasia/cardiomyopathy</td>
</tr>
<tr>
<td>CABG</td>
<td>Coronary artery bypass grafting surgery</td>
</tr>
<tr>
<td>CAD</td>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>CCT</td>
<td>Cardiac CT</td>
</tr>
<tr>
<td>CCTA</td>
<td>Coronary CT angiography</td>
</tr>
<tr>
<td>CHF</td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>CMR</td>
<td>Cardiac magnetic resonance (imaging)</td>
</tr>
<tr>
<td>CT</td>
<td>Computed tomography</td>
</tr>
<tr>
<td>CTA</td>
<td>Computed tomographic angiography</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
</tr>
<tr>
<td>GLS</td>
<td>Global longitudinal strain (measure of left ventricular function)</td>
</tr>
<tr>
<td>HF</td>
<td>Heart failure</td>
</tr>
<tr>
<td>LBBB</td>
<td>Left bundle-branch block</td>
</tr>
<tr>
<td>LV</td>
<td>Left ventricular</td>
</tr>
<tr>
<td>MI</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>MPI</td>
<td>Myocardial perfusion imaging</td>
</tr>
<tr>
<td>MR(I)</td>
<td>Magnetic resonance (imaging)</td>
</tr>
<tr>
<td>PCI</td>
<td>Percutaneous coronary intervention</td>
</tr>
<tr>
<td>PET</td>
<td>Positron emission tomography</td>
</tr>
<tr>
<td>RNA</td>
<td>Radionuclide angiography</td>
</tr>
<tr>
<td>RV</td>
<td>Right ventricle</td>
</tr>
<tr>
<td>SE</td>
<td>Stress echocardiography</td>
</tr>
<tr>
<td>Tn</td>
<td>Troponin</td>
</tr>
<tr>
<td>TR</td>
<td>Tricuspid regurgitation</td>
</tr>
</tbody>
</table>
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INTRODUCTION

(Gerber 2018; Hecht 2017; Blankstein 2017; Greenland 2018)

➢ Coronary artery calcium (CAC) testing is a cardiovascular risk assessment tool, applicable only to the patient without known cardiovascular disease, for the purpose of primary prevention. It is not for the patient with suspected or known cardiovascular disease, coronary or otherwise, who already require aggressive risk factor modification.

➢ CAC testing, by either EBCT or non-contrast CCT, provides a quantitative assessment of coronary artery calcium content in Agatston units, which is an adjunct to the estimation of global risk for coronary or cardiovascular events over the next 10 years (McClelland 2015). A CAC Score > 0 is highly specific feature of coronary atherosclerosis.

➢ Despite controversies that exist (Nasir 2012; Blaha 2017), a growing concern about overutilization of statin therapy in large numbers of patients at lower than conventionally determined risk has led to promotion of CAC testing as a way to address this problem. It infrequently (5% of those who would ordinarily not warrant a statin) shows an increase over conventionally determined risk (see explanatory table in Additional Information section) (Nasir 2015; Greenland 2018; Michos 2017; Pender 2016; Mahabadi 2017).

➢ CAC score > 100 can also provide support for aspirin therapy (Hecht 2017).

Indications for CAC Testing

(Greenland 2018; Hecht 2017; Blankstein 2017; Pender 2016; Goff 2014; Nasir 2015; McClelland 2015; Piepoli 2016; Mahabadi 2017; Gerber 2018)

• In the context of shared decision making among patients aged 40 to 75 years who are free of clinical atherosclerotic cardiovascular disease and deemed to be at intermediate-to-low or intermediate risk (5 - 20%), and adjusting that risk up or down based upon the CAC score has been documented in the record as necessary to adjust cardiovascular risk management, such as decisions with respect to statin therapy (Stone 2013; Michos 2017; Hecht 2017; Wilkins 2018).

• Patients who are over 75 or younger than 40 are far less likely to have meaningful alteration in risk, but CAC testing can be considered in these patients when there is strong, well-documented evidence that the result of CAC testing could alter management, in the context of documented patient-physician shared decision making (Tota-Maharaj 2012).

• Patients with estimated 10-year risk of less than 5%, but are suspected to be at elevated atherosclerotic cardiovascular disease (ASCVD) risk because of a major risk factor not accounted for in the global risk equations, such as erectile dysfunction, rheumatologic diseases (lupus, psoriasis, ankylosing spondylitis, or rheumatoid arthritis), or family history of premature CAD (Greenland 2018; Michos 2017; Hecht 2017).
• Patients in whom statin therapy is indicated but who have intolerable adverse effects from statins or reluctance to take statin medication, to guide the need for alternative lipid-lowering strategies (Nasir 2015; Michos 2017; Blankstein 2017).

• Repeat CAC testing may be repeated for risk re-assessment after a minimum of 5 years, if documentation indicates it will alter management (e.g. prior CAC = 0), which should be rare in patients who already have a prior CAC score > 0 (Michos 2017; Greenland 2018; Hecht 2017). It should not be repeated if the patient has already had two CAC Scores of zero 5 years apart (Greenland 2018).

The Determination of Global Cardiovascular Risk*

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

Links to Global Cardiovascular Risk Calculators
(D'Agostino 2008; Ridker 2007; McClelland 2015; Goff 2014)

<table>
<thead>
<tr>
<th>Risk Calculator</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Reynolds Risk Score</td>
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<td>MESA Risk Calculator</td>
<td><a href="https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx">https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx</a></td>
</tr>
</tbody>
</table>

Risk tiers:
• **Low** < 10%.
• **Moderate** 10% - 20%.
• **High risk** > 20%.

Management Approach Using CAC Scoring
(Greenland 2018)
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASCVD</td>
<td>Atherosclerotic cardiovascular disease</td>
</tr>
<tr>
<td>CAC</td>
<td>Coronary artery calcium</td>
</tr>
<tr>
<td>CAD</td>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>CCT</td>
<td>Cardiac computed tomography</td>
</tr>
<tr>
<td>EBCT</td>
<td>Electron beam computed tomography</td>
</tr>
</tbody>
</table>
REFERENCES


Nasir K, Bittencourt MS, Blaha MJ, et al. Implications of coronary artery calcium testing among statin candidates according to American College of Cardiology/American Heart Association cholesterol


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CPT Codes: 75572, 75573

INTRODUCTION

➢ Cardiac computed tomography (Heart CT) serves to image the cardiac chambers, great vessels, valves, myocardium and pericardium to assess cardiac structure and function, particularly when echocardiography (transthoracic echocardiography and transesophageal echocardiography) cannot provide adequate information.

➢ CT imaging can be used for assessment of the
   o Structures of the heart (chambers, valves, great vessels, masses, etc.), as in this guideline
   o The coronary circulation, as in the separate coronary computed tomography angiography (CCTA) guideline
   o Quantitative level of calcium in the walls of the coronary arteries, in the separate coronary artery calcium (CAC) scoring guideline

➢ CT imaging is frequently competitive with CMR (Cardiac Magnetic Resonance Imaging), or MRI (Warnes 2008, Baumgartner 2010, Pennell 2010)

<table>
<thead>
<tr>
<th>Modality</th>
<th>Cardiac CT</th>
<th>Cardiac MR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrast</td>
<td>Often required</td>
<td>Required for some tissue characterization studies, often unnecessary</td>
</tr>
<tr>
<td>Radiation*</td>
<td>Yes</td>
<td>None, advantage for young patients and those requiring frequent exams</td>
</tr>
<tr>
<td>Resolution</td>
<td>Higher spatial</td>
<td>Higher temporal</td>
</tr>
<tr>
<td>Flow</td>
<td>Not standard</td>
<td>Standard</td>
</tr>
<tr>
<td>Patient comfort</td>
<td>Easy</td>
<td>Claustrophobia issues</td>
</tr>
<tr>
<td>Ferromagnetic implants</td>
<td>No issue</td>
<td>Relative contraindication</td>
</tr>
<tr>
<td>Cost</td>
<td>Moderate to High</td>
<td>High</td>
</tr>
</tbody>
</table>

*Hirshfeld 2018

Some scenarios might provide more detail with low dose CT than with CMR, thereby overriding the radiation risk (Ohana 2015, Schoenhagen 2005).

INDICATIONS FOR HEART CT
(Taylor 201; Douglas 2011)

<table>
<thead>
<tr>
<th>Evaluation of Cardiac Structure and Function</th>
<th>(Warnes 2008; Wiant 2009; Baumgartner 2010; Orwat 2014; Kilner 2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Congenital Heart Disease</td>
<td></td>
</tr>
<tr>
<td>• For evaluation of anomalous thoracic arteriovenous vessels, such as TGA, when MRI cannot be performed (Cohen 2016; Warnes 2008).</td>
<td></td>
</tr>
</tbody>
</table>
• Further assessment of complex adult congenital heart disease after confirmation by transthoracic echocardiography (TTE), but TTE was inadequate for clinical management (consider advantages of CMR below).

• When TTE and/or transesophageal echocardiography (TEE) has been or would be insufficient for clinical management, for the choice between CMR and CT, several aspects must be considered including radiation exposure, resolution required, sum of information required, its impact upon management, the presence of a pacemaker/implantable cardioverter defibrillator (ICD) or other implants, and patient claustrophobia. Sample indications include:
  o Quantification of RV volumes and ejection fraction (tetralogy of Fallot, systemic RV, and tricuspid regurgitation) [CMR better than CT, if available] (Haddad 2008, Dupont 2009, Benza 2008).
  o Evaluation of the RV outflow tract and RV-PA conduits (CMR or CT).
  o Evaluation of the entire aorta (aneurysm, dissection, intramural hematoma, Loeys-Dietz, Ehlers-Danlos, or confirmed genetic mutation known to predispose to aortic aneurysm and dissection. CMR or CT initially, with annual CMR (MRI) for Loeys-Dietz, Ehlers Danlos; multiple options for Marfan’s, Turner’s (see Aortic Pathology section below) (Hiratzka 2010).
  o Evaluation of pulmonary arteries (stenosis and aneurysms) and the aorta (coarctation) (CMR or CT).
  o Evaluation of systemic and pulmonary veins (anomalous connection, obstruction, etc) (CMR or CT).
  o Aorto-pulmonary collaterals and arteriovenous malformations (either, but CT is superior to CMR for spatial resolution, if needed).
  o Coronary anomalies and CAD (indication for CCTA, better than CMR).
  o Quantification of myocardial (muscle) mass (CMR or CT).

• Assessment of right ventricular morphology in arrhythmogenic right ventricular dysplasia/cardiomyopathy, based upon reason for suspicion, of which examples are:
  o Nonsustained VT
  o Syncope
  o ECG abnormality: Prolonged S wave upstroke, epsilon waves, or right precordial T wave inversions (> 14 yr old) in the absence of complete RBBB
  o First degree relative with phenotype or genotype of ARVD/C (either, but CMR is superior to CT) (Marcus 2010; McKenna 2018; te Riele 2015).

### Left Ventricular Function Assessment

• Evaluation of left ventricular function following acute MI or in HF patients, when echocardiography (even with contrast) and radionuclide angiography/ventriculography are inadequate (Fihn 2012; Patel 2013).

### Valvular Assessment

• Characterization of native or prosthetic valves with clinical signs or symptoms suggesting valve dysfunction, when TTE, TEE, and fluoroscopy have been inadequate (e.g. bioprosthetic valve thrombus post transcatheter or surgical valve replacement) (Doherty 2017).
• Evaluation of the calcium score of the aortic valve in symptomatic patients with severe calcific aortic stenosis by calculated valve area (≤ 1.0 square cm), low flow (stroke volume ≤ 35 mL/square M) with low gradient (mean < 40 mm Hg or Doppler < 4 M/sec), and ejection fraction < 50%, when low dose dobutamine shows no flow (contractile reserve (failure to increase stroke volume > 20%), to assist with the determination of the severity of the aortic stenosis. Severe (in Aggatston units): >1,200 women, >2,000 men) (Baumgartner 2017; Steiner 2017; Clavel 2017).

• Evaluation of the calcium score of the aortic valve in symptomatic patients with severe calcific aortic stenosis by calculated valve area (≤ 1.0 square cm), low flow (stroke volume ≤ 35 mL/square M) with low gradient (mean < 40 mm Hg or Doppler < 4 M/sec), and preserved ejection fraction ≥ 50%, to assist with the determination of the severity of the aortic stenosis. Severe (in Aggatston units): >1,200 women, >2,000 men) (Clavel 2017).

• Evaluation of the calcium score of the aortic valve in symptomatic patients with severe calcific aortic stenosis by calculated valve area (≤ 1.0 square cm and index ≤ 0.6 square cm/square M), normal flow (stroke volume ≥ 35 mL/square M) with low gradient (mean < 40 mm Hg or Doppler < 4 M/sec), and preserved ejection fraction ≥ 50%, to assist with the determination of the severity of the aortic stenosis. Severe (in Aggatston units): >1,200 women, >2,000 men) (Baumgartner 2017; Clavel 2017).

• Evaluation of RV systolic function, including systolic and diastolic volumes, in severe tricuspid TR, when TTE images are inadequate and CMR is not readily available.

• Evaluation of suspected infective endocarditis with moderate to high pretest probability (i.e. staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inadequate.
  
  • Evaluate morphology/anatomy in the setting of suspected paravalvular infections when the anatomy cannot be clearly delineated by TTE and TEE (Nishimura 2014).

• Patients with bicuspid aortic valve and aortic dilation > 4.0 cm require annual imaging with CT, MRI, or echo. Echo is required when it can evaluate the full extent of pathology under surveillance. This would increase to biannual (twice-yearly) imaging in the event of any one of the additional conditions: diameter > 4.5 cm, rapid rate of change 0.5 cm/yr, or a family history of a first degree relative with aortic dissection. Initial imaging with first 6 month re-evaluation for rate of expansion is appropriate.

### Evaluation of Intra- and Extracardiac Structures

• Evaluation of cardiac mass (suspected tumor or thrombus, including valvular mass or vegetation), when imaging with TTE and TEE have been inadequate (consider advantage of CMR for superior tissue characterization).

  (Doherty 2017; Kassop 2014; Baumgartner 2017; Nishimura 2014; Sexton 2018)

Evaluation of pericardial anatomy, when TTE and/or TEE are inadequate or for better tissue characterization of a mass and detection of metastasis, if malignancy is suspected (CMR superior for physiologic assessment (constrictive versus restrictive) and tissue characterization, CT superior for calcium assessment) (Klein 2013; Pennell 2010).

### Electrophysiologic Procedure Planning

• Evaluation of pulmonary venous anatomy prior to radiofrequency ablation of atrial fibrillation and for follow up when needed for evaluation of pulmonary vein stenosis (Wai-ee, 2012; Ohana, 2015; Niinuma 2008; Schoenhagen 2010; Raijah 2013).
• Non-invasive coronary vein mapping prior to placement of biventricular pacing leads (Raijah 2013; Van de Veire 2006; Heydari 2012)

**Transcatheter Structural Intervention Planning**

- When TTE and TTE cannot provide adequate imaging, CT imaging can be used for planning: robotic mitral valve repair, atrial septal defect closure, left atrial appendage closure, ventricular septal defect closure, endovascular grafts, and percutaneous pulmonic valve implantation (Raijah 2013; Schoenhagen 2010; Flachskampf 2014; Pison 2015).
- Evaluation for suitability of TMVR, transcatheter mitral annuloplasty, and transcatheter mitral PVML closure, alone or in addition to TEE (Wunderlich 2018).

**Aortic Pathology:**
(Hiratzka 2010; Erbel 2014; Schiller 2017; Wright a&b 2018; Woo a&b 2018; Svensson 2013; Doherty 2017; Nishimura 2014; Baumgartner 2014; Hendel 2006; Bhave 2018)

Echo is required when it can evaluate the full extent of pathology under surveillance.

- CT, MR, or echo can be used for screening and follow up, with CT and MR preferred for imaging beyond the proximal ascending thoracic aorta (see table below for top normal sizes).
  - Screening first degree relatives of individuals with a history of thoracic aortic aneurysm (defined as ≥ 50% above top normal) or dissection or an associated high risk mutation for thoracic aneurysm in common.
  - Screening second degree relative of a patient with thoracic aortic aneurysm (defined as ≥ 50% above top normal), when the first degree relative has aortic dilation, aneurysm, or dissection.
  - Six month follow up after initial finding of a dilated thoracic aorta, for assessment of rate of change.
  - Annual follow up of enlarged thoracic aorta that is above top normal for age, gender, and size up to 4.4 cm.
  - Biannual (twice/yr) follow up of enlarged aortic root ≥ 4.5 cm (> 4.5 cm for bicuspid aortic valve) or showing growth rate ≥ 0.5 cm/year.
An aneurysm is defined as >50% greater than top normal (Cikach 2018, Hiratzka 2010).

- Marfan’s patients require annual imaging with CT, MRI (avoids radiation, especially, when frequent evaluation required), or echo when it can evaluate the full extent of pathology, with increase to biannual (twice-yearly) when diameter ≥ 4.5 cm or when expansions is > 0.5 cm/yr (complete aortic annual CMR is recommended for Loeys-Dietz, Ehlers-Danlos, and certain other noted genetic mutations, wherein surgical intervention is recommended as at low as 4.2 cm).

- Turner’s syndrome patients should undergo imaging (CT, MRI - avoids radiation, especially when frequent evaluation required, or echo (when it can evaluate the full extent of pathology), of the heart and aorta for evidence of dilatation of the ascending thoracic aorta, and with normal imaging and no risk factors for aortic dissection, repeat imaging should be performed every 5-10 years, or if otherwise indicated. If the aorta is enlarged, appropriate follow up imaging should be done according to size, as above. With a bicuspid aortic valve, the recommendation below applies.

### Aortic diameters: Upper limits of normal

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>BSA (m²)</th>
<th>Ascending aorta (mm)</th>
<th>Descending aorta (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Women (n = 1,147)</td>
<td>Men (n = 1,805)</td>
</tr>
<tr>
<td>&lt; 45</td>
<td>&lt; 1.70</td>
<td>33.8</td>
<td>33.0</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>34.4</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>35.0</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.1</td>
<td>NA</td>
<td>38.3</td>
</tr>
<tr>
<td>45–54</td>
<td>&lt; 1.70</td>
<td>35.2</td>
<td>38.6</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>37.2</td>
<td>38.1</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>38.9</td>
<td>39.7</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.1</td>
<td>40.6</td>
<td>40.6</td>
</tr>
<tr>
<td>55–64</td>
<td>&lt; 1.70</td>
<td>36.9</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>37.0</td>
<td>39.7</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>39.0</td>
<td>41.2</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.1</td>
<td>42.0</td>
<td>43.1</td>
</tr>
<tr>
<td>≥ 65</td>
<td>&lt; 1.70</td>
<td>37.5</td>
<td>38.5</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>39.2</td>
<td>41.0</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>42.7</td>
<td>42.2</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.1</td>
<td>NA</td>
<td>42.4</td>
</tr>
</tbody>
</table>

*Upper limits of normal are 2 standard deviations above the mean. Not calculated if there were fewer than 6 patients in a group.

BSA = body surface area; NA = not available.

(Table above from Wolak 2008, as adapted by Cikach 2018)
• Patients with bicuspid aortic valve and aortic dilation > 4.0 cm require annual imaging with CT, MRI, or echo. (Echo is required when is can evaluate the full extent of pathology under surveillance.) This would increase to biannual (twice-yearly) imaging in the event of any one of the additional conditions: diameter > 4.5 cm, rapid rate of change 0.5 cm/yr, or a family history of a first degree relative with aortic dissection. Initial imaging with first 6 month re-evaluation for rate of expansion is appropriate.

• Any interval increase > 3 mm on echo should be validated by CT or CMR (Baumgartner 2014).

• When higher resolution measurement is required for determining an indication for surgery, CT appears slightly better (Baumgartner 2014).

• Computed tomographic imaging or magnetic resonance imaging of the thoracic aorta is reasonable after a Type A or B aortic dissection or after prophylactic repair of the aortic root/ascending aorta.

• Computed tomographic imaging or magnetic resonance imaging of the aorta is reasonable at 1, 3, 6, and 12 months post un-operated dissection, penetrating atherosclerotic aortic ulcer, and, if stable, annually thereafter, so that any threatening enlargement can be detected in a timely fashion.

• Postoperative surveillance recommendations are taken from the 2010 ACC Thoracic Aortic Disease Guideline (see table below) (Hiratzka 2010).
Table 17. Suggested Follow-Up of Aortic Pathologies After Repair or Treatment

<table>
<thead>
<tr>
<th>Pathology</th>
<th>Interval</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dissection</td>
<td>Before discharge, 1 mo, 6 mo, yearly</td>
<td>CT or MR, chest plus abdomen TTE</td>
</tr>
<tr>
<td>Chronic dissection</td>
<td>Before discharge, 1 y, 2 to 3 y</td>
<td>CT or MR, chest plus abdomen TTE</td>
</tr>
<tr>
<td>Aortic root repair</td>
<td>Before discharge, yearly</td>
<td>TTE</td>
</tr>
<tr>
<td>AVR plus ascending</td>
<td>Before discharge, yearly</td>
<td>TTE</td>
</tr>
<tr>
<td>Aortic arch</td>
<td>Before discharge, 1 y, 2 to 3 y</td>
<td>CT or MR, chest plus abdomen</td>
</tr>
<tr>
<td>Thoracic aortic stent</td>
<td>Before discharge, 1 mo, 2 mo, 6 mo, yearly or 30 days*</td>
<td>CXR, CT, chest plus abdomen</td>
</tr>
<tr>
<td>Acute IMH/PAU</td>
<td>Before discharge, 1 mo, 3 mo, 6 mo, yearly</td>
<td>CT or MR, chest plus abdomen</td>
</tr>
</tbody>
</table>

*US Food and Drug Administration stent graft studies usually required before discharge or at 30-day CT scan to detect endovascular leaks. If there is concern about a leak, a predischARGE study is recommended; however, the risk of renal injury should be borne in mind. All patients should be receiving beta blockers after surgery or medically managed aortic dissection, if tolerated. Adapted from Erbel et al (539).

AVR indicates aortic valve replacement; CT, computed tomographic imaging; CXR, chest x-ray; IMH, intramural hematoma; MR, magnetic resonance imaging; PAU, penetrating atherosclerotic ulcer; and TTE, transthoracic echocardiography.

CT and MR preferred for imaging beyond the proximal ascending thoracic aorta.

(Hiratzka 2010)
ADDITIONAL INFORMATION
(Taylor 2010; Schoenhagen 2005; Raijah 2013)

Scenarios for which approval of Heart CT is generally not approvable

- For same imaging tests less than six weeks apart unless specific guideline criteria states otherwise.
- For different imaging tests, such as CT and MRI, of same anatomical structure less than six weeks apart without high level review to evaluate for medical necessity.
- For re-imaging of repeat or poor quality studies.

Echocardiography
This study remains the best test for initially examining children in the assessment of congenital heart disease. However, if findings are unclear or need confirmation, CMR or CT can be useful.

CT and CMR in Congenital Heart Disease (CHD)
Many more children with congenital heart disease (CHD) are surviving to adulthood, increasing the need for specialized care and sophisticated imaging. Currently more adults than children have CHD. CT and CMR provide 3D anatomic relationship of the blood vessels and chest wall, and depict cardiovascular anatomic structures. (Warnes 2008; Wiant 2009).

CT and Cardiac Masses
CT and CMR are used to evaluate cardiac masses, describing their size, density, tissue characteristics, and spatial relationship to adjacent structures. Nearly all cardiac tumors are metastases. Primary tumors of the heart are rare, and most are benign. Cardiac myxoma is the most common type of primary heart tumor in adults and usually develops in the left atrium. Echocardiography is typically the first method for evaluation of cardiac myxoma. CT and CMR can provide adjunctive information on myxomas when necessary (Kassop 2014).

CT and Pericardial Disease
While echocardiography is most often used in the initial examination of pericardial disease, CT and CMR can evaluate pericardial thickening and masses which are often detected initially with echocardiography. CT and CMR can accurately define the site and extent of masses, e.g., cysts, hematomas and neoplasms (Klein 2013).

CT and Radiofrequency Ablation for Atrial Fibrillation
Atrial fibrillation, an arrhythmia triggered by abnormal electrical activity in the pulmonary veins, is the most common supraventricular arrhythmia in the United States. In patients with atrial fibrillation, radiofrequency ablation is used to electrically disconnect the pulmonary veins from the left atrium. Prior to this procedure, CT or CMR is useful to define the pulmonary venous anatomy encountered during the procedure. Determination of how many pulmonary veins are present and their ostial locations is important to make sure that all the ostia are ablated. Post ablation pulmonary vein stenosis can also be diagnosed with CT and CMR. The higher resolution detail of CT might make it preferable over CMR in some cases (Ohana 2015).
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARV/C</td>
<td>Arrhythmogenic right ventricular dysplasia/ cardiomyopathy</td>
</tr>
<tr>
<td>CABG</td>
<td>Coronary artery bypass grafting surgery</td>
</tr>
<tr>
<td>CAD</td>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>CCS</td>
<td>Coronary calcium score</td>
</tr>
<tr>
<td>CCT</td>
<td>Cardiac (heart) CT</td>
</tr>
<tr>
<td>CHD</td>
<td>Coronary heart disease</td>
</tr>
<tr>
<td>CMR</td>
<td>Cardiac magnetic resonance (imaging)</td>
</tr>
<tr>
<td>CT</td>
<td>Computed tomography</td>
</tr>
<tr>
<td>CTA</td>
<td>Computed tomography angiography</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
</tr>
<tr>
<td>EF</td>
<td>Ejection fraction</td>
</tr>
<tr>
<td>HF</td>
<td>Heart failure</td>
</tr>
<tr>
<td>MI</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>MPI</td>
<td>Myocardial perfusion Imaging or cardiac nuclear imaging</td>
</tr>
<tr>
<td>MR(I)</td>
<td>Magnetic resonance (imaging)</td>
</tr>
<tr>
<td>PCI</td>
<td>Percutaneous coronary intervention</td>
</tr>
<tr>
<td>PVML</td>
<td>Paravalvular mitral leak</td>
</tr>
<tr>
<td>RV</td>
<td>Right ventricle</td>
</tr>
<tr>
<td>SE</td>
<td>Stress Echocardiogram</td>
</tr>
<tr>
<td>TAVR</td>
<td>Transcatheter Aortic Valve Replacement</td>
</tr>
<tr>
<td>TMVR</td>
<td>Transcatheter mitral valve replacement</td>
</tr>
<tr>
<td>TR</td>
<td>Tricuspid regurgitation</td>
</tr>
<tr>
<td>TTE</td>
<td>Transthoracic echocardiography</td>
</tr>
</tbody>
</table>
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INTRODUCTION

- Coronary computed tomographic angiography (CCTA) is a noninvasive imaging study that uses intravenously administered contrast material and high-resolution, rapid imaging computed tomography (CT) equipment to obtain detailed volumetric images of the coronary blood vessels (while cardiac CT perfusion imaging is sometimes added to CCTA, the current utility of CT perfusion imaging is low and appears to require further study) (Gerber & Manning 2018).

- CCTA remains controversial for the assessment of asymptomatic high risk individuals, and while endorsed by some literature (Taylor 2010), it is not clearly recommended by most others (Mark 2010; Gerber & Manning 2018; Douglas 2018; Wolk 2013; Greenland 2010).

- Image quality depends on keeping HR < 70, a regular rhythm, limited calcification and stents, ≥ 5 second breath hold, and vessels requiring imaging ≥ 1.5 mm diameter (Gerber & Manning 2018).

- Coronary artery disease (CAD) stenosis ≥ 50% is considered clinically significant or obstructive CAD. CAD and ischemic heart disease (IHD) mean the same thing. Hemodynamically or functionally significant CAD means the degree of stenosis is severe enough to cause ischemia. This is discussed in more detail in the Additional Information section (Fihn 2012; Wolk 2013; Montalescot 2013; Gerber & Manning 2018; Tobis 2007).

- **Stable patients without known CAD** fall into 2 categories (Fihn 2012; Wolk 2013; Montalescot 2013):
  - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Part III in the Additional Information section).
  - **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant (≥ 50%) CAD

The Three Types of Chest Pain or Discomfort

- **Typical Angina (Definite)** is defined as including all 3 characteristics:
  1) Substernal chest pain or discomfort with characteristic quality and duration
  2) Provoked by exertion or emotional stress
  3) Relieved by rest and/or nitroglycerin

- **Atypical Angina (Probable)** has only 2 of the above characteristics

- **Nonanginal Chest Pain/Discomfort** has only 0 · 1 of the above characteristics
Once the type of chest pain has been established from the medical record, the Pretest Probability of significant CAD is estimated from the Diamond Forrester Table below, recognizing that additional coronary risk factors could increase pretest probability (Wolk 2013):

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Gender</th>
<th>Typical/Definite Angina Pectoris</th>
<th>Atypical/Probable Angina Pectoris</th>
<th>Nonanginal Chest Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>40–49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td>≥ 60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
</tbody>
</table>

- **Very low**: < 5% pretest probability of CAD, usually not requiring stress evaluation (Fihn 2012)
- **Low**: 5-10% pretest probability of CAD
- **Intermediate**: 10% - 90% pretest probability of CAD
- **High**: > 90% pretest probability of CAD (Fihn 2012)

**Indications for CCTA**
(Gerber & Manning 2018; Fihn 2012; Montalescot 2013; Wolk 2010; Taylor 2010)

- **Evaluation in suspected CAD** (Douglas 2015; Newby 2015; Nicol 2008; Fordyce 2016; Moss 2017):
  - Intermediate pretest probability patients who are not suitable for stress echo (see Additional Information section)
  - Low pretest probability patients who are not suitable for either exercise stress ECG (uninterpretable) or stress echo (see Additional Information section)
  - Appropriate exercise electrocardiogram (ECG) stress test with low Duke Score (≥ 5) and continued symptoms that are concerning for CAD, usually typical or atypical angina
  - Appropriate exercise ECG stress test with intermediate (negative 10 to +4) Duke Score.
  - Equivocal, borderline, discordant, or inconclusive prior stress imaging evaluation, including discordant exercise ECG and stress imaging
  - Repeat non-invasive coronary testing in patient with new or worse symptoms since prior normal stress imaging (Wolk 2013; Taylor 2010)
  - Newly diagnosed clinical systolic heart failure without known CAD or current CAD evaluation, in the presence of angina or an anginal equivalent (Patel 2012; Patel 2013; Wolk 2013; Taylor 2010)
  - Reduced left ventricular ejection fraction (<40% EF), when invasive coronary arteriography is not the preferred method of evaluation
  - An alternative to coronary angiography before valve surgery or transcatheter intervention in patients with severe valvular heart disease (VHD) and low or
intermediate pretest probability of CAD or in whom conventional coronary angiography is technically not feasible or associated with a high risk (Baumgartner 2017; Nishimura 2014)

- Unable to undergo otherwise appropriate non-invasive coronary evaluation with any of the following: exercise ECG, myocardial perfusion imaging (MPI), and stress echocardiography (SE) (Douglas 2015; Newby 2015; Nicol 2008; Fordyce 2016)
- To establish the etiology of chronic secondary mitral regurgitation (Nishimura 2014)
- Evaluation of coronary anomaly or aneurysm (e.g. post Kawasaki’s disease) when CMR is not available (Datta 2005; Newburger 2016; Newburger 2018; Grani 2017)
- For evaluation of coronary artery bypass grafts, to assess (Eisenberg 2017):
  - Patency and location, when invasive coronary arteriography was unable to acquire adequate images
  - Patency, if it might avoid invasive coronary arteriography
  - Coronary bypass graft location when reoperative cardiac or other chest surgery requires

## ADDITIONAL INFORMATION

**Unsuitability for Stress Echo**
(Askew 2018; Henzlova 2016)

### I. Poor Quality Echo Image
- Obesity with BMI over 40 or poor acoustic imaging window

### II. Inability to Exercise
- Physical infirmities precluding a reasonable ability to exercise for at least 3 full minutes of Bruce protocol
- The patient has limited functional capacity (< 4 METS) such as one of the following:
  i. Cannot take care of their activities of daily living (ADLs) or ambulate
  ii. Cannot walk 2 blocks on level ground
  iii. Cannot climb 1 flight of stairs
  iv. Cannot vacuum, dust, do dishes, sweep, or carry a small grocery bag
- Patients who cannot walk up a single flight of stairs at even a slow pace or even perform ADLs based upon documented limitations

### III. Comorbidity Related
- Prior cardiac surgery (coronary artery bypass graft or valvular), CHF with left ventricular ejection fraction ≤ 40%
- Severe chronic obstructive pulmonary disease (COPD) with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
- Poorly controlled hypertension, with systolic blood pressure (BP) > 180 or Diastolic BP > 120
• Medical instability or serious acute illness, where maximal exercise is not recommended or appropriate (e.g. acute myocarditis or pericarditis, active infective endocarditis, acute aortic dissection)
• Resting wall motion abnormalities that would make exercise stress echocardiography (SE) interpretation difficult, which includes left bundle branch block (LBBB)
• More than moderate valvular heart disease, when coronary data, not valvular hemodynamics, are required

IV. ECG Related Uninterpretable Wall Motion
• Pacemaker or implantable cardioverter defibrillator (ICD)
• Poorly controlled atrial fibrillation/ectopy
• Frequent premature ventricular contractions (PVCs)
• Ventricular pre-excitation (e.g. Wolff Parkinson White)
• Complete LBBB (SE doable, but more difficult to interpret)

V. Risk Related
• High pretest probability in suspected CAD
• Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs
• Patients with prior coronary revascularization
• Arrhythmia risk with exercise and provocation of arrhythmia not required for test
• Left ventricular ejection fraction ≤ 40%

Unsuitability for MPI
(Henzlova 2016; Chareonthaitawee 2018)

• Patient cannot be adequately positioned or imaged with MPI due to comorbidity, body habitus
• Intolerance to required coronary vasodilators, pulmonary or allergic, either documented or anticipated.
• Uncontrolled hypertension, systolic > 200 or diastolic > 110
• Dipyridamole within < 48 hours
• Relative unsuitability due to:
  o Hypotension or marked bradyarrhythmia
  o Interfering medications: Theophylline/aminophylline, caffeine, or theobromine within the past 12-24 hours
  o Severe aortic stenosis
  o Seizure disorder with potential for adenosine provocation

Coronary Artery Calcium Scoring
(Gerber & Kramer 2018)

Non-contrast coronary computed tomography (non-contrast coronary CT) and its older technological version, electron beam computed tomography (EBCT), provide quantitative coronary artery calcium scoring, which is appropriate for further evaluation of coronary risk in asymptomatic patients without known cardiovascular disease, who are at low to intermediate or intermediate global risk for coronary or
overall cardiovascular disease. Non-contrast coronary CT (computed tomography) and EBCT are supported by a separate CPT code and guideline document with references titled EBCT or Non-Contrast Coronary CT.

**Definitions of Coronary Artery Disease**  
(Fihn 2012; Montalescot 2013; Patel 2017; Mintz 2016; Tobis 2007)

9. Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and refers to cross sectional narrowing when intravascular ultrasound (IVUS) is the method of determination.

10. Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a risk stratification tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.

11. Stenoses ≥ 50% are considered obstructive coronary artery disease (also referred to as clinically significant), while stenoses ≤ 50% are considered nonobstructive coronary artery disease (Gerber & Manning 2018).

12. Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
   i. Suggested by percentage diameter stenosis ≥ 70% by angiography; borderline lesions are 40-70% (Fihn 2012; Tobis 2007)
   ii. For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross sectional area on IVUS < 6 square mm (Fihn 2012; Mintz 2016)
   iii. FFR (fractional flow reserve) ≤ 0.80 for a major vessel (Mintz 2016)
   iv. Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree

13. A major vessel would be a coronary vessel that would typically be substantial enough for revascularization, if it were indicated. Lesser forms of coronary artery disease would be labeled as “limited” and not major (i.e. a 50% lesion in a tiny septal or modest size mid PDA would be limited obstructive coronary artery disease).

14. Microvascular ischemic coronary artery disease, as might be described by a normal FFR (fractional flow reserve) above 0.80 with a reduced CFR (coronary flow reserve less than 2.5), has not otherwise been addressed in this manuscript, because it is very rarely an issue in compliance determinations. However, it would constitute a form of ischemic heart disease.

15. FFR is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow. Newer iterations such as iFR (instantaneous wave free ratio) might supersede basic FFR technology in the near future.

16. New technology is evolving that estimates FFR from CCTA images. This is covered under the separate NIA Guideline for FFR-CT.

**Anginal Equivalent**  
(Moya 2009; Shen 2017; Fihn 2012)

Development of an anginal equivalent (e.g. shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g. dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into
the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ACS</td>
<td>Acute coronary syndrome</td>
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<tr>
<td>CABG</td>
<td>Coronary artery bypass grafting surgery</td>
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<tr>
<td>CAD</td>
<td>Coronary artery disease</td>
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<td>CCS</td>
<td>Coronary calcium score</td>
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<tr>
<td>CCTA</td>
<td>Coronary computed tomography angiography</td>
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<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<td>MI</td>
<td>Myocardial infarction</td>
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<tr>
<td>MPI</td>
<td>Myocardial Perfusion Imaging</td>
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<tr>
<td>PCI</td>
<td>Percutaneous coronary intervention</td>
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<tr>
<td>SE</td>
<td>Stress echocardiography</td>
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<tr>
<td>TTE</td>
<td>Transthoracic echocardiography</td>
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<tr>
<td>TAVR</td>
<td>Transcatheter aortic valve replacement</td>
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REFERENCES


Gerber TC, Manning WJ. Summary of indications for CCTA. Up-to-Date. Waltham MA; March, 2018. Available at:


CPT Codes: 75635

IMPORTANT NOTE: Abd/Pelvis CTA & Lower Extremity CTA Runoff Requests: Only one authorization request is required, using CPT Code 75635 Abdominal Arteries CTA. This study provides for imaging of the abdomen, pelvis and both legs and is the noninvasive equivalent to an “aortogram and run-off”. The CPT code description is CTA aorto-iliofemoral runoff; abdominal aorta and bilateral ilio-femoral lower extremity runoff.

INTRODUCTION
Computed tomography angiography (CTA) provides a cost-effective and accurate imaging assessment in patients with suspected thoracic aortic aneurysms, aortic dissections, or peripheral arterial disease. Early detection and treatment of a thoracic aortic aneurysm is important as it may rupture or dissect resulting in life-threatening bleeding. High resolution CTA may be used in the diagnosis and follow-up of patients with aortic dissection and lower extremity peripheral arterial disease (PAD).

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ABDOMINAL ARTERIES CTA:
For evaluation of known or suspected abdominal vascular disease (Conte, 2015):
- For known or suspected peripheral arterial disease based on prior imaging or noninvasive ultrasound.
- Significant ischemia that could be related to the presence of an ulcer, gangrene or significant claudication.

Pre-operative evaluation:
- Evaluation of interventional vascular procedures for luminal patency versus restenosis due to conditions such as atherosclerosis, thromboembolism, and intimal hyperplasia.

Post-operative or post-procedural evaluation:
- Evaluation of post-operative complications, e.g. pseudoaneurysms, related to surgical bypass grafts, vascular stents and stent-grafts.
- Follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

ADDITIONAL INFORMATION RELATED TO ABDOMINAL ARTERIES CTA:
Abd/Pelvis CTA & Lower Extremity CTA Runoff Requests: Only one authorization request is required, using CPT Code 75635 Abdominal Arteries CTA. This study provides for imaging of the abdomen, pelvis and both legs. The CPT code description is CTA aorto-iliofemoral runoff; abdominal aorta and bilateral ilio-femoral lower extremity runoff.
Thoracic Aortic Aneurysm – CTA is useful in diagnosing thoracic aortic aneurysms, determining their extent, and predicting best treatment. The Dual Source 64 slice CTA allows for removal of many artifacts on the images, thus improving image quality. Prior to initiating thoracic endovascular aneurysm repair for a ruptured aneurysm, CTA may assess the access route for device delivery.

Thoracic Aortic Dissection – Thoracic aortic dissection is difficult to diagnose as many other conditions share similar symptoms with dissection. It is the most common aortic life-threatening emergency and must be diagnosed and treated quickly. With a small amount of contrast medium, the 64-slice CT scanner can accurately locate aortic dissection and other vascular problems within a short period of time.

Suspected Peripheral Arterial Disease – CTA is an excellent tool to diagnose lower extremity peripheral arterial disease (PAD). Benefits include the fast scanning time and accurate detection of occlusions and stenoses. According to the Society for Vascular Surgery guidelines (Conte, 2015) “Measurement of the ankle-brachial index (ABI) is the primary method for establishing the diagnosis of PAD. An ABI of $\leq 0.90$ has been demonstrated to have high sensitivity and specificity for the identification of PAD compared with the gold standard of invasive arteriography. In symptomatic patients in whom revascularization treatment is being considered, we recommend anatomic imaging studies, such as arterial duplex ultrasound, CTA, MRA, and contrast arteriography”. This later statement is accompanied by a “B” (moderate) rating for the accompanying evidence (“A’ = high, “C’ = low).
REFERENCES


CPT Codes: 76376, 76377

IMPORTANT NOTE:

These procedures should always be approved.

NIA does not review these services for medical necessity.
CPT Codes: 76390

INTRODUCTION:

Magnetic resonance spectroscopy (MRS) is a noninvasive imaging technique that determines the concentration of brain metabolites such as N-acetylaspartate, choline, creatine, and lactate within the body tissue examined. Radiofrequency waves are translated into biochemical composition of the scanned tissue; the resulting metabolic profile is useful in identifying brain tumors, e.g., differentiating radiation necrosis from recurring brain tumor.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR BRAIN MRS (ACR, 2017; Barajas, 2009; Debnam, 2007; Lee, 2004; Lin, 2005; Smith, 2009; Sundgren, 2009; Vezina, 2008):

- For the evaluation of a recurrent or residual brain tumor from post-treatment changes e.g., radiation necrosis.
- To assess progress after surgery. A documented medical reason must clearly explain the medical necessity for the post-operative follow up.

ADDITIONAL INFORMATION RELATED TO BRAIN MRS:

Tumor Recurrence vs. Radiation Necrosis – Differentiation between recurrent brain tumors and treatment related injury, e.g., radiation necrosis, is difficult using conventional MRI. The typical appearance of radiation necrosis is similar to that of recurrent brain tumors. MRS allows a new, quantitative approach, measuring various brain metabolic markers, to help in the differentiation of recurrent tumors and radiation necrosis. This differentiation is important as additional radiation can benefit recurrent disease but can be detrimental to radiation necrosis. It may help in determining treatment options and in preventing unnecessary surgery. In addition, a tumor recurrence diagnosed by MRS allows the surgeon to begin treatment early instead of having to wait for symptoms of recurrence or biopsy confirmation.

Cystic lesions vs. cystic metastasis or cystic primary neoplasm – MRS may determine the concentration of certain brain metabolites whose ratios help in distinguishing abscesses from cystic necrotic tumors. For example, an increased choline signal or the ratio of certain brain metabolites may indicate the presence of cancerous cells. MRS may be used to diagnose the disease and to determine appropriate treatment.

MRS in other diseases (Oz, 2014) - A role for MRS has been suggested in the management of neurodegenerative disease, epilepsy, and stroke. However, to better define this role, it will be necessary to standardize the MRS methodology, as well as the collection, analysis, and interpretation of data so it can be consistently translated to the applicable clinical settings. Currently, these potential applications remain experimental.
REFERENCES


76497 - Unlisted CT

IMPORTANT NOTE:

The CPT code that has been selected is considered to be an “unlisted code”.

CPT Code 76498, Unlisted MRI, can be used in the context of radiation treatment planning.

For all other studies, another CPT code should be selected that describes the specific service being requested, otherwise this procedure cannot be approved.
76498 – Unlisted MRI

IMPORTANT NOTE:

The CPT code that has been selected is considered to be an “unlisted code”.

CPT Code 76498, Unlisted MRI, can be used in the context of radiation treatment planning.

For all other studies, another CPT code should be selected that describes the specific service being requested, otherwise this procedure cannot be approved.
CPT Codes:  CT: 77011, 77012, 77013, 77014  
        MRI: 77021, 77022

IMPORTANT NOTE:

The CPT codes describe the CT or MRI “guidance” component of a diagnostic procedure. Requests for these services should always be approved. This organization does not review these for medical necessity.
CPT Codes:
Unilateral without contrast 77046
Bilateral without contrast 77047
Unilateral without and with contrast 77048
Bilateral without and with contrast 77049

INTRODUCTION:

Magnetic resonance imaging (MRI) of the breast is a useful tool for the detection and characterization of breast disease, assessment of local extent of disease, evaluation of treatment response, and guidance for biopsy and localization (Panourgies et al, 2018). Breast MRI should be bilateral except for those with a history of mastectomy or when the MRI is being performed expressly to further evaluate or follow findings in one breast. MRI findings should be correlated with clinical history, physical examination, and the results of mammography and any other prior breast imaging.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR BREAST MRI:

Silicone Implants (ACR, 2018; Laurence et al, 2018):
- Confirmation of silicone gel-filled breast implant ruptures, when this diagnosis cannot be confirmed by mammography or breast ultrasound.
- For postoperative evaluation of silicone breast implant complications.

No History of Known Breast Cancer

For screening examination to detect breast cancer in any of the following situations:
- Inconclusive screening mammogram due to breast characteristics limiting the sensitivity of mammography (e.g., extremely or heterogeneously dense breasts, implants) (ACR, 2018; Fomvik et al, 2018).
- A Breast Cancer Risk Assessment (by the Gail, or modified Gail risk or other validated breast cancer risk assessment models) that identifies the patient as having a lifetime risk of 20% or greater of developing breast cancer (Approve annually) (ACR, 2018; Marino et al, 2018).
- Two or more first degree relatives (parents, siblings, and children) have history of breast cancer.
- Patients with histories of extensive chest irradiation (usually as treatment for Hodgkin’s or other lymphoma before the age of thirty). Approve annually starting at age 30.
- Patients with known BRCA mutation. Approve annually starting at age 25.
- Patients not yet tested for BRCA gene, but with known BRCA mutation in first degree relative. Approve annually starting at age 25.

For evaluation of identified lesion, mass or abnormality in breast in any of the following situations:
- Two or more first degree relatives (parents, siblings, and children) have history of breast cancer.
- Evaluation of suspected breast cancer when other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy could not be performed (e.g. seen only in single view mammogram without ultrasound correlation). Includes patients with suspicious nipple discharge (Geiss, 2017; Yader et al, 2018).
• Inconclusive screening mammogram due to breast characteristics limiting the sensitivity of mammography (e.g., extremely or heterogeneously dense breasts, implants) (ACR, 2018).
• When the presence of a palpable lesion is questionable (does not meet the criteria for biopsy by clinical exam) and remains indeterminate on mammography and ultrasound (ASBrS, 2017).
• For evaluation of axillary node metastasis or adenocarcinoma with normal physical examination and normal breast mammogram (ASBrS, 2017; Zhou, 2018).
• Patients diagnosed with biopsy-proven lobular neoplasia or ADH (atypical ductal hyperplasia) (Hartman, 2015; McLaughlin, 2015).
• Personal history of or first-degree relative with Li-Fraumeni syndrome (TP53 mutation), Cowden syndrome (PTEN) or Bannayan-Riley-Ruvalcaba syndrome (BRRS).

History of Known Breast Cancer

For screening examination to detect breast cancer in any of the following situations:
• Patients with a known history of Breast Cancer: Approve initial staging, with treatment [within three (3) months], and yearly surveillance for detection of recurrence or a new cancer (Park et al, 2018).

For evaluation of identified lesion, mass or abnormality in breast in any of the following situations:
• For evaluation of breast lesion, identifying whether single or multi-focal, in patient with newly diagnosed breast cancer (NCCN, 2018).
• For evaluation of suspicious mass, lesion, distortion or abnormality of breast in patient with history of breast cancer.

Pre-operative:
• For preoperative evaluation for known breast cancer when surgery planned within thirty (30) days (Susnik et al, 2018; Wong, 2018).

Post-operative/procedural evaluation:
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested (ACR, 2018).

================================================================

ADDITIONAL INFORMATION RELATED TO BREAST MRI:

MRI as First-Line Screening Modality – Only recently has the use of MRI for screening been encouraged. It is now used for screening in patients with increased risk for breast cancer due to certain factors, e.g., history of mediastinal irradiation for Hodgkin disease, mutation in a breast cancer susceptibility gene, and familial clustering of breast cancer. Certain mutations, including BRCA1 and BRCA2 genes confer significantly elevated risk of breast cancer. Even when a patient tests negative for BRCA mutations, this patient may still be at risk for breast cancer if the patient has first degree relatives with a history of breast cancer or positive BRCA mutations.

MRI in Patient with Normal Physical Examination and Normal Mammogram but with Clinical Signs of Breast Cancer – Metastatic spread in the axillary lymph nodes suggest the breast as the site of the primary cancer even when the results of a mammogram are normal. MRI is useful in detecting primary breast malignancies in these cases. A negative MRI may also be used to prevent an unnecessary mastectomy.
**MRI during or after Neoadjuvant Chemotherapy** – Dynamic contrast enhanced MRI may be used to monitor response of a tumor to neoadjuvant chemotherapy used to shrink the tumor before surgery. This is very important in clinical decision making as alternative therapies may be selected based upon the results obtained from the MRI. It may also be used to depict residual disease after neoadjuvant chemotherapy. MRI-compatible localization tissue markers should be placed prior to neoadjuvant chemotherapy to evaluate the location of the tumor in the event of complete response (ACR, 2018).

**MRI and Breast Implants** – MRI may be used in patients with breast implants to evaluate breast implant integrity. It may also detect cancers arising behind an implant that may not be diagnosed with mammography.

**MRI and Invasive Lobular Carcinoma** – Invasive lobular carcinoma (ILC) is not the most common type of breast carcinoma but it is second to invasive ductal carcinoma. Because of its multicentricity nature, MRI is used in the evaluation of ILC and can measure the extent of the disease with high reliability.

**Breast pain:** NCCN Guidelines and the ASBrS do not recommend breast MRI for evaluation of breast pain (ASBrS, 2017).
REFERENCES


CPT Codes: 77078

INTRODUCTION:

Bone mineral density (BMD) measurement identifies patients with low bone density and increased fracture risk. Methods for measuring BMD are non-invasive, painless, and available on an outpatient basis. Dual energy x-ray absorptiometry (DXA), previously referred to as DEXA, is the most commonly used method of evaluating BMD and is the only BMD technology for which World Health Organization (WHO) criteria for the diagnosis of osteoporosis can be used. Patients who have a BMD that is 2.5 standard deviations below that of a “young normal” adult (T-score at or below -2.5) are deemed to have osteoporosis. Quantitative computed tomography (QCT) has not been validated for WHO criteria but can identify patients with low BMD compared to the QCT reference database and it can be used to identify patients who are at risk of fracture.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CT BONE DENSITY STUDY:

For first time baseline screening in patient with suspected osteoporosis or osteopenia when DEXA scanning is not available or for patients >50 years of age with advanced degenerative changes of the spine that may limit the efficacy of DEXA scans (ACR 2016, 2017; Cosman, 2014; ISCD, 2015):

- Asymptomatic women 65 years of age or older and men 70 and older
- Women aged 50-64 years old with a 9.3% or greater 10-year fracture risk based on the WHO (World Health Organization Fracture Risk Assessment (FRAX) tool (USPSTF, 2011)*.
- Individuals with at least ONE of the following risk factors:
  - Currently on medications associated with development of osteoporosis (e.g., steroids or glucocorticosteroids, anticonvulsants, heparin, lithium, estrogen receptor modulators (SERMs), calcitonin, or bisphosphonates, etc.)
  - Post menopausal women younger than 65 and a low body weight (BMI <21 kg/m²)
  - Estrogen deficiency and low calcium intake or alcoholism.
  - In postmenopausal women and men age 50 and older who have had an adult age fracture or individuals of any age who develop 1 or more insufficiency fractures.
  - Evidence of osteoporosis or osteopenia from x-ray or ultrasound.
- Back pain associated with loss of vertebral body height per x-ray without significant traumatic event
- Loss of body height (>4 cm (>1.5 inches)) (ACR, 2017).
- Multiple fractures including compression fractures of the spine.
- Conditions that cause or contribute to osteoporosis and fractures (e.g. malabsorption syndromes, inflammatory bowel disease and other gastrointestinal conditions, metabolic bone disease, hyperparathyroidism, hypogonadism, thyroid hormone therapy or hyperthyroidism, chemotherapy, long term heparin therapy, rheumatologic and autoimmune diseases, renal failure, hematologic disorders, etc.).
- Amenorrhea for greater than 1 year before the age of 42
For screening of an individual with known osteoporosis or osteopenia:

- Has not had a bone mineral density study within the past 23 months.
- Had bone density within past 23 months AND meets any one of the above risk factor criteria. (More frequent BMD testing may be warranted in certain clinical situations and should be determined on a case by case basis).
- After initiation of medical therapy for osteoporosis**: 1 to 2 years after initiating therapy for osteoporosis and every two years subsequent to the initial study (More frequent BMD testing may be warranted in certain clinical situations and should be determined on a case by case basis) (Cosman, 2014).

**ADDITIONAL INFORMATION RELATED TO CT BONE DENSITOMETRY:**

DXA – Dual energy x-ray absorptiometry (DXA) is most often used to measure bone mineral density due to its low radiation exposure, low precision error, and capacity to measure multiple skeletal sites (spine, hip, or total body).

Axial DXA – This provides the “gold standard”. Axial DXA predicts fracture risk at the site being measured.

Peripheral DXA – This device measures BMD at peripheral sites, generally at the heel or wrist. It is relatively cheap and portable and is an option when there is limited access to axial DXA.

Fracture Risk Assessment*: The fracture risk assessment (FRAX) tool developed by the World Health Organization estimates the 10 year risk of having a fracture based on factors such as age, sex, body mass index (BMI), previous fractures, parental fracture history, glucocorticoid use, Rheumatoid arthritis, and conditions predisposing to secondary osteoporosis (insulin dependent diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (<45 years), chronic malnutrition, or malabsorption and chronic liver disease) and tobacco and alcohol use. Based on FRAX, a 65 year old women without any additional conditions increasing fracture risk has a 9.3% 10-year risk of developing a fracture. This value is therefore used as the risk level cut-off recommending screening in patients younger than 65. The FRAX tool is available on line at https://www.sheffield.ac.uk/FRAX/tool.jsp.

Ethnicity and Screening: Due to the potential negative consequences of fractures and the lack of an optimal age at which to screen populations of different ethnicity the USPSTF now recommends screening of all women aged 65 and older regardless of race and ethnicity.

Follow up Imaging**: Follow up imaging is performed on patients at risk of developing osteoporosis or to evaluate the outcome of osteoporosis treatment. Follow up imaging is generally performed at 1-2 years after initiation of therapy for osteoporosis and subsequently every 2 years unless clinical circumstances prompt earlier imaging. In patients at increased risk for developing osteoporosis, imaging may be performed more frequently, particularly with patients with certain medical conditions and taking medications predisposing to fracture. The later population includes those undergoing long term therapy with common medications such as heparin or glucocorticoids.

Bone mineral density (BMD) testing should be performed:

- In women age 65 and older and men age 70 and older
- In postmenopausal women and men above age 50–69, based on risk factor profile
• In postmenopausal women and men age 50 and older who have had an adult age fracture, to diagnose and determine degree of osteoporosis
• At dual-energy X-ray absorptiometry (DXA) facilities using accepted quality assurance measures

Variant 1: Asymptomatic BMD Screening or Individuals with Established or Clinically Suspected Low BMD

• All women age 65 years and older and men age 70 years and older (asymptomatic screening)
• Women younger than age 65 years who have additional risk for osteoporosis, based on medical history and other findings. Additional risk factors for osteoporosis include:
  ➢ Estrogen deficiency
  ➢ A history of maternal hip fracture that occurred after the age of 50 years
  ➢ Low body mass (<127 lb or 57.6 kg)
  ➢ History of amenorrhea (>1 year before age 42 years)
• Women younger than age 65 years or men younger than age 70 years who have additional risk factors, including:
  ➢ Current use of cigarettes
  ➢ Loss of height, thoracic kyphosis
• Individuals of any age with bone mass osteopenia or fragility fractures on imaging studies such as radiographs, CT, or MRI
• Individuals age 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma, excluding pathologic fractures
• Individuals of any age who develop 1 or more insufficiency fractures
• Individuals being considered for pharmacologic therapy for osteoporosis
• Individuals being monitored to:
  ➢ Assess the effectiveness of osteoporosis drug therapy
  ➢ Follow up medical conditions associated with abnormal BMD
REFERENCES


Fracture Risk Assessment Tool (FRAX). https://www.sheffield.ac.uk/FRAX/tool.jsp


**CPT Codes:** 78205, 78206

**INTRODUCTION:**

Single-photon emission computed tomography (SPECT) is a nuclear medicine imaging technique based on the use of computed tomography to localize data from gamma ray emitting injected radiopharmaceuticals to specific anatomical locations within the patient. The resulting 3D images can be reconstructed in multiple planes. As a general rule, the detection efficiency and spatial resolution improves as the number of detecting cameras comprising the imaging system increases. Radiopharmaceuticals used vary based on the clinical indication. The technique is applied in brain, cardiac, pulmonary, abdominal, endocrine and musculoskeletal imaging.

Due to the improved anatomical detail afforded by CT, MRI and Ultrasound, these techniques have largely replaced radionuclide liver and spleen imaging. Liver and spleen Single-Photon Emission Computed Tomography (SPECT) imaging, depending on the indication, can be undertaken using either the IV injection of sulfur colloid or red blood cells labeled with Tc99M. Sulfur colloid images are created by taking advantage of the reticuloendothelial cells ability to phagocytize the agent. Indications using this agent include the detection of hepatosplenomegaly, hepatocellular disease, and certain focal hepatic lesions. Red blood cell scanning is limited to the evaluation of liver hemangiomas. The ability to create 3D multiplanar images with the SPECT technique greatly improves the diagnostic capability over traditional planar imaging.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

**INDICATIONS FOR A LIVER/SPLEEN SPECT SCAN:**

Complex clinical scenarios involving the following indications wherein routine dynamic planar imaging and other imaging (US, CT (A), MRI (A) or angiography) is insufficient alone (ACR, 2017):

- Evaluation of hepatic artery catheter placement. (For evaluation of the hepatosplenic vascular distribution and or aberrant flow pattern prior to chemotherapeutic infusion) when CT angiography cannot be performed or is indeterminate (Morsbach, 2014).
- Detection of accessory splenic tissue or asplenia and abdominal CT and/or MRI are indeterminate or contraindicated.
- Evaluation of suspected hepatic hemangioma or focal nodular hyperplasia and abdominal CT and MRI are contraindicated.
- Evaluation of patients with suspected liver or spleen rupture or hematoma and Abdominal CT and MRI are contraindicated.
- Evaluation of size, shape, and position of liver and spleen and Abdominal CT and MRI are contraindicated.
- Detection of space-occupying lesions: abscesses, cysts, and primary tumors and Abdominal CT and MRI are contraindicated.
- Evaluation of hepatic primary or metastatic tumors (pre and post-therapy) and Abdominal CT and MRI are contraindicated.
A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

**ADDITIONAL INFORMATION RELATED TO A LIVER SPECT SCAN:**

**SPECT Scan** - Single photon emission computed tomography (SPECT) is a nuclear medicine tomographic imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera to acquire multiple 2-D images (also called projections), from multiple angles.

**Hepatobiliary imaging or HIDA (hepatobiliary iminodiacetic acid) scan** - Unlike liver spleen scans, HIDA is an imaging procedure utilizing the IV administration of Tc99M labeled iminodiacetic acid which is excreted by hepatocytes like bile. This technique utilizes a series of standard planar images over time to determine the progression of the radionuclide through the biliary system. HIDA scanning is used primarily to evaluate cystic duct obstruction (cholecystitis), common bile duct obstruction, congenital biliary system anomalies, and bile leaks, rather than hepatic parenchymal abnormalities for which liver spleen scanning and cross sectional imaging (CT, MRI, US) is utilized.
REFERENCES


CPT Codes: 78320

INTRODUCTION:

Single-photon emission computed tomography (SPECT) is a nuclear medicine imaging technique based on the use of computed tomography to localize data from gamma ray emitting injected radiopharmaceuticals to specific anatomical locations within the patient. The resulting 3D images can be reconstructed in multiple planes. As a general rule, the detection efficiency and spatial resolution improves as the number of detecting cameras comprising the imaging system increases. Radiopharmaceuticals used vary based on the clinical indication. The technique is applied in brain, cardiac, pulmonary, abdominal, endocrine, and musculoskeletal imaging.

Bone Single-Photon Emission Computed Tomography (SPECT) differs from traditional “planar” or 2D bone scan imaging (scintigraphy) through the use of computerized techniques and advanced imaging systems to help improve the localization of osseous pathology. The ability to manipulate the imaging data into distinct multiplanar slices improves the diagnostic capability and spatial resolution while using the same pharmaceutical as with traditional planar bone scan. Due to advances in cross sectional imaging, the technique currently has limited indications for detecting bone pathology. It is used in patients who cannot undergo MRI or CT imaging. The major utility of bone scanning is in defining the distribution of disease (metastasis or multifocal bone lesions) by imaging the entire skeleton. Furthermore, for many indications SPECT imaging is not routinely employed unless precise anatomical localization of pathology is required.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR A BONE/JOINT SPECT SCAN:

Complex clinical scenarios involving the following indications wherein routine dynamic planar imaging is insufficient alone (ACR, 2017; O’Sullivan, 2017; SNM, 2003; Donohoe/SNM, 2017).

- Evaluation of high risk patients with primary bone tumors or tumors that are known to metastasize frequently to bone and patient has any of the following tumors (such as breast, lung, prostate, thyroid or kidney) diagnosed by biopsy or other imaging study and patient has NOT had a previous nuclear bone scan within the past three (3) months.
- Detection of early osteomyelitis with documented history of having a plain x-ray AND an MRI of the area performed, unless MRI is contraindicated.
- Detection of early avascular necrosis, bone infarct, or bone graft viability and patient has had a plain x-ray or a CT of the suspicious area and MRI is contraindicated or inconclusive.
- Detection of stress fractures and other occult skeletal trauma and patient has localized pain in the suspected area. (If history of recent MRI of suspected area, those MRI results should be either positive or inconclusive to necessitate bone SPECT.)
- Resolution of questionable/inconclusive abnormal skeletal radiographs when MRI or CT is inconclusive or cannot be performed.
- Assess the distribution of osteoblastic activity before radionuclide therapy for bone pain (SNM, 2003).
• For evaluation of unexplained extremity pain when clinical criteria and other imaging (x-ray, MRI, Ultrasound or CT) evaluation is inconclusive (e.g. differentiating complex regional pain syndrome from other causes of pain) (Kwon, 2011; Shin, 2017).
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

ADDITIONAL INFORMATION RELATED TO BONE/JOINT SPECT SCAN:

**SPECT Scan** - Single photon emission computed tomography (SPECT) is a nuclear medicine tomographic imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera to acquire multiple 2-D images (also called projection), from multiple angles.

Nuclear medicine bone imaging is commonly performed with Technicium-99m-MDP (methylene diphosphonate) or less frequently to evaluate infection with Indium-111 labelled white blood cells. The technique for all indications of bone imaging has largely been replaced by MRI and CT. Ultrasound has also replaced nuclear medicine imaging as a quick, readily available and less expensive study to determine soft tissue sterile or infected fluid collections. When indicated, for patients with impaired renal function who cannot receive iodinated or gadolinium based contrast agents or undergo MRI for other reasons, SPECT imaging can improve the performance of conventional planar nuclear bone imaging. Although 18F labelled sodium fluoride (NaF) PET scanning is highly sensitive for detecting bone lesions, its routine use has not replaced conventional bone scanning due to the latter’s “effectiveness, widespread availability, low cost and favorable dosimetry” (O'Sullivan, 2015).

In the evaluation of Complex regional pain syndrome (CRPS), formerly reflex sympathetic dystrophy, three phase bone scintigraphy (flow, blood pool and delayed images) and MRI imaging sensitivities reported in the medical literature, ranges widely (Shin, 2017). In general, scintigraphy is more specific than MRI. SPECT imaging however is not routinely used for this indication.

The Society of Nuclear Medicine recently released updated guidelines for bone scanning in patients with breast and prostate cancer (Donohoe, 2017). For prostate cancer “Bone scintigraphy is usually not appropriate for initial staging in patients with a low risk of metastatic disease (PSA level, <10 ng/mL, Gleason score, < 6, and no other clinical signs or symptoms of disease)”. “Breast neoplastic disease discovered at an early stage is unlikely to metastasize to bone: therefore, unless there are signs or symptoms suggesting metastasis in early-stage disease, bone imaging is not necessary.”
REFERENCES


CPT Codes: 77084

INTRODUCTION:

Magnetic Resonance Imaging (MRI) is currently used for the detection of metastatic disease in the bone marrow. Whole body MRI, using moving tables and special coils to survey the whole body, is used for screening to search for primary tumors and metastases. The unique soft-tissue contrast of MRI enables precise assessment of bone marrow infiltration and adjacent soft tissues allowing detection of alterations within the bone marrow earlier than with other imaging modalities. MRI results in a high detection rate for both focal and diffuse disease, mainly due to its high sensitivity in directly assessing the bone marrow components: fat and water bound protons.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR BONE MARROW MRI:

- For vertebral fractures with suspected bone metastasis.
- For the diagnosis, staging and follow-up of patients with multiple myeloma and related disorders (Dutoit, 2016).
- Suspected progression of smoldering multiple myeloma (SMM) to multiple myeloma (MM) or high risk SMM patients (IMWG, 2015; Caers, 2016).
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

ADDITIONAL INFORMATION RELATED TO BONE MARROW MRI:

**General Information** - MRI allows bone marrow components to be visualized and is the most sensitive technique for the detection of bone marrow pathologies. The soft-tissue contrast of MRI enables detection of alterations within the bone marrow before osseous destruction becomes apparent in CT. Whole-body MRI has been applied for bone marrow screening of metastasis, as well as for systemic primary bone malignancies such as multiple myeloma (MM). Sensitive detection is mandatory in order to estimate prognosis and to determine adequate therapy.

MRI findings are included as one of the International Myeloma Working Group (IMWG) diagnostic criteria of active myeloma (Dutoit, 2016). Although MRI is not the only imaging tool for diagnosis, when “more than one focal lesion on MRI that is at least 5mm or greater in size” in addition to >10% clonal bone marrow plasma cells the diagnosis of active myeloma can be made. For smoldering multiple myeloma (SMM), defined as asymptomatic patients with increased levels of M protein and increased bone marrow plasma cells, “The IMWG now recommends that one of PET-CT, [Low dose whole body CT] (LDWBCT), or MRI of the whole body or spine be done in all patients with suspected smoldering myeloma, with the exact imaging modality determined by availability and resources” (IMWG, 2015). The importance of imaging in the diagnosis of active myeloma is highlighted as “The IMWG consensus statement now recommends that SMM patients with more than one unequivocal focal lesion
(diameter > 5 mm) should be considered to have symptomatic myeloma that requires treatment” (Dutoit, 2016). Recent advances have allowed the identification of a subset of SMM patients with a greater than 80% risk of progression to MM in 2 years based on biomarkers (Caers, 2016).
REFERENCES


CPT Code: 78451, 78452, 78453, 78454, 78466, 78468, 78469, 78481, 78483, 78499

INTRODUCTION

➢ Myocardial perfusion imaging (MPI) with either exercise stress or pharmacologic coronary vasodilation is the subject of this guideline.

➢ Since MPI and stress echocardiography (SE) provide similar information, with SE performed at lower cost and without radiation, this guideline requires diversion from MPI to SE when feasible (Askew 2018; Douglas 2011; Metz 2007; Einstein 2012; Fazel 2011; Fleischmann 1998; Garber 1999; Heijenbrok-Kal 2007; Hirshfeld 2018; Marwick 2003; Pellikka 2007; Schinkel 2003; Scott-Moncrieff 2011; Sicari 2008; Sicari 2017; Yao 2003; Zhang 2014).

➢ However, this diversion is limited due to practical issues and physician preferences that endorse MPI without diversion in any of the following cases (see details in Scenarios that support MPI over SE in the Additional Information section) (Henzlova 2016; Askew 2018; Wolk 2013):
  - Poor quality echo images
  - Inability to exercise
  - Specific comorbidities
  - Electrocardiography (ECG)-related wall motion abnormalities
  - Elevated coronary risk

➢ Coronary artery disease (CAD) stenosis ≥ 50% is considered clinically significant or obstructive CAD. CAD and ischemic heart disease (IHD) mean the same thing. Hemodynamically or functionally significant CAD means the degree of stenosis is severe enough to cause ischemia. This is discussed in more detail in the Additional Information section (Fihn 2012; Wolk 2013; Montalescot 2013; Gerber 2018; Tobis 2007).

➢ Stable patients without known CAD fall into 2 categories (Fihn 2012; Wolk 2013; Montalescot 2013):
  - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Part III in the Additional Information section).
  - **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant (≥ 50%) CAD (below):

  *The 3 Types of Chest Pain or Discomfort*

  - **Typical Angina (Definite)** is defined as including all 3 characteristics:
    1) Substernal chest pain or discomfort with characteristic quality and duration
    2) Provoked by exertion or emotional stress
    3) Relieved by rest and/or nitroglycerine
• **Atypical Angina (Probable)** has only 2 of the above characteristics

• **Nonanginal Chest Pain/Discomfort** has only 0-1 of the above characteristics

• Once the type of chest pain has been established from the medical record, the Pretest Probability of obstructive CAD is estimated from the **Diamond Forrester Table** below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability (Wolk 2013; Fihn 2012):

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Gender</th>
<th>Typical/Definite Angina Pectoris</th>
<th>Atypical/Probable Angina Pectoris</th>
<th>Nonanginal Chest Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;=39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>40–49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>&gt;=60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
</tbody>
</table>

- **Very low**: < 5% pretest probability of CAD, usually not requiring stress evaluation
- **Low**: 5-10% pretest probability of CAD
- **Intermediate**: 10% - 90% pretest probability of CAD
- **High**: > 90% pretest probability of CAD
  (Fihn 2012)

**INDICATIONS for MPI**
(Fihn 2012; Wolk 2013; Montalescot 2013; Hendel 2009)

**Suspected CAD**
(Without known history of CAD)

1. **Symptomatic patients without known CAD**

- Low pretest probability who are unable to exercise
- Intermediate pretest probability
- High pretest probability (SE diversion not required) (Hachamovitch 2004)
- Repeat testing in patient with recurrent symptomatic presentation and negative result over 2 years ago
- Repeat testing in patient with new or worse symptoms and negative result at least one year ago

2. **Asymptomatic patients without known CAD:**
- Previously unevaluated ECG evidence of possible myocardial ischemia such as substantial ischemic ST segment or T wave abnormalities (SE diversion not required if wall motion abnormality present)
- Previously unevaluated pathologic Q waves or wall motion abnormality (evidence of prior myocardial infarction) (SE diversion not required)
- Unevaluated complete left bundle branch block (SE diversion not required)
- Following radiation therapy to the anterior or left chest, at 5 years post inception of radiation and every 5 years thereafter (Lancellotti 2013)

3. Incomplete or inconclusive CAD evaluation, within the past 2 years without known CAD
- Exercise stress ECG with low risk Duke treadmill score, but patient’s current symptoms indicate an intermediate or high pretest probability, which should include stress imaging (diversion not required for high pretest probability)
- Exercise stress ECG with intermediate Duke treadmill score
- Inconclusive/borderline coronary computed tomography angiography (CCTA) (e.g. 40-70% lesions)
- An indeterminate (equivocal, borderline, or discordant) evaluation by prior stress imaging (SE or CMR) within the past 2 years, for whom a noninvasive approach is preferable to proceeding to invasive coronary arteriography (e.g. unclear symptoms, ECG and imaging discordant, etc., but patient has severe contrast allergy, CKD, etc.)

**Known Major Vessel CAD**
(SE diversion not required due to increased risk in this category)  
(Patel 2017)

- Validated concern for a previous acute coronary syndrome without subsequent invasive or non-invasive coronary evaluation
- Follow up MPI at 2 year intervals is approvable, if it will affect consideration of coronary revascularization (initial or additional), in patients with one of the following:
  - History of silent ischemia with severe unrevascularized CAD, and revascularization could be feasible (Deedwania 2018)
  - History of severe unrevascularized major multivessel CAD, and revascularization could be feasible
  - Ejection fraction <= 40% with severe unrevascularized CAD, and revascularization could be feasible
- Ischemia assessment following inconclusive findings of invasive coronary arteriography or CCTA, for the purpose of assessing extent of ischemia and need for additional medical, interventional, or surgical therapy
- Resting MPI, is appropriate for patients with reduced LVEF ≤50% requiring myocardial viability assessment to assist with decisions regarding coronary revascularization (Patel 2013; Yancy 2013)
- New or worsening symptoms of ischemia in the absence of an acute coronary syndrome, unless the most current stress imaging study would warrant invasive coronary arteriography instead (e.g. history of high risk stress test without subsequent invasive
coronary arteriography might warrant invasive coronary angiography) (Patel 2012)

- De novo HF, who have known CAD, even without angina, unless the patient is not eligible for revascularization of any kind, or unless invasive coronary arteriography is immediately planned (Yancy 2013)

**Special Diagnostic Conditions Requiring Coronary Evaluation**

- Newly diagnosed systolic or diastolic heart failure, especially with symptoms or signs of ischemia AND without invasive coronary angiography immediately planned (SE diversion not required) (Yancy 2013; Patel 2013; Fihn 2012)
- Newly found wall motion abnormality (SE diversion not required) (Colucci 2018)
- Ventricular arrhythmias (SE diversion not required.)
  - Sustained ventricular tachycardia (VT) >100 bpm, ventricular fibrillation (VF), or exercise induced VT, when invasive coronary arteriography is not the initially required test (Al-Khatib 2018, in press)
  - Nonsustained VT, multiple episodes, each ≥ 3 beats at ≥100 bpm, without known cause or associated cardiac pathology, when an exercise ECG has shown an intermediate risk Duke Score or an exercise ECG could not be performed (Zimetbaum 2018)
  - Frequent PVCs ≥ 30/hour, or any PVC on a 12 lead ECG, without known cause or associated cardiac pathology, when an exercise ECG has shown an intermediate risk Duke Score OR an exercise ECG is not feasible due to inability to exercise or due to an uninterpretable ECG (Cha 2012; Manolis 2018; Al-Khatib 2017)
- Prior to Class IC antiarrhythmic drug initiation in intermediate and high global risk patients (SE diversion not required) (see global risk calculators in Additional Information section) (Kumar 2018)
- Assessment of hemodynamic significance of one of the following documented conditions (SE diversion not required) (Anagnostopoulos 2004):
  - Anomalous coronary arteries (Grani 2017)
  - Muscle bridging of coronary artery (perform with exercise stress) (Sorajja 2018)
  - Coronary aneurysms in Kawasaki’s disease (Newburger 2018)

**Prior to Elective Noncardiac Surgery**
(Fleischer 2014; Patel 2015)

- Patients who have no other indication for a non-invasive coronary evaluation, but are referred for preoperative cardiac evaluation, are eligible for MPI, based upon cardiac risk ≥ 1%, if all 4 criteria are met:
  - Surgery is supra-inguinal vascular, intrathoracic, or intra-abdominal.
  - The patient has at least one of the additional cardiac complication risk factors:
    - History of stroke or TIA
    - History of congestive heart failure or ejection fraction <=35%
    - Insulin-requiring diabetes mellitus
- Creatinine ≥ 2.0 mg/dl

**AND**

- The patient has limited functional capacity (< 4 METS), such as one of the following:
  - Cannot take care of their activities of daily living (ADLs) or ambulate
  - Cannot walk 2 blocks on level ground
  - Cannot climb 1 flight of stairs
  - Cannot vacuum, dust, do dishes, sweep, or carry small grocery bag

**AND**

- There has been no non-invasive coronary testing within one year, and the result of such a test would be likely to substantially alter therapy and/or preclude proceeding with the intended surgery.

- Planning for solid organ (mainly kidney or liver) transplantation is an indication for preoperative MPI, if there has not been a conclusive stress evaluation within the past year and one of the following: (SE diversion not required) (Lentine 2012).

  - The patient has limited functional capacity (< 4 METS), such as one of the following:
    - Cannot take care of their ADLs or ambulate
    - Cannot walk 2 blocks on level ground
    - Cannot climb 1 flight of stairs
    - Cannot vacuum, dust, do dishes, sweep, or carry small grocery bag
  
  (Wolk 2013)

**OR**

- In a patient with ≥ 3 of the following:
  - Age > 60
  - Smoking
  - Hypertension
  - Dyslipidemia
  - Left ventricular hypertrophy
  - > 1 year on dialysis (for renal transplant patients)
  - Diabetes mellitus
  - Prior cardiovascular disease
  
  (Lentine 2012)

- When the above risk calculators prove inadequate, and cardiac risk could be ≥1%, the American College of Surgeons NSQIP cardiac risk calculator can be used as a less validated alternative, available at [http://www.surgicalriskcalculator.com/miocardiocarearrest](http://www.surgicalriskcalculator.com/miocardiocarearrest), with an application download required.

**Post Cardiac Transplantation**

(Gustafsson 2016)
During the first five years post cardiac transplantation, patients with glomerular filtration rates less than 40 mL/min/1.73 BSA, or who otherwise should not undergo annual invasive coronary arteriography.

After the first five years post cardiac transplantation:

- Patients considered at low risk for transplant vasculopathy (i.e. with normal invasive coronary arteriography)
- Patients with transplant coronary vasculopathy, if the risk of annual invasive coronary arteriography is not acceptable (e.g. high risk of contrast nephropathy).

**ADDITIONAL INFORMATION**

(Fihn 2012; Wolk 2013; Montalescot 2013)

**Scenarios that support MPI over SE**

(Henzlova 2016; Askew 2018)

VI. Poor Quality Echo Image
- Obesity with body mass index (BMI) over 40 or poor acoustic imaging window

VII. Inability to Exercise
- Physical infirmities precluding a reasonable ability to exercise for at least 3 full minutes of Bruce protocol
- The patient has limited functional capacity (< 4 METS) such as one of the following:
  i. Cannot take care of their ADLs or ambulate
  ii. Cannot walk 2 blocks on level ground
  iii. Cannot climb 1 flight of stairs
  iv. Cannot vacuum, dust, do dishes, sweep, or carry small grocery bag
- Patients who cannot walk up a single flight of stairs at even a slow pace or even perform ADLs based upon documented limitations

VIII. Comorbidity Related
- Prior cardiac surgery (coronary artery bypass graft or valvular), CHF with left ventricular ejection fraction ≤ 40%
- Severe chronic obstructive pulmonary disease (COPD) with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
- Poorly controlled hypertension, with systolic BP > 180 or diastolic BP > 120
- Medical instability or serious acute illness, where maximal exercise is not recommended or appropriate (e.g. acute myocarditis or pericarditis, active infective endocarditis, acute aortic dissection)
- Resting wall motion abnormalities that would make exercise SE interpretation difficult, which includes left bundle branch block
- More than moderate valvular heart disease, when coronary data, not valvular hemodynamics, are required

IX. ECG Related Uninterpretable Wall Motion
• Pacemaker or ICD
• Poorly controlled atrial fibrillation/ectopy
• Frequent PVCs
• Ventricular pre-excitation (e.g. Wolff Parkinson White)
• Complete LBBB (SE doable, but more difficult to interpret)

X. Risk Related

• High pretest probability in suspected CAD
• Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs
• Patients with prior coronary revascularization
• Arrhythmia risk with exercise and provocation of arrhythmia not required for test
• LVEF ≤ 40%

**Unsuitability for MPI**
(Henzlova 2016; Chareonthaitawee 2018)

- Patient cannot be adequately positioned or imaged with MPI due to comorbidity, body habitus
- Intolerance to required coronary vasodilators, pulmonary or allergic, either documented or anticipated.
- Uncontrolled hypertension, systolic > 200 or diastolic > 110
- Dipyridamole within < 48 hours
- Relative unsuitability due to:
  - Hypotension or marked bradyarrhythmia
  - Interfering medications: Theophylline/aminophylline, caffeine, or theobromine within the past 12-24 hours
  - Severe aortic stenosis
  - Seizure disorder with potential for adenosine provocation

**ECG Stress Test Alone versus Stress Testing with Imaging**

Prominent scenarios suitable for an ECG stress test WITHOUT imaging (i.e. exercise treadmill ECG test) are inferred from the guidelines presented above, often (but not always) requiring that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate AND has an interpretable ECG for ischemia during exercise (Wolk 2013):

- The (symptomatic) low pretest probability patient who is able to exercise and has an interpretable ECG
- The (asymptomatic) high global risk patient who is able to exercise and has an interpretable ECG
  - The patient who is under evaluation for exercise induced arrhythmia (or long QT interval evaluation when the resting QTc is normal), and coronary artery disease is not suspected (Al-Khatib 2017)
- The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription.

**Duke Exercise ECG Treadmill Score** calculates risk from ECG treadmill alone:
- The equation for calculating the Duke treadmill score (DTS) is: DTS = exercise time in minutes \( \times \) (5 x ST deviation in mm or 0.1 mV increments) \( \times \) (4 x exercise angina score), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.
The score typically ranges from -25 to +15. These values correspond to low-risk (with a score of \( \geq +5 \)), intermediate risk (with scores ranging from -10 to +4), and high-risk (with a score of \( \leq -11 \)) categories.

An uninterpretable baseline ECG includes (Fihn 2012):
- Abnormalities of ST segment depression of 0.1 mV (1 mm with conventional calibration) or more
- Ischemic looking T wave inversions of at least 0.25 mV (2.5 mm with conventional calibration)
- ECG findings of probable or definite LVH, WPW, a ventricular paced rhythm, or left bundle branch block
- Digitalis use or hypokalemia
- Resting HR under 50 bpm on a beta blocker and an anticipated suboptimal workload (e.g. rate-pressure product less than 20-25K) could render inconclusive result
- Prior false positive stress ECG

**Global Risk of Cardiovascular Disease**

**Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to asymptomatic patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging (Douglas 2018). There are rare exemptions, such as patients requiring a I-C antiarrhythmic drug, who might require coronary risk stratification prior to initiation of the drug, when global risk is moderate or high.

- **CAD Risk—Low**
  10-year absolute coronary or cardiovascular risk less than 10%.
- **CAD Risk—Moderate**
  10-year absolute coronary or cardiovascular risk between 10% and 20%.
- **CAD Risk—High**
  10-year absolute coronary or cardiovascular risk of greater than 20%.

**Links to Global Cardiovascular Risk Calculators**

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

(D’Agostino 2008; Ridker 2007; McClelland 2015; Goff 2014)

<table>
<thead>
<tr>
<th>Risk Calculator</th>
<th>Link to Online Calculator</th>
</tr>
</thead>
</table>
Definitions of Coronary Artery Disease  
(Fihn 2012; Montalescot 2013; Patel 2017; Mintz 2016; Tobis 2007)

17. Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and refers to cross sectional narrowing when intravascular ultrasound (IVUS) is the method of determination.

18. Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a risk stratification tool. Its incorporation into Global Risk can be achieved by using the MESA risk calculator.

19. Stenoses > 50% are considered obstructive coronary artery disease (also referred to as clinically significant), while stenoses ≤ 50% are considered nonobstructive coronary artery disease. (Gerber 2018)

20. Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
   i. Suggested by percentage diameter stenosis ≥ 70% by angiography; borderline lesions are 40-70% (Fihn 2012; Tobis 2007)
   ii. For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross sectional area on IVUS ≤ 6 square mm (Fihn 2012; Mintz 2016)
   iii. FFR (fractional flow reserve) ≤ 0.80 for a major vessel (Mintz 2016)
   iv. Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree

21. A major vessel would be a coronary vessel that would typically be substantial enough for revascularization, if it were indicated. Lesser forms of coronary artery disease would be labeled as “limited” and not major (i.e. a 50% lesion in a tiny septal or modest size mid PDA would be limited obstructive coronary artery disease).

22. Microvascular ischemic coronary artery disease, as might be described by a normal FFR (fractional flow reserve) above 0.80 with a reduced CFR (coronary flow reserve less than 2.5), has not otherwise been addressed in this manuscript, because it is very rarely an issue in compliance determinations. However, it would constitute a form of ischemic heart disease.

23. FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow. Newer iterations such as iFR (instantaneous wave free ratio) might supersede basic FFR technology in the near future.

24. New technology is evolving that estimates FFR from CCTA images. This is covered under the separate NIA Guideline for FFR-CT.

Anginal Equivalent

Development of an anginal equivalent (e.g. shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g. dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung
exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent (Moya 2009; Shen 2017; Fihn 2012).

Peripheral Arterial Disease/Cerebrovascular Disease

Arterial vascular disease below the renal arteries is generally referred to as peripheral arterial disease, when the ankle brachial index is <0.9 or there is at least 50% vessel diameter narrowing on ultrasound or angiography (Hussain 2018).

Cerebrovascular disease generally refers to a history of transient ischemic attack (TIA) or stroke, or cerebrovascular lesions that put the patient at considerable risk for stroke (Caplan 2018).

There is no evidence to demonstrate that screening all patients with peripheral arterial disease for asymptomatic atherosclerosis in other arterial beds improves clinical outcome. Intensive treatment of risk factors through guideline directed medical therapy is the principal method for preventing adverse cardiovascular ischemic events secondary to atherosclerotic disease in other arterial beds (Gerhard-Herman 2016)

Abbreviations

AAD  Antiarrhythmic drug
ADLs  Activities of daily living
BSA  Body surface area in square meters
CAD  Coronary artery disease
ECG  Electrocardiogram
FFR  Fractional flow reserve
LBBB  Left bundle-branch block
LVEF  Left ventricular ejection fraction
LVH  Left ventricular hypertrophy
MI  Myocardial infarction
MET  Estimated metabolic equivalent of exercise
MPI  Myocardial perfusion imaging
PFT  Pulmonary function test
PVCs  Premature ventricular contractions
SE  Stress echocardiography
VT  Ventricular tachycardia
VF  Ventricular fibrillation
WPW  Wolf Parkinson White
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TOC

78459 – PET Scan, Heart (Cardiac)

CPT Codes: 78459, 78491, 78492, 0482T

INTRODUCTION
(Askew 2018; Bateman 2016; Chareonthaitawee 2018; Soman 2018; Fazel 2011)

➢ Cardiac positron emission tomography (PET) can characterize myocardial blood flow by perfusion scanning with either rubidium-82 (Rb-82) or nitrogen-13 (N-13) ammonia.

➢ PET can identify regions of myocardial viability with hibernating myocardium (viable, with poor flow and contractility) by imaging with fluorine18 (F-18) fluorodeoxyglucose (FDG or 18-FDG) for this purpose.

➢ PET stress testing provides prognostic data with respect to CAD, comparable to SE and myocardial perfusion imaging (MPI) (Parker 2012; Nandular 2008; Bengel 2009).

➢ PET poses a reduced radiation burden (2-3 mSv) compared to stress myocardial perfusion imaging (MPI) with technetium based tracers (7-24 mSv), the short half-life of PET tracers does not work well for exercise stress testing.

➢ PET can be use useful in the evaluation of inflammation: e.g. evaluation and therapy monitoring in patients with sarcoidosis, after documentation of cardiac involvement by echo or electrocardiography (ECG), when cardiac magnetic resonance (CMR) cannot be performed as a prior test, or subsequent to CMR if needed to help with an uncertain diagnosis (Vita 2018).

➢ With respect to coronary artery disease (CAD) evaluation:

- Coronary evaluation by cardiac PET should generally be used only when vasodilator MPI is otherwise indicated (e.g. inability to exercise, MPI with complete left bundle branch block) but not suitable due to an exemption below:

- Exemptions from the above diversion from coronary evaluation by PET to SE or MPI are for any one of the following:
  - Alternative perfusion imaging is not suitable due to body habitus or marked obesity (e.g. body mass index ≥ 40) interfering significantly with imaging
  - For assessment of suspected significant hibernating myocardium in the presence of known severe major vessel CAD, when EF is below 40%, in order to determine a patient’s potential benefit from coronary revascularization (Patel 2013; Tsai 2014; Yancy 2013; Askew 2018; Chareonthaitawee 2018; Soman 2018)
  - Evaluation of young (< 55 years old) patients with documented complex CAD, who are likely to need frequent non-invasive coronary ischemia evaluation and/or frequent radiation exposure from other testing (Bateman 2016; Hirshfeld 2018)
When strong suspicion of balanced ischemia is noted, and further non-invasive coronary evaluation required, PET can be used, without diversion from PET (Bengel 2009)

Prior alternative perfusion (MPI or CMR) imaging resulted in an indeterminate evaluation for CAD

- PET is frequently performed in modern dual scanners that include low dose CT (computerized tomography) imaging, and the synergistic hybrid technology of PET/CT produces high quality images without additional radiation compared to PET alone (Dorbala 2012; Bateman 2016). This guideline implicitly allows for PET/CT when PET is appropriate.

- CAD stenosis ≥ 50% is considered clinically significant or obstructive CAD. CAD and ischemic heart disease (IHD) mean the same thing. Hemodynamically or functionally significant CAD means the degree of stenosis is severe enough to cause ischemia. This is discussed in more detail in the Additional Information section. (Fihn 2012; Wolk 2013; Montalescot 2013; Gerber 2018; Tobis 2007)

- **Coronary application of PET** includes evaluation of **stable patients without known CAD**, who fall into two categories (Fihn 2012; Wolk 2013; Montalescot 2013):
  - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Part III in the Additional Information section)
  - **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant (≥ 50%) CAD (below):

**The 3 Types of Chest Pain or Discomfort**

- **Typical Angina (Definite)** is defined as including all 3 characteristics:
  1) Substernal chest pain or discomfort with characteristic quality and duration
  2) Provoked by exertion or emotional stress
  3) Relieved by rest and/or nitroglycerine

- **Atypical Angina (Probable)** has only 2 of the above characteristics

- **Nonanginal Chest Pain/Discomfort** has only 0-1 of the above characteristics

Once the type of chest pain has been established from the medical record, the Pretest Probability of CAD (meaning obstructive CAD defined as coronary arterial narrowing ≥ 50%) is estimated from the **Diamond Forrester Table** below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability (Wolk 2013; Fihn 2012):

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Gender</th>
<th>Typical/Definite Angina Pectoris</th>
<th>Atypical/Probable Angina Pectoris</th>
<th>Nonanginal Chest Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Group</td>
<td>Men</td>
<td>Intermediate</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>-----</td>
<td>--------------</td>
<td>-----</td>
<td></td>
</tr>
<tr>
<td>&lt;=39</td>
<td></td>
<td>Intermediate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>40–49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td>&gt;=60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
</tbody>
</table>

- **Very low:** < 5% pretest probability of CAD, usually not requiring stress evaluation
- **Low:** 5-10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD

(Fihn 2012)

**Indications for Cardiac PET**

(Diversion required as described in Introduction)

(Fihn 2012; Montalescot 2013; Bateman 2016; Wolk 2013; Hendel 2009; Bengel 2009; Soman 2018)

### Suspected CAD (Without known history of CAD)

**When neither SE nor MPI were or would be satisfactory**

1. **Symptomatic patients without known CAD**
   - Intermediate pre-test probability
   - High pre-test probability
   - Repeat testing in patient with recurrent symptomatic presentation and negative result over 2 years ago
   - Repeat testing in patient with new or worse symptoms and negative result at least one year ago

2. **Asymptomatic patients without known CAD**
   - Previously unevaluated ECG evidence of possible myocardial ischemia such as potentially ischemic ST segment or T wave abnormalities
   - Previously unevaluated pathologic Q waves or wall motion abnormality (evidence of prior myocardial infarction)
   - Un evaluated complete left bundle branch block
   - Following radiation therapy to the anterior or left chest, at 5 years post inception of radiation and every 5 years thereafter (Lancellotti 2013)

3. **Incomplete or inconclusive CAD evaluation, within the past 2 years without known CAD**
   - Exercise stress ECG with low risk Duke treadmill score, but patient's current symptoms indicate an intermediate or high pretest probability, which should include stress imaging
   - Exercise stress ECG with intermediate Duke treadmill score
   - Inconclusive/borderline coronary computed tomography angiography (CCTA) (e.g. 40-70% lesions)
   - An indeterminate (equivocal, borderline, or discordant) evaluation by prior stress imaging (SE, MPI or CMR) within the past 2 years, for whom a noninvasive approach is preferable to proceeding to
invasive coronary arteriography (e.g. unclear symptoms, ECG and imaging discordant, in a patient who has severe contrast allergy or chronic kidney disease)

<table>
<thead>
<tr>
<th>Known Major Vessel CAD</th>
<th>When neither SE nor MPI were or would be satisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>When LVEF ≤40% with known severe CAD, and revascularization is under consideration (diversion from PET not required)</td>
</tr>
</tbody>
</table>

(Patel 2017)

- Validated concern for a previous acute coronary syndrome without subsequent invasive or non-invasive coronary evaluation
- Follow up stress imaging at 2-year intervals is approvable, if it will affect consideration of coronary revascularization (initial or additional), in patients with one of the following:
  - History of silent ischemia with severe unrevascularized CAD, and revascularization could be feasible (Deedwania 2018)
  - History of severe unrevascularized major multivessel CAD, and revascularization could be feasible
  - Ejection fraction ≤40% with severe unrevascularized CAD, and revascularization could be feasible
- Ischemia assessment following inconclusive findings of invasive coronary arteriography or CCTA, for the purpose of assessing extent of ischemia and need for additional medical, interventional, or surgical therapy. When strong suspicion of balanced ischemia noted, and further non-invasive coronary evaluation required, PET can be used (quantitative coronary flow), without diversion from PET (Bengel 2009).
- PET (can be FDG only) is appropriate for patients with LVEF ≤ 50% requiring myocardial viability assessment of significant dysfunctional myocardium (so-called hibernating myocardium) to assist with decisions regarding coronary revascularization in known severe major vessel CAD (Diversion from PET not required when LVEF ≤ 40%) (Askew 2018; Chareonthaitawee 2018; Patel 2013; Soman 2018; Tsai 2014; Yancy 2013).
- New or worsening symptoms of ischemia in the absence of an acute coronary syndrome, unless the most current stress imaging study would warrant invasive coronary arteriography instead (e.g. History of high risk stress test without subsequent invasive coronary arteriography might warrant invasive coronary angiography) (Patel 2012).
- De novo heart failure (HF), who have known CAD, even without angina, unless the patient is not eligible for revascularization of any kind, or unless invasive coronary arteriography is immediately planned (Yancy 2013).

<table>
<thead>
<tr>
<th>Special Diagnostic Conditions Requiring Coronary Evaluation</th>
<th>When neither SE nor MPI were or would be satisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly diagnosed systolic or diastolic heart failure, especially with symptoms or signs of ischemia AND without invasive coronary angiography immediately planned (Yancy 2013; Patel 2013; Fihn 2012)</td>
<td></td>
</tr>
</tbody>
</table>
- Newly found wall motion abnormality (Colucci 2018)
- Ventricular arrhythmias
  - Sustained ventricular tachycardia (VT) >100 bpm, ventricular fibrillation (VF), or exercise induced VT, when invasive coronary arteriography is not the initially required test (Al-Khatib 2018 in press)
  - Nonsustained VT, multiple episodes, each ≥ 3 beats at ≥100 bpm, without known cause or associated cardiac pathology, when an exercise ECG has shown an intermediate risk Duke Score or an exercise ECG could not be performed (Zimetbaum 2018)
- Frequent PVCs > 30/hour, or any PVC on a 12 lead ECG, without known cause or associated cardiac pathology, when an exercise ECG has shown an intermediate risk Duke Score OR an exercise ECG is not feasible due to inability to exercise or due to an uninterpretable ECG (Cha 2012; Manolis 2018)
- Prior to Class IC antiarrhythmic drug initiation in intermediate and high global risk patients (see global risk calculators in Additional Information section) (Kumar 2018)
- Assessment of hemodynamic significance of one of the following documented conditions (Anagnostopoulos 2004):
  - Anomalous coronary arteries (Grani 2017)
  - Coronary aneurysms in Kawasaki’s disease (Newburger 2018)

### Cardiac Sarcoidosis
(Blankstein 2018; Blankstein 2014; Bravo 2017; Vita 2018)
- Evaluation and therapy monitoring in patients with sarcoidosis, after documentation of suspected cardiac involvement by echo or ECG, when CMR cannot be the prior study
- Evaluation of suspected cardiac sarcoid, after CMR has shown equivocal or negative findings in the setting of a high clinical suspicion (Vita 2018)
- Evaluation of CMR findings showing highly probable cardiac sarcoidosis, when PET could serve to identify inflammation and the consequent potential role for immunosuppressive therapy (Vita 2018)
- Initial and follow up PET in monitoring therapy for cardiac sarcoid with immunosuppressive therapy, typically about 4 times over 2 years (Osborne 2014; Bokhari 2017)

### Infective Endocarditis
- In suspected infective endocarditis with moderate to high probability (i.e. staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inconclusive with respect to diagnosis of infective endocarditis or characterization of paravalvular invasive complications (Doherty 2017; Karchmer 2018a; Karchmer 2018b; Sexton 2018; Wang 2018; Habib 2016), but it is not appropriate for pure native valve endocarditis (Salaun 2018)

### Aortitis
- For diagnosis and surveillance of Aortitis, PET/CT or PET/MRI hybrid imaging (Bhave 2018)

### Prior to Elective Non-Cardiac Surgery
When SE or MPI was or would not be adequate
(Fleischer 2014; Patel 2015)
- Patients who have no other indication for a non-invasive coronary evaluation, but are referred for preoperative cardiac evaluation, are eligible for stress imaging based upon cardiac risk ≥1%, if all 4 criteria are met:
  - Surgery is supra-inguinal vascular, intrathoracic, or intra-abdominal.
  - The patient has at least one of the additional cardiac complication risk factors:
    - Ischemic Heart Disease
    - History of stroke or transient ischemic attack (TIA)
    - History of congestive heart failure or ejection fraction ≤35%
    - Insulin-requiring diabetes mellitus
    - Creatinine ≥ 2.0 mg/dl
AND

- The patient has limited functional capacity (< 4 METS), such as one of the following:
  - Cannot take care of their activities of daily living (ADLs) or ambulate
  - Cannot walk 2 blocks on level ground
  - Cannot climb 1 flight of stairs
  - Cannot vacuum, dust, do dishes, sweep, or carry small grocery bag

AND

- There has been no non-invasive coronary testing within one year, and the result of such a test would be likely to substantially alter therapy and/or preclude proceeding with the intended surgery.

- Planning for solid organ (mainly kidney or liver) transplantation is an indication for preoperative stress imaging, if there has not been a conclusive stress evaluation within the past year and one of the following (Lentine 2012):

  - The patient has limited functional capacity (< 4 METS), such as one of the following:
    - Cannot take care of their activities of daily living (ADLs) or ambulate
    - Cannot walk 2 blocks on level ground
    - Cannot climb 1 flight of stairs
    - Cannot vacuum, dust, do dishes, sweep, or carry small grocery bag
  
  (Wolk 2013)

OR

- In a patient with ≥ 3 of the following: (Lentine 2012)
  - Age > 60
  - Smoking
  - Hypertension
  - Dyslipidemia
  - Left ventricular hypertrophy
  - > 1 year on dialysis (for renal transplant patients)
  - Diabetes mellitus
  - Prior cardiovascular disease

(Lentine 2012)

- When the above risk calculators prove inadequate, and cardiac risk could be ≥1%, the American College of Surgeons NSQIP cardiac risk calculator can be used as a less validated alternative: and is available at http://www.surgicalriskcalculator.com/miorcardiacarrest, with an application download required.

<table>
<thead>
<tr>
<th>Post Cardiac Transplantation</th>
</tr>
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<tbody>
<tr>
<td>When SE or MPI was or would not be adequate</td>
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<td>(Gustafsson 2016)</td>
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</table>

- During the first five years post cardiac transplantation, patients with glomerular filtration rates less than 40 mL/min/1.73 BSA, or who otherwise should not undergo annual invasive coronary arteriography
• After the first five years post cardiac transplantation, one of the following:
  o Patients considered at low risk for transplant vasculopathy (i.e., with normal invasive coronary arteriography)
  o Patients with transplant coronary vasculopathy, if the risk of annual invasive coronary arteriography is not acceptable (e.g. high risk of contrast nephropathy)

**ADDITIONAL INFORMATION**

**I. General Information about PET**

**Quantitation of Myocardial Blood Flow and Flow Reserve by PET**
While this technology has been progressively promising, and can assist in the evaluation of coronary microvascular dysfunction, its use is still investigation, although easily added to the cardiac PET examination. At this time it is not justifiable as a stand-alone test. (Bateman 2016, Juneau 2017)

**Cardiac neoplasm and metastasis**
The use of PET has shown promise in the evaluation of cardiac neoplasm. Precise indications for the use of this technology are currently in evolution, but are promising (Rahbar 2012; Fathala 2017). CT and MR are presently better supported for this use (Gaasch 2018).

**Endocarditis** (Sexton 2018; Karchmer 2018a; Wang 2018; Habib 2016)
TTE and TEE remain the main imaging modalities for the diagnosis of infective endocarditis. Use of FDG PET/CT for paravalvular abscess and for confirmation of prosthetic valve endocarditis has been demonstrated, but issues of necessary expertise for interpretation and false positivity have limited its use. It has been much less helpful in the diagnosis of native valve infective endocarditis (Salaun 2018)**.

**Cardiac Device Infection** (Karchmer 2018b, Wang 2018, Habib 2016)
FDG PET/CT has an adjunctive role in the diagnosis of cardiac electrical device infectious complications when conventional TTE/TEE and blood culture methods have been unsuccessful.**

**While not endorsed by the AHA 2015 Infective Endocarditis Guidelines (Baddour 2015), since 2015 there appears to have been an increase in evidence supporting the utilization of PET/CT in this scenario ad the above references indicate.**

**II. ECG Stress Test Alone versus Stress Testing with Imaging**
Prominent scenarios suitable for an ECG stress test WITHOUT imaging (i.e. exercise treadmill ECG test) are inferred from the guidelines presented above, often (but not always) requiring that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate AND has an interpretable ECG for ischemia during exercise (Wolk 2013):
  • The (symptomatic) low pretest probability patient who is able to exercise and has an interpretable ECG
  • The (asymptomatic) high global risk patient who is able to exercise and has an interpretable ECG
  • The patient who is under evaluation for exercise induced arrhythmia (or long QT interval evaluation when the resting QTc is normal), and coronary artery disease is not suspected (Al-Khatib 2017)
• The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription.

**Duke Exercise ECG Treadmill Score** calculates risk from ECG treadmill alone:

- The equation for calculating the Duke treadmill score (DTS) is:  
  \[ \text{DTS} = \text{exercise time in minutes} \times (5 \times \text{ST deviation in mm or 0.1 mV increments}) \times (4 \times \text{exercise angina score}), \text{with angina score being} \]
  \[ 0 = \text{none}, \quad 1 = \text{non-limiting}, \quad \text{and} \quad 2 = \text{exercise-limiting}. \]

- The score typically ranges from -25 to +15. These values correspond to low-risk (with a score of \( \geq +5 \)), intermediate risk (with scores ranging from -10 to +4), and high-risk (with a score of \( \leq -11 \)) categories.

An uninterpretable baseline ECG includes (Fihn 2012):

- Abnormalities of ST segment depression of 0.1 mV (1 mm with conventional calibration) or more
- Ischemic looking T wave inversions of at least 0.25 mV (2.5 mm with conventional calibration)
- ECG findings of probable or definite LVH, WPW, a ventricular paced rhythm, or left bundle branch block
- Digitalis use or hypokalemia
- Resting HR under 50 bpm on a beta blocker and an anticipated suboptimal workload (e.g. rate-pressure product less than 20-25K) could render inconclusive result
- Prior false positive stress ECG

### III. Global Risk of Cardiovascular Disease

**Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to asymptomatic patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging. (Douglas 2018) There are rare exemptions, such as patients requiring a I-C antiarrhythmic drug, who might require coronary risk stratification prior to initiation of the drug, when global risk is moderate or high.

- **CAD Risk—Low**
  10-year absolute coronary or cardiovascular risk less than 10%.
- **CAD Risk—Moderate**
  10-year absolute coronary or cardiovascular risk between 10% and 20%.
- **CAD Risk—High**
  10-year absolute coronary or cardiovascular risk of greater than 20%.

**Links to Global Cardiovascular Risk Calculators**

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

(D’Agostino 2008; Ridker 2007; McClelland 2015; Goff 2014)
<table>
<thead>
<tr>
<th>Risk Calculator</th>
<th>Link to Online Calculator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reynolds Risk Score</td>
<td><a href="http://www.reynoldsriskscore.org/">http://www.reynoldsriskscore.org/</a></td>
</tr>
<tr>
<td>Can use if no diabetes</td>
<td></td>
</tr>
<tr>
<td>Unique for use of family history</td>
<td></td>
</tr>
<tr>
<td>Pooled Cohort Equation</td>
<td><a href="http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example">http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example</a></td>
</tr>
<tr>
<td>MESA Risk Calculator</td>
<td><a href="https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx">https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx</a></td>
</tr>
<tr>
<td>With addition of Coronary Artery Calcium Score, for</td>
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<tr>
<td>CAD-only risk</td>
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</table>

**IV. Definitions of Coronary Artery Disease**

(Fihn 2012; Montalescot 2013; Patel 2017; Mintz 2016; Tobis 2007)

1. Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and refers to cross sectional narrowing when intravascular ultrasound (IVUS) is the method of determination.

2. Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a **risk stratification** tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.

3. Stenoses ≥ 50% are considered obstructive coronary artery disease (also referred to as clinically significant), while stenoses ≤ 50% are considered nonobstructive coronary artery disease (Gerber 2018).

4. Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
   i. Suggested by percentage diameter stenosis ≥ 70% by angiography; borderline lesions are 40-70% (Fihn 2012; Tobis 2007)
   ii. For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross sectional area on IVUS ≤ 6 square mm (Fihn 2012; Mintz 2016)
   iii. Fractional flow reserve (FFR) ≤ 0.80 for a major vessel (Mintz 2016)
   iv. Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree

5. A major vessel would be a coronary vessel that would typically be substantial enough for revascularization, if it were indicated. Lesser forms of coronary artery disease would be labeled as “limited” and not major (i.e. a 50% lesion in a tiny septal or modest size mid PDA would be limited obstructive coronary artery disease.)

6. Microvascular ischemic coronary artery disease, as might be described by a normal FFR above 0.80 with a reduced coronary flow reserve (CFR) (CFR < 2.5), has not otherwise been addressed in this manuscript, because it is very rarely an issue in compliance determinations. However, it would constitute a form of ischemic heart disease.

7. FFR is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is
considered a significant reduction in coronary flow. Newer iterations such as instantaneous wave free ratio (iFR) might supersede basic FFR technology in the near future.

8. New technology is evolving that estimates FFR from CCTA images. This is covered under the separate NIA Guideline for FFR-CT.

V. Anginal Equivalent

Development of an anginal equivalent (e.g. shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g. dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent (Moya 2009; Shen 2017; Fihn 2012)

VI. Peripheral Arterial Disease/Cerebrovascular Disease

Arterial vascular disease below the renal arteries is generally referred to as peripheral arterial disease, when the ankle brachial index is <0.9 or there is at least 50% vessel diameter narrowing on ultrasound or angiography (Hussain 2018).

Cerebrovascular disease generally refers to a history of TIA (transient ischemic attack) or stroke, or cerebrovascular lesions that put the patient at considerable risk for stroke (Caplan 2018).

There is no evidence to demonstrate that screening all patients with peripheral arterial disease for asymptomatic atherosclerosis in other arterial beds improves clinical outcome. Intensive treatment of risk factors through guideline directed medical therapy is the principal method for preventing adverse cardiovascular ischemic events secondary to atherosclerotic disease in other arterial beds (Gerhard-Herman 2016.)

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAD</td>
<td>Antiarrhythmic drug</td>
</tr>
<tr>
<td>ADLs</td>
<td>Activities of daily living</td>
</tr>
<tr>
<td>BSA</td>
<td>Body surface area in square meters</td>
</tr>
<tr>
<td>CAD</td>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
</tr>
<tr>
<td>FFR</td>
<td>Fractional flow reserve</td>
</tr>
<tr>
<td>LBBB</td>
<td>Left bundle-branch block</td>
</tr>
<tr>
<td>LVH</td>
<td>Left ventricular hypertrophy</td>
</tr>
<tr>
<td>MI</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>MET</td>
<td>Estimated metabolic equivalent of exercise</td>
</tr>
<tr>
<td>MPI</td>
<td>Myocardial perfusion imaging</td>
</tr>
<tr>
<td>PFT</td>
<td>Pulmonary function test</td>
</tr>
<tr>
<td>PVCs</td>
<td>Premature ventricular contractions</td>
</tr>
<tr>
<td>SE</td>
<td>Exercise stress echocardiography</td>
</tr>
<tr>
<td>VT</td>
<td>Ventricular tachycardia</td>
</tr>
<tr>
<td>VF</td>
<td>Ventricular fibrillation</td>
</tr>
<tr>
<td>WPW</td>
<td>Wolf Parkinson White</td>
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</table>
REFERENCES

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CPT Codes: 78472, 78473, 78494, +78496

INTRODUCTION
(Srichai 2018; Mitra 2102; Patel 2013)

➢ Multiple-gated acquisition (MUGA) scanning uses radio-labelled red blood cells to scan right and left ventricular images in a cine loop format that is synchronized with the ECG, which requires a regular rhythm for accuracy.

➢ Right and left ventricular systolic wall motion, ejection fraction, ventricular volumes, stroke volume ratios, diastolic function, pulmonary blood volumes, regurgitant fractions, and exercise response can be derived from the data acquired by the gamma camera (Scheiner 2002; Ritchie 1995). However, in the current era, the test is primarily for a left ventricular ejection fraction (LVEF) determination, when transthoracic echocardiography (TTE) has been inadequate, and cardiac magnetic resonance imaging (CMR) precision is not demanded.

INDICATIONS FOR A MUGA SCAN
(Srichai 2018; Mitra 2102; Patel 2013; Corbett 2008; Friedman 2009)

• In the course of cardiotoxic chemotherapy and/or subsequent to radiation to the anterior or left chest, when TTE has not been helpful and CMR is not available, to evaluate left ventricular systolic function (Zamorano 2016; Plana 2014; Patel 2013; Yancy 2013):
  o Prior to cardiotoxic chemotherapy, and subsequently for monitoring and follow up (see cardio-oncology section under Additional Information)
  o For radiation to the anterior or left chest, left ventricular function assessment at baseline, 5 years post inception, and every 5 years thereafter (Lancellotti 2013)

• To evaluate biventricular or left ventricular function in a patient with CAD, valvular heart disease, myocardial disease, or congenital heart disease, in any of the following scenarios:
  o When ventricular function is required for management and/or post therapeutic/post interventional/post-operative follow up, and echocardiography or other required concomitant imaging has proven inadequate (e.g. COPD, obesity) for an adequate determination of ejection fraction (Yancy 2013; Patel 2013)
  o With new, worsening, intractable (Mitra 2012) or other major status change in congestive heart failure (CHF), when TTE or other required concomitant imaging has proven inadequate (e.g. COPD, obesity interfering with TTE) (Fihn 2012; Yancy 2013; Patel 2013)
  o In the presence of significant resting wall motion abnormalities or distorted geometry (Patel 2013)
  o For accurate verification of ejection fraction in meeting criteria for an implantable cardioverter defibrillator (ICD) and/or cardiac resynchronization therapy (CRT) implantation (Krahn 2008)
• As an alternative form of stress imaging instead of myocardial perfusion imaging, based upon similar
necessity criteria for the evaluation of coronary artery disease, recognizing some prohibitive
limitations with respect to (Ritchie 1995; Corbett 2008; Friedman 2009):
  o Localization of ischemia (superior with MPI)
  o Quantitation of myocardium at risk (superior with MPI)
  o Requirement for ability/safety with performance of exercise or with inotropic stimulation
  o Lack of interpretability when
    ▪ Resting MUGA images are poor
    ▪ ECG-related issues are present (affecting wall motion or gating technique)
      • Complete left bundle branch block
      • Ventricular pacing or ICD
      • Ventricular pre-excitation (e.g. Wolff Parkinson White)
      • Atrial fibrillation
      • Frequent ectopy, irregular rhythm

Additional Information

Imaging Surveillance for Cardiotoxic Chemotherapy
(Plana 2014; Zamorano 2016; Maleszewski 2018; Herrmann 2014)

TTE is the method of choice for the evaluation of patients before, during, and after cancer therapy. Ideally
accuracy prefers that 3D and global longitudinal strain (GLS) are part of the exam, and serum troponin
(Tn) should also be measured. However, GLS and Tn might not have been performed, in which case
determinations might need to be made with left ventricular ejection fraction (LVEF) only. Serum troponin
(Tn) and GLS abnormalities constitute an abnormal assessment of LV function, because their abnormalities
frequently herald an imminent fall in LVEF (Plana 2014; Zamorano 2016).

CMR is recommended when TTE has been unreliable and/or candidacy for cardiotoxic chemotherapy
based upon LVEF is questionable (Plana 2014). MUGA can also be considered when TTE is inadequate
and CMR is not available.

MUGA is accurate and reproducible, but lacks information about pericardium and valves, incurs repeated
radiation exposure, and is inaccurate during an irregular cardiac rhythm (Plana 2014).

Surveillance guidelines are somewhat complex, possibly beyond the scope of this guideline, especially in
patients with additional risk factors for LV dysfunction (Herrmann 2014). As with all guidelines,
adequate information for complex decisions might be impractical to acquire. However, if the reader
requires more rigorous recommendations, they are summarized concisely in the table below. Necessity
determinations might not require strict adherence to this table at this time, but it is here to serve as a
helpful reference for the reader, if desired.

| TTE Surveillance Strategy for Cardiotoxic Chemotherapy (Optional Information) |
|-------------------------------|-------------------------------|-------------------------------|
| Suspected/Detected LV Status at Baseline, During, or After Completion of Therapy (LVEF is minimum information, Type I Anthracyclines: Doxorubicin, Epirubicin, Idarubicin Mitoxantrone (Asnani 2018) | Type II Trastuzumab, Labatinib, Pertuzumab, Sorafenib, Sunitinib, Bevacizumab, Bortezomib ** |
### GLS and Tn can reveal early LV dysfunction prior to LVEF

<table>
<thead>
<tr>
<th><strong>Normal:</strong> EF is $\geq 55%$, troponin is negative, and global longitudinal strain (GLS) $&gt;\text{lower limit of normal}^*$</th>
<th><strong>Normal assessment:</strong> Assess after a cumulative dose $&gt;200\text{mg/M}^2$ (or its anthracycline equivalent) and prior to each additional $50\text{mg/M}^2$, and at completion of therapy, and 6 months later, and for cumulative dose $&gt;300\text{mg/M}^2$ include assessment at 1 year and at 5 years post completion of therapy. (Zamorano 2016)</th>
<th><strong>Normal assessment:</strong> Assess every 3 months during therapy and at 6 months post completion of therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Abnormal:</strong> any one of:</td>
<td><strong>Abnormal assessment:</strong> Assess after every cycle, and reassess for verification 2-3 weeks later if a drop in LV function has been detected/suspected; assess 6 months post completion of therapy, followed by re-assessment every 6 months until stable, and for cumulative dose $&gt;300\text{mg/M}^2$ include assessment at 1 year and 5 years post completion of therapy. (Maleszewski 2018)</td>
<td><strong>Abnormal assessment:</strong> Assess after every cycle, and re-assess for verification 2-3 weeks later if a drop in LV function has been detected/suspected; assess 6 months post completion of therapy, and if still not stable re-assess every 6 months until stable.</td>
</tr>
<tr>
<td>o GLS reduced $\geq 10$-15% below normal (about 20 is normal*, labs vary)</td>
<td></td>
<td></td>
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<tr>
<td>o Troponin positive</td>
<td></td>
<td></td>
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<tr>
<td>o LVEF started $&lt; 55%$</td>
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<tr>
<td>o During therapy LVEF drops below 55% AND $&gt; 5$ points for a symptomatic, $\geq 10$ points for an asymptomatic patient. (Maleszewski 2018)</td>
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* GLS of (negative) 20 is generally normal, but individual labs vary (Collier 2017).
** Imatinib, rarely cardiotoxic, does not require surveillance of LV function (Floyd 2018).

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### First Pass Radionuclide Angiography

*(Friedman 2009)*

First pass radionuclide ventriculography provides similar information by radiotracer blood pool scanning, but requires only a single pass of isotope through the heart, made possible by rapid, high count rate acquisition, achievable with certain multi-crystal gamma cameras. Its indications are essentially the same as for MUGA, also referred to as equilibrium radionuclide angiography, which requires time (i.e. multiple cardiac cycles) for isotope circulation.

### Combination of Other Studies with MUGA

**Abdomen CT/Pelvis CT/Chest CT/Neck MRI/Neck CT with MUGA** – known tumor/cancer for initial staging or evaluation before starting chemotherapy or radiation treatment.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CMR</td>
<td>Cardiac Magnetic Resonance Imaging</td>
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<tr>
<td>CT</td>
<td>Computed Tomography Imaging</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
</tr>
<tr>
<td>GLS</td>
<td>Global longitudinal strain (measurement of left ventricular function)</td>
</tr>
<tr>
<td>mg</td>
<td>Milligrams</td>
</tr>
<tr>
<td>MUGA</td>
<td>Multiple Gated Acquisition (nuclear scan of ventricular function)</td>
</tr>
<tr>
<td>PAC</td>
<td>Premature atrial contraction</td>
</tr>
<tr>
<td>PVC</td>
<td>Premature ventricular contraction</td>
</tr>
<tr>
<td>sqM</td>
<td>Square meters of body surface area</td>
</tr>
<tr>
<td>Tn</td>
<td>Troponin</td>
</tr>
<tr>
<td>TTE</td>
<td>Transthoracic echocardiography</td>
</tr>
<tr>
<td>WPW</td>
<td>Wolf Parkinson White Syndrome (electrical pre-excitation)</td>
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REFERENCES


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INTRODUCTION:

Positron Emission Tomography (PET) scanning using FDG (fluorodeoxyglucose) assesses brain metabolism and perfusion. Uses include identifying epileptic foci prior to surgery, differentiation of residual tumor versus scar, and causes of cognitive decline.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR BRAIN PET SCAN:

Known brain tumor or cancer:
- New signs or symptoms indicative of a recurrence (Heiss, 2011).
- Short-term follow-up to differentiate scarring/fibrosis from residual tumor, as an adjunct to Brain MRI (Heiss, 2011; Bashir, 2015).

Pre-operative for refractory seizures (Jones, 2016).

Post-operative/procedural evaluation:
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) of requested imaging.

Mild Cognitive Impairment or Dementia:
- Diagnosis: both have been met
  - Objective cognitive impairment on longitudinal assessment, i.e., historical or observed evidence of decline over time (Albert, 2011; Iaccarino, 2017).
    - Mini Mental Status Evaluation (MMSE) or Montreal Cognitive Assessment (MoCA) less than 26 (Davis, 2015)
    - Formal neuropsyhc testing showing mild cognitive impairment
  - Potential treatable causes assessed and addressed (Albert, 2011)
    - Metabolic such as thyroid or vitamin deficiency, anemia, or chemical encephalopathy
    - Medication side effects (Campbell, 2010).
    - Medical causes such as vascular or traumatic
REFERENCES


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CPT Codes: 78647

INTRODUCTION

Single-photon emission computed tomography (SPECT) is a nuclear medicine imaging technique based on the use of computed tomography to localize data from gamma ray emitting injected radiopharmaceuticals to specific anatomical locations within the patient. The resulting 3D images can be reconstructed in multiple planes. As a general rule, the detection efficiency and spatial resolution improves as the number of detecting cameras comprising the imaging system increases. Radiopharmaceuticals used vary based on the clinical indication. The technique is applied in brain, cardiac, pulmonary, abdominal, endocrine, and musculoskeletal imaging.

Cerebrospinal fluid (CSF) flow studies for the evaluation of obstructive or non-obstructive hydrocephalus of various etiologies or CSF leaks (CSF cisternography) are performed after the intrathecal administration of radionuclide. In patients without hydrocephalus or CSF leak there is a predictable radiopharmaceutical distribution. To evaluate ventriculoperitoneal shunt patency, radionuclide is injected into the shunt reservoir. The radionuclides used for CSF flow studies are Indium-111 DTPA for cisternography and leaks and Tc-99m DTPA for shunt studies (Ma, 2015). Due to advances in thin section CT, as well as MRI and CT myelographic techniques, CSF flow studies for detecting leaks have been reserved for complex cases where the diagnosis is in question (Lloyd, 2008). Advanced MRI CSF flow dynamic techniques have largely replaced scintigraphy for evaluating normal pressure hydrocephalus (Shprecher, 2009; ACR).

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR A CEREBROSPINAL FLUID FLOW (CSF) SPECT SCAN:

Complex clinical scenarios involving the following indications wherein CT, MRI, or routine dynamic planar imaging is insufficient alone:

- Evaluation of hydrocephalus in the absence of CSF shunting and the patient has had a CT or MRI imaging of the head recently performed and compared to prior exam.
- Detection of CSF leak and the patient has had a recent surgical procedure and CT or MRI imaging of the surgical site has been performed (Lloyd, 2008: Epstein, 2013).
- Detection of CSF leak AND patient experienced recent trauma and CT or MRI imaging has been performed (Lloyd, 2008).
- Evaluation of the function of a CSF shunt, and the patient has had a CT or MRI imaging of the head recently performed and compared to prior exams, and radiographic evaluation of shunt catheter has been recently performed (Pitetti, 2007).
- For evaluation of Normal Pressure hydrocephalus where differentiation from other, or the presence of concurrent, neurodegenerative disorders based on clinical criteria is difficult and MRI for evaluating CSF dynamics is contraindicated (Thut, 2014; Shprecher, 2009).
- Suspected spontaneous intracranial hypotension (SIH) with CSF pressure below 6 cm H₂O and preliminary CT or MRI and/or MRI or CT myelography have been performed (Lin, 2017).
• A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.

ADDITIONAL INFORMATION RELATED TO CSF SPECT SCAN:

SPECT SCAN - Single photon emission computed tomography (SPECT) is a nuclear medicine tomographic imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera to acquire multiple 2-D images (also called projections), from multiple angles.

According to Tsai, more than 30% of patients treated with CSF shunting for hydrocephalus will develop shunt obstruction within the first year of shunt insertion (Tsai, 2017). In the setting of hydrocephalus from suspected shunt obstruction the diagnostic evaluation, following CT or MRI scanning of the head and x-ray shunt series, involves injection of radiopharmaceutical into the shunt reservoir. Normal shunt patency is confirmed by showing activity along the entire course of the shunt, ultimately spilling into the abdominal cavity.

CSF scintigraphy is also utilized in diagnosing hydrocephalus unrelated to shunt malfunction (e.g. normal pressure hydrocephalus). In the absence of hydrocephalus, radionuclide activity is normally seen over the convexities of the brain at 24 hours and may be transiently present in the lateral ventricles within the first 24 hours. Persistence of activity in the lateral ventricles after 24 hours of imaging is diagnostic of hydrocephalus. Cine phase contrast MRI is the preferred technique for evaluating CSF flow dynamics and helps determines which patients with NPH will benefit from treatment (Shprecher, 2009).

CSF leaks are more commonly acquired, either iatrogenic or post traumatic (Lloyd, 2008), than congenital or spontaneous and can occur anywhere along the cranial spinal axis. Scintigraphy for detecting CSF leaks has been superseded by CT and MRI myelographic techniques due to their better spatial resolution (Epstein, 2013). Diagnosis using scintigraphy requires intrathecal administration of radionuclide followed by imaging typically at three, six, and twenty four hours. Pledgets can be placed in the nasal cavity or auditory canal in the setting of CSF rhinorrhea and otorrhea, respectively. The greatest limitation of the technique relative to CT or MRI imaging is that CSF has to be actively leaking at the time of imaging. By comparison, for cranial trauma or post operative complications, thin section CT can detect osseous skull base defects with a sensitivity of 92% and specificity of nearly 100% without the need for active CSF leaking (Lloyd, 2008).

The usefulness of scintigraphy is primarily as a second line study in patients with suspected CSF leaks who have undergone MRI and or CT myelography without detecting the leak. Because delayed imaging can be carried out, CSF scintigraphy is useful for evaluating slow or intermittent CSF leaks and as a second line study in the work up of spontaneous idiopathic hypotension (SIH). In this condition a CSF leak anywhere along the neuraxis is not detected in nearly one third of patients thought to be due to the slow or intermittent nature of these leaks (Lin, 2017).

Spontaneous idiopathic hypotension (SIH), also known as craniospinal hypotension, poses a diagnostic challenge due to its protean clinical symptoms, inconsistently demonstrated imaging findings on conventional MRI scanning and lack of awareness of the diagnosis among clinicians. SIH often presents a variable mix of symptoms including orthostatic headaches, visual defects or blurred vision, limb paresthesia, transient cranial 3rd cranial nerve palsy, numbness in the face or limbs, cognitive deficits, behavioral changes, neck pain and stiffness, taste alteration, or Parkinsonism.
REFERENCES


CPT Codes: 78710

INTRODUCTION:

Single-photon emission computed tomography (SPECT) is a nuclear medicine imaging technique based on the use of computed tomography to localize data from Gamma ray emitting injected radiopharmaceuticals to specific anatomical locations within the patient. The resulting 3D images can be reconstructed in multiple planes. As a general rule, the detection efficiency and spatial resolution improves as the number of detecting cameras comprising the imaging system increases. The technique is applied in brain, cardiac, pulmonary, abdominal, endocrine, and musculoskeletal imaging.

Renal scintigraphy remains an important technique for evaluation of the renal circulation, parenchyma, and collecting system. Through the acquisition of serial images over time and graphic depiction of radionuclide activity, information about renal blood flow and function not typically afforded by cross sectional imaging can be achieved. Tailored studies utilizing the administration of diuretic or angiotensin-converting enzyme inhibitors, in conjunction with the radionuclide imaging agent, allows for evaluation of suspected hydronephrosis or renovascular hypertension, respectively. The ability to create 3D multiplanar images with the SPECT technique greatly improves the diagnostic capability over traditional planar imaging.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR A KIDNEY DYNAMIC PLANAR SCAN WITH SPECT:

Complex clinical scenarios involving the following indications wherein cross sectional imaging and routine nuclear medicine dynamic planar imaging is insufficient alone:

- Evaluation of renal, ureteral, or other urinary tract trauma or surgery, with signs, symptoms and laboratory findings supporting the need for such an evaluation and CT has been performed and is inconclusive, or contraindicated.
- For diagnosis of reno-vascular hypertension, with signs, symptoms, laboratory findings or other imaging supporting the need for such a diagnosis when MRA or CTA cannot be performed or is contraindicated AND Ultrasound is inconclusive AND the patient has adequate renal function (GFR >30) mL/min/1.73 m2.) to undergo the study (ACR, 2017).
- Detection and evaluation of renal collecting system obstruction and ultrasound has been performed (ACR, 2017).
- Diagnosis of acute tubular necrosis when other causes of renal failure have been excluded and evaluated with ultrasound or the diagnosis is suspected due to a preceding ischemic or toxic event.
- Diagnosis of renal transplant complications after ultrasound has been performed (ACR, 2017).
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
ADDITIONAL INFORMATION RELATED TO KIDNEY SPECT SCAN:

**SPECT Scan** - Single photon emission computed tomography (SPECT) is a nuclear medicine tomographic imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera to acquire multiple 2-D images (also called projections), from multiple angles.

**Renal Transplant evaluation:** Vascular compromise (arterial stenosis/occlusion, venous thrombosis, and segmental infarction), ureteral obstruction, acute rejection and acute tubular necrosis can affect renal transplants. Renal ultrasound with doppler is the initial modality for evaluation of renal transplants and allows detection of vascular compromise, hydronephrosis or post operative fluid collections (urinoma/seroma/hematoma. The occurrence of various insults to the transplant usually involve a predictable post-operative timeframe and provides a clue to the cause of deteriorating renal function. Acute tubular necrosis (ATN) is the most common medical complication observed at renal scintigraphy and is more common in cadavaeric transplants than living donors owing to organ ischemia as the underlying cause. ATN is differentiated from acute rejection as it usually occurs within the first few days after transplantation whereas acute rejection occurs from one week to months after transplantation. In cases of ATN parenchymal perfusion to the transplant is relatively well maintained but there is no excretion. With rejection both perfusion and function are compromised.
REFERENCES


INTRODUCTION:

Positron emission tomography (PET) is a rapidly developing technology that is able to detect biochemical reactions, e.g., metabolism, or abnormal distribution of cell receptors within body tissues. A radioactive tracer is used during the procedure. Unlike other nuclear medicine examinations, PET can measure metabolic activity of the cells of body tissues, providing information about the functionality and structure of the particular organ or tissue examined. PET may also detect biochemical changes that help to evaluate malignant tumors and other lesions.

The degree of radioactive tracer uptake may indicate increased metabolism in the cells of body tissues or an abnormal distribution of cell receptors. Cancer cells may show increased radioactive tracer relative to tissue not involved with tumor. Radioactive tracer uptake is often higher in fast-growing tumors; PET is often not as useful or beneficial for slow growing tumors.

Radioactive tracer uptake may occur in various types of active inflammation and is not specific for cancer. Thus it is not used for the initial diagnosis of cancer, but is useful in staging and monitoring cancer cell viability and for the diagnosis and detection of recurrence of cancer. PET is also useful for monitoring the response to treatment of various cancers.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

IMPORTANT NOTE:

The appropriateness of an ordered PET/CT study is fully dependent on the answer to the question of which radiopharmaceutical will be used for the PET/CT. This guideline only covers the radiopharmaceuticals FDG, Dotatate, and 18F-Fluciclovine.

- The following are noncovered for all other indications including (but not limited to):
  - **Breast Cancer** – Initial Treatment Strategy (formerly diagnosis and initial staging) of axillary lymph nodes.
  - **Melanoma** – Initial Treatment Strategy (formerly Evaluation) of regional lymph nodes.
  - **Prostate Cancer** – Initial Treatment Strategy (formerly Diagnosis and initial staging.)
  - **Infection and/or Inflammation** - PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin.

INDICATIONS FOR AN ONCOLOGICAL FDG PET SCAN:

Initial Treatment Strategy
All solid tumors, including myeloma, with biopsy proven cancer or strongly suspected based on other diagnostic testing:

Including

- CLL – chronic lymphocytic leukemia (PET/CT is generally not useful in CLL/SLL but may be necessary to direct nodal tissue sampling when high-grade histologic transformation is suspected) (NCCN, 2018).
- SPN – solitary (or clearly dominant) indeterminate pulmonary nodule $\geq$ to 8mm in size without existing tissue diagnosis (note: patient may have other non-suspicious nodules in the lung, such as granulomas and hamartomas) (Vansteenkiste, 2006).

Excluding

- ALL - acute lymphoblastic leukemia
  - Unless prior CT imaging suggest lymphomatous involvement
- AML – acute myelogenous leukemia
  - Unless clinical suspicion for extramedullary disease
- BCC – basal cell carcinoma (of the skin)
- Prostate cancer (NCCN, 2018)

- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor, or
- To determine if patient is an appropriate candidate for an invasive diagnostic or therapeutic procedure, or
- To determine the optimal anatomic location for an invasive procedure.

Subsequent Treatment Strategy

Restaging or monitoring response to active treatment, and/or a single evaluation after completion/cessation of therapy not to be performed within 4 weeks of completion of therapy (ideally FDG PET is delayed 2-3 months after surgical therapy, 2-3 months after radiation therapy if locoregional assessment is the imaging goal), and/or evaluation for suspicion of recurrence due to new or changing signs/symptoms. (Asymptomatic surveillance is not approvable) (NCCN, 2018).

- Breast cancer (female and males)
- Cervical cancer
- Colorectal cancer (including colon, rectal, appendiceal or anal cancer)
- Esophageal cancer
- Head and neck cancer (not including Brain cancer/tumor; thyroid noted below)
- Lung cancer - Non-small cell
- Lymphoma
- Melanoma
- Myeloma
- Ovarian cancer
- Soft tissue sarcoma (Schuetze, 2005)
- Vulvar/vaginal (Robertson, 2016)

Subsequent PET Scans may be performed only if other imaging (ie. US, CT, MRI, NM) is inconclusive in determining a treatment plan or unable to be performed:
• Brain cancer: (with metastasis to non-head areas) Refer to Brain PET Scan Guidelines to image the brain
• Lung cancer - Small cell (Tucker, 1997)
• Neuroendocrine cancer (e.g. carcinoid, pheochromocytoma, etc)
• Pancreatic cancer (Rijkers, 2014)
• Prostate cancer (Bach-Gansmo, 2017)
• Testicular cancer (Hinz, 2005)
• Tumors of unknown origin (Møller, 2012)
• Other malignancies where the tumor has been shown to be FDG avid on prior PET/CT imaging if done, and other imaging (ie: US, CT, MRI, NM) is inconclusive in determining a treatment plan or unable to be performed

**Thyroid cancer:**
- Subsequent treatment strategy for recurrence or distant metastasis for thyroid cancer of Papillary, Follicular, or Hurthle cell origin AND patient has the following:
  - A thyroidectomy and radiiodine ablation initially, and
  - Stimulated serum thyroglobulin > 2 ng/ml, and
  - Current whole body I-131 scan is negative (Kloos, 2005).

Medullary thyroid cancer when calcitonin levels > 150 pg/ml post-operatively (Wells, 2015)
Anaplastic
  - 3-6 months after initial treatment
  - 3-6 month interval if persistent structural disease (Smallridge, 2012)

**Surveillance/Remission**

Surveillance/remission PET scan testing to assess for possible changes in status with no signs or symptoms of active cancer changes and not on any active treatment. Unless otherwise specified above, PET scan is not indicated for surveillance/remission.

**INDICATIONS FOR AN ONCOLOGICAL GALLIUM 68 DOTATATE PET/CT SCAN:**

**Initial Treatment Strategy or Subsequent Treatment Strategy (Deppen, 2016a,b)**

*For the following neuroendocrine tumors:*
  - Gastrointestinal tract, pancreas, lung, thymus (carcinoid tumors)
  - Pheochromocytoma, paraganglioma
  - Large or small cell carcinoma other than lung
  - Neuroendocrine tumors of unknown primary

*OR syndromes:*
  - Multiple endocrine neoplasia 1 (MEN-1)
  - Multiple endocrine neoplasia 2 (MEN-2)

Neuroendocrine tumors should be biopsy proven (required in unknown primary cases) or very strongly suspected based on other diagnostic testing WITH recent Chest/Abdominal (for example, if lung or thymus) or Abdominal/pelvic (for example, if GI tract, pancreatic, MEN-1, MEN-2) multiphasic CT or MRI having been performed and reasonably deemed insufficient for the following:

- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor, or
• To determine if patient is an appropriate candidate for an invasive diagnostic or therapeutic procedure, or
• To determine the optimal anatomic location for an invasive procedure.
• Restaging or monitoring response to active treatment, and/or evaluation for suspicion of recurrence due to new or changing signs/symptoms. (Asymptomatic surveillance is not approvable).

NOTE: Gallium-68 DOTATATE PET/CT scans should be performed only if other imaging (CT, MRI) is inconclusive/insufficient AND the patient has not already been evaluated with Somatostatin Receptor SPECT scanning (another form of somatostatin receptor imaging performed on standard nuclear cameras), or that scanning was negative or equivocal.

Surveillance/Remission

Both somatostatin receptor imaging (Gallium-68 DOTATATE PET) and FDG PET/CT are NOT recommended for routine surveillance.

INDICATIONS FOR AN ONCOLOGICAL 18F-Fluciclovine PET/CT SCAN (Recurrent Prostate Cancer) (Bach-Gansmo, 2017):

18F-Fluciclovine PET/CT scans should be performed only if other imaging (CT, MRI, US, NM) is inconclusive/insufficient AND the patient has not already been evaluated with an FDG PET/CT Scan. Known prostate cancer for workup of recurrence and response to treatment:

• Initial treatment by radical prostatectomy with
  o Failure of PSA to fall to undetectable levels or PSA detectable and rising on at least 2 subsequent determinations
• Initial treatment radiation therapy with
  o Post-RT rising PSA or positive digital exam and is candidate for local therapy

NOTE: Not all plans cover 18F-Fluciclovine (A9588), such as Magellan Complete Care of Florida and Magellan Complete Care of Arizona. If you are unsure, you should check with the Health Plan prior to requesting a PET with Fluciclovine from NIA.
REFERENCES


Kloos RT, Mazzaferri EL. A single recombinant human thyrotropin-stimulated serum thyroglobulin measurement predicts differentiated thyroid carcinoma metastases three to five years later. *J Clin Endocrinol Metab*. September 2005; 90(9):5047-5057.


Møller AK, Loft A, Berthelsen AK, et. al. A prospective comparison of 18F-FDG PET/CT and CT as diagnostic tools to identify the primary tumor site in patients with extracervical carcinoma of unknown primary site. Oncologist. 2012; 17(9):1146-1154.


CPT Codes: 0042T

INTRODUCTION:

Cerebral perfusion computed tomography (CT) or CT perfusion (CTP) is an imaging technique that provides quantitative evaluation of cerebral perfusion by generating maps of cerebral blood flow, cerebral blood volume and mean transit time. It may assist in differentiating the unsalvageable core infarct and salvageable ischemic regions of the brain that may benefit from thrombectomy or thrombolysis (Lui, 2010). It is useful in specific scenarios after initial CT and/or MRI imaging has been obtained for assessment, not only of patients with acute stroke, but also a wide range of patients with other cerebrovascular diseases. It may provide the information needed to assess the most effective procedures or treatments for the conditions. Cerebral perfusion CT is less invasive than CT angiography and is fast and available for most standard spiral CT scanners equipped with the appropriate software.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CEREBRAL PERFUSION CT (Dapeng, 2016; Guerrero, 2012; Hoeffner, 2004; Jain, 2004; Katramados, 2009; Lui, 2010; Masterson, 2009):

In the following settings after initial CT and/or MRI has been performed:

- For noninvasive diagnosis of cerebral ischemia and infarction and for evaluation of vasospasm after subarachnoid hemorrhage (Hoeffner, 2004; Lui, 2010).
- For assessment of cerebrovascular reserve by using acetazolamide challenge in patients with intracranial vascular stenosis who are potential candidates for bypass surgery or neuroendovascular treatment (Hoeffner, 2004; Lui, 2010).
- For the evaluation of patients undergoing temporary balloon occlusion to assess collateral flow and cerebrovascular reserve (Hoeffner, 2004; Jain, 2004).
- For the assessment of microvascular permeability in patients with intracranial neoplasms (Hoeffner, 2004).
- For the assessment of cerebral blood flow after carotid artery stent placement in patients with severe carotid artery stenosis (Dapeng, 2016; Guerrero, 2012; Hoeffner, 2004; Jain, 2004; Katramados, 2009; Lui, 2010; Masterson, 2009).
- For early detection of acute cerebral ischemia (Dapeng, 2016; Guerrero, 2012; Hoeffner, 2004; Jain, 2004; Katramados, 2009; Lui, 2010; Masterson, 2009).
- A follow-up study may be needed to help evaluate a patient’s progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested.
- Differentiating post ictal paralysis from acute stroke or seizure secondary to stroke after MRI has been completed or is contraindicated (Guerrero, 2012; Katramados, 2009; Lui, 2010; Masterson, 2009).
- Pre-operative evaluation of cerebral blood flow in patients at high risk for developing cerebral hyperperfusion after carotid revascularization (Dapeng, 2016).
ADDITIONAL INFORMATION RELATED TO CEREBRAL PERFUSION CT:

Cerebral Ischemia and Infarction and Evaluation of Vasospasm after Subarachnoid Hemorrhage – Cerebral perfusion CT measures cerebral blood flow, cerebral blood volume, and mean transit time which can be useful in identifying patients at risk for cerebral ischemia or infarction and for evaluation of vasospasm after subarachnoid hemorrhage. This information may be useful in identifying urgent medical or endovascular treatment.

Cerebrovascular Reserve - Cerebral perfusion CT, in conjunction with acetazolamide challenge in patients with intracranial vascular stenosis can evaluate cerebrovascular reserve capacity and help in estimating the potential risk of stroke. It may help to identify candidates for bypass surgery and endovascular treatment to increase cerebral blood flow.

Temporary Balloon Occlusion – Balloon occlusion testing is utilized prior to a planned endovascular or surgical procedure that will disrupt blood supply to a part of the brain. Quantitative analysis of cerebral blood flow may be useful in identifying patient who may not tolerate permanent or prolonged occlusion.

Intracranial Tumors – Cerebral perfusion CT generates permeability measurements in images of brain tumors depicting areas of different blood flow within tumors and the surrounding tissues. This may allow for diagnosis and grading of tumors and may help to monitor treatment.

Carotid Artery Stent Placement/Revascularization – Cerebral perfusion CT provides a quantitative evaluation of cerebral perfusion and helps in the assessment of the hemodynamic modifications in patients with severe carotid stenosis. Pre-operatively, CTP may help identify patients at high risk of developing hyperperfusion syndrome after carotid revascularization. The condition may occur in patients who have undergone surgery. Presenting symptoms include “…throbbying frontotemporal or periorbital headache, confusion, macular edema, visual disturbances, seizures, or focal neurological deficits” (Dapeng, 2016). “The presence of internal carotid artery (ICA) stenosis ≥90% is a main risk factor for the development of HPS. Other important risk factors include severe contralateral ICA disease, poor collateral flow, hypertension, and recent stroke or ischaemia” (Dapeng, 2016). Post-operatively CTP provides valuable information for a more thorough assessment in the follow-up of patients after they have undergone carotid stent placement.

Acute Cerebral Ischemia (Stroke) – Cerebral perfusion CT can quantitatively distinguish the extent of irreversibly infarcted brain tissue (infarct core) from the severely ischemic but salvageable tissue (penumbra), providing a basis for the selection of acute stroke patients that are most likely to benefit from thrombolytic treatment.
REFERENCES


CPT Codes: +0159T

**INTRODUCTION:**

There is no evidence the use of CAD systems would provide statistically significant improvement in accuracy of MRI of the breast and is therefore impossible to evaluate the impact of CAD on health outcomes such as treatment success and survival of patients with breast cancer.

**INDICATIONS FOR CAD BREAST MRI:**

"No proven indications for use of CAD with/without an approved Breast MRI".

**REFERENCES**

CPT Codes: G0219

IMPORTANT NOTE:

PET scan for whole body; melanoma for non-covered indications is considered to be not medically necessary and is therefore a non-covered study.
CPT Codes: G0235

IMPORTANT NOTE:

PET imaging, any site, not otherwise specified, is a non-covered CPT code.
CPT Codes: G0252

IMPORTANT NOTE:

PET scan imaging, full and partial-ring pet scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g. initial staging of axillary lymph nodes) is considered to be not medically necessary and is therefore a non-covered study.
Fractional flow reserve computed tomography (FFR-CT) is a relatively new technology that estimates the effect of coronary arterial narrowing on blood flow, based upon the images acquired in a coronary computed tomography angiography (CCTA) study.

Its role is to provide information that can safely defer performance of invasive coronary arteriography in patients without a known history of CAD (coronary artery disease).

INDICATIONS FOR FFR-CT
(Douglas 2016; Norgaard 2015; Hulten 2015; Hulten 2017; Maroules 2017)

• In a patient for whom ICA is under consideration, based upon results of clinical evaluation and/or non-invasive testing, both criteria #1 and #2 below should be met: (Douglas 2016; Norgaard 2017; Hulten 2017)

1. Immediately before CCTA, the patient was stable with a pre-test probability between 20% and 80% of obstructive (≥ 50%) coronary artery disease, based upon a reliable calculator (updated Diamond Forrester, ESC Consortium, University of Washington, or similar calculators, for which links are provided in the Additional Information section) (Fihn 2012).

2. The medical record presents at least one of the following scenarios:
   a. Patient has a pretest probability of 20-50% (low-to-moderate) prior to CCTA and was selected for evaluation with CCTA as a non-invasive test for significant coronary artery disease. The CCTA result shows lesions of 40-80%

   OR

   b. Patient had a pretest probability of 51-70% (moderate or high moderate) prior to CCTA and was selected for evaluation with CCTA as a non-invasive test for significant coronary artery disease. The CCTA result shows lesions of 30-70%.

• Lesions which could realistically fall into the above ranges, with the stipulation that calcification has made percentage stenosis interpretation difficult, could support approval of FFR-CT, in conjunction with the above criteria (Norgaard 2015).

Inapplicable Scenarios for FFR-CT
(Douglas 2016; Pontone 2015)

➢ None of the following clinical scenarios below apply since FFR-CT either
   o Has not been adequately validated due to inapplicability of computational dynamics

   OR
Due to problematic artifacts, and/or clinical circumstances.

➢ When such patients have artifacts (heavy calcium) or body habitus (BMI > 35) that could interfere with the examination, the suitability for FFR-CT is at the discretion of the vendor who provides the FFR-CT service.

• Suspicion of an acute coronary syndrome, unless the patient has unstable angina, myocardial infarction was excluded, and ICA would not be recommended if FFR-CT were negative
• Known ischemic coronary artery disease that has not been revascularized, and there has been no change in patient status or in the CCTA images
• Recent myocardial infarction within 30 days (Gaur 2017)
• Prior coronary artery bypass graft surgery
• Patients who require emergent or urgent ICA or have any evidence of ongoing or active clinical instability, including acute chest pain (sudden onset), cardiogenic shock, unstable blood pressure with systolic blood pressure <90 mmHg, severe congestive heart failure (New York Heart Association (NYHA) III or IV) or acute pulmonary edema
• Complex congenital heart disease or ventricular septal defect (VSD) with pulmonary-to-systemic flow ratio > 1.4
• BMI > 35 (can be done at discretion of vendor)
• Metallic stents in the coronary system
• Coronary vessels with extensive or heavy calcification (can be done at discretion of vendor)
• Coronary lesions needing evaluation in which vessel diameter < 1.8 mm
• Cardiac Implanted Electrical Devices (CIEDs)
• Prosthetic Heart Valves
• Severe wall motion abnormality on CCTA results
• Severe myocardial hypertrophy
• High risk indicators on stress test
• ICA within the past 90 days
• Marginal quality of the submitted imaging data, due to motion, blooming, misalignment, arrhythmia, etc.

Additional Information

The Development of FFR-CT as a Technology

History of FFR: Fractional Flow Reserve (FFR) is the ratio of baseline coronary flow to coronary flow during maximal hyperemia. Its use in the cardiac catheterization laboratory has successfully demonstrated utility in the quantitation of intracoronary flow dynamics secondary to lesional and microvasculature conditions. This technology has proven helpful in evaluating individual patients, with respect to prognostication of coronary artery disease and decisions regarding the appropriateness of coronary revascularization (Pijls 2007; Tonino 2009; De Bruyne 2014; van Nunen 2015; Xaplanteris 2018).

Adaptation to CCTA: CCTA has shown utility in the evaluation of stable patients with stable chest pain, typically intermediate pretest probability, warranting non-invasive evaluation (Oberweis 2017; Newby 2015; Williams 2016; Douglas 2015b), as well as in low risk emergency department scenarios (Hulten 2013). Fractional flow reserve using coronary computed tomography angiography is a new technology that seeks to provide an estimation of FFR by non-invasive methodology. Following assessment of quality
CCTA images, in the appropriate subsets of patients with coronary stenoses, the technology makes mathematical assumptions to simulate maximal hyperemia and calculates an estimation of FFR (fractional flow reserve) for those coronary vessels with lesions, based upon the principles of fluid mechanics inherent to the Navier-Stokes Theorem (Taylor 2013).

- **Effort to reduce unnecessary invasive coronary arteriography (ICA):** Since traditional FFR measurement has been performed in conjunction with invasive coronary arteriography (ICA), FFR-CT has been developed with the intention of noninvasively adding hemodynamic information to the anatomic findings on CCTA, with the purpose of safely reducing the frequency of unnecessary ICA procedures, (defined as all ICA lesions < 50%). Such a reduction in ICA by FFR-CT has been suggested, but not rigorously proven, by the clinical trials to date. Its use appears appropriate for stable patients without known CAD (Koo 2011; Min 2011; Norgaard 2014; Douglas 2015a; Douglas 2016; Labounty 2015; Norgaard 2017; Hulten 2016; Hulten 2017). An economic analysis suggested that FFR-CT could reduce cost and improve upon quality of life for some patients (Hlatky 2015), but this might not be an improvement over CCTA alone (Hulten 2016).

- **Current Methodology:** The analysis requires a CCTA scanner with at least a 64-slice capability and good-quality images. At present, the process involves transmitting the CCTA data to an offsite location, where a digital model of coronary anatomy is constructed, and using the CCTA data, FFR is calculated using the above described computational fluid dynamics. In this fashion, a report of estimated FFR for the vessels in question is generated, with the intention of reporting coronary hemodynamic information to the requesting clinician (Hulten 2017).

I. **FFR-CT Results:**

The working assumption is that quantitative estimation of coronary lesional hemodynamic severity using FFR-CT might enable deferral of invasive coronary arteriography when values are above 0.80, since such lesions would not warrant revascularization.

Although FFR-CT measurements appear reproducible (Gaur 2014), there remains concern regarding the accuracy of FFR-CT relative to invasive FFR (Hulten 2015). Aside from excellent reproducibility (Johnson 2015), invasive FFR has a demonstrated track record of favorable outcomes when used in the selection of patients and vessels worthy of PCI (Tonino 2009; De Bruyne 2014; Van Nunen 2015; Xaplanteris 2018). While evidence suggests that FFR-CT might be a better predictor of revascularization or adverse events than severe stenosis alone on CCTA (Lu 2016), the FFR-CT data to date provide no evidence showing that revascularization based upon FFR-CT improves outcomes over invasive angiographic assessment. As a consequence of the above considerations, current revascularization guidelines do not advocate FFR-CT as a surrogate for invasive FFR, although, those guidelines refer to FFR-CT as an “emerging technology” (Patel 2017).

More recently publication of a study on the use of FFR-CT to derive a functional SYNTAX Score in multivessel CAD demonstrated a fair correlation with invasive iFR (instantaneous flow reserve, a reliable variation of FFR). With respect to detection of functionally significant lesions identified on invasive FFR (<=0.80), FFR-CT showed good sensitivity (95%) and negative predictive value (87%), but weak specificity (61%) and positive predictive value (81%), area under the receiver operator curve (ROC) of 0.85. This suggests a possible future role for this technology (Collet 2018).
About this Guideline

Because of the lack of long term outcomes data and flaws in the design of multiple trials, and given the controversy evidenced by numerous editorials and review articles in peer reviewed journals, there is a lack of a formal guideline from any professional society at this time. While endorsed by the British healthcare system, details are lacking for UM purposes (Groves 2017).

Based upon findings in the important PLATFORM trial, for patients who are evaluated initially by non-invasive stress testing, without yet being considered for ICA, CCTA with contingent FFR-CT could be perceived as actually having a similar or higher rate of unnecessary ICA. In addition, PLATFORM did not study the question of whether FFR-CT adds to CCTA alone in preventing ‘unnecessary’ invasive coronary angiography (Hulten 2017; Dewey 2016), although there is some evidence that it might (Lu 2016). In the absence of randomized trials, numerous considerations were based upon a diverse body of literature, in the interest of formulating this de novo guideline (Packard 2016; Min 2017; Hulten 2013; Hulten 2015; Hulten 2016; Hulten 2017).

Calculations of pre and post-test probability

Prior to each non-invasive test there is a pretest probability of finding significant coronary artery disease. The result of a non-invasive test yields a post-test probability, which then becomes the pretest probability for a subsequent non-invasive test. This is helpful when a patient who had a prior stress test is being considered for FFR-CT (Detrano 1984).

The 3 Types of Chest Pain or Discomfort

- **Typical Angina (Definite)** is defined as including all 3 characteristics:
  1) Substernal chest pain or discomfort with characteristic quality and duration
  2) Provoked by exertion or emotional stress
  3) Relieved by rest and/or nitroglycerine

- **Atypical Angina (Probable)** has only 2 of the above characteristics

- **Nonanginal (Nonspecific) Chest Pain/Discomfort** has only 0-1 of the above characteristics

Once the type of chest pain has been established from the medical record, the Pretest Probability of obstructive CAD is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability (Fihn 2012):

1. **Updated Diamond Forrester Pretest Probability Table**, based upon symptoms prior to initial non-invasive testing (Graham 2011):
2. **University of Washington pretest and post-test probability table** (preferred), to determine a pretest probability for patients undergoing FFR-CT subsequent to a prior non-invasive test. The University of Washington Calculator for Pre and Post-test Probability can be found at this address (Linker 2000): [http://faculty.washington.edu/dtlinker/CAD.html](http://faculty.washington.edu/dtlinker/CAD.html)

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<th>Age (years)</th>
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<td>Non-specific chest pain</td>
<td>Atypical chest pain</td>
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<td>BMI</td>
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<td>CCTA</td>
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<td>ESC</td>
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<td>FFR</td>
<td>Fractional Flow Reserve</td>
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<td>FFR-CT</td>
<td>Fractional Flow Reserve derived noninvasively from CCTA</td>
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<td>ICA</td>
<td>Invasive Coronary Arteriography</td>
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<td>Major Adverse Coronary Events</td>
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<td>NPV</td>
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<tr>
<td>Qp/Qx</td>
<td>Pulmonary to Systemic Flow Ratio</td>
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Taylor CA, Fonte TA, Min JK. Computational fluid dynamics applied to cardiac computed tomography for noninvasive quantification of fractional flow reserve: Scientific Basis. *JACC*. 2013; 61:2233–41.


INTRODUCTION:

Magnetic resonance cholangiopancreatography (MRCP) is a non-invasive radiologic technique for imaging the biliary and pancreatic ducts, and it is used to evaluate patients with cholestatic liver function tests, right upper quadrant pain, and recurrent pancreatitis. The MRCP uses magnetic resonance imaging (MRI) to produce detailed pictures of the pancreas, liver and bile ducts. MRCP is reliable for the diagnosis of ductal abnormalities, e.g., pancreas divisum. It is also used to diagnose bile duct stones and assess the level of obstruction. MRCP is especially useful as an alternative to ERCP (Endoscopic retrograde cholangiopancreatography) when a noninvasive exam is desired. Due to the variable accuracy of ultrasound in detecting choledocholithiasis, preoperative MRCP prior to cholecystectomy has been advocated particularly in the setting of acute cholecystitis, near normal common bile duct diameter (where ultrasound is less accurate) and elevated liver functions, especially alanine amino transaminase (ALT).

In diagnosing acute pancreatitis MRI and MRCP are not as practical as CT. The latter can be performed more quickly and provide better images due to less motion artifact (if patient cannot cooperate with instructions for MRI) in acutely ill patients (ACR, 2017). In selected patients who cannot receive iodinated contrast for CT, MRI and MRCP may be considered. Complications of chronic pancreatitis using MRCP are well imaged in cooperative patients.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR MRCP (Akisik, 2013; ACR, 2017; Lindor/ACG, 2015):

- Evaluation of suspected congenital anomaly of the pancreaticobiliary tract, e.g., aberrant ducts, choledochal cysts, pancreas divisum or related complications.
- Evaluation of chronic pancreatitis or related complications (pseudocysts and bile duct strictures).
- Pre-operative evaluation: Prior to surgery or other invasive procedure.
- Post-operative evaluation: For evaluation of suspected biliary abnormalities after surgery or invasive procedure (e.g. bile duct leak, stricture, etc.).
- Further evaluation of inconclusive abnormalities identified on other imaging (ultrasound, CT, or MRD).
- Evaluation of abnormality related to the pancreatic or biliary tree based on symptoms or laboratory findings and initial imaging has been performed or is contraindicated (e.g. renal failure prevents contrast CT or body habitus limits US).
- Evaluation of pancreatobiliary disease in pregnant patients after ultrasound has been done (ACR, 2017).
- As an alternative to CT for evaluating acute pancreatitis when iodinated contrast is contraindicated due to impaired renal function or allergy (ACR, 2017).

ADDITIONAL INFORMATION RELATED TO MRCP:
Ultrasound - Ultrasound is the initial imaging technique used for screening suspected biliary or pancreatic disease, but it has limited ability to characterize abnormalities in the biliary and pancreatic ducts.

Endoscopic retrograde cholangiopancreatography (ERCP) – ERCP can combine diagnosis with therapeutic intervention, e.g., removal of stones, but it is an invasive procedure that carries significant risk of complications, e.g., pancreatitis. ERCP is also technically challenging in patients with post-surgical biliary and/or surgical anastomoses.

Magnetic resonance Cholangiopancreatography (MRCP) – MRCP is a noninvasive method for depicting biliary and pancreatic ducts and assessing the level of obstruction. It is also used to evaluate congenital anomalies of these structures. In clinical practice MRCP is often combined with conventional MRI imaging of the liver and pancreas. MRCP does not require the use of any contrast materials. Unlike ERCP, it does not combine diagnosis with therapeutic intervention. MRCP is not cost effective if the patient will need ERCP mediated intervention after the MRCP. MRCP is preferred over ERCP when a noninvasive examination is needed or when there is a very small likelihood that the patient will need therapeutic intervention afforded by ERCP. Secretin-enhanced MR Cholangiopancreatography has been recently developed to improve the diagnostic quality of MRCP images.

Cystic Pancreatic neoplasms: In the evaluation of cystic neoplasms, MRCP is more sensitive than ERCP in differentiating mural nodules from mucin globules and in studying the duct anatomy, as ERCP quality is negatively affected when intraductal mucin plugs obscure the filling of the pancreatic duct (Cao et al). It also consistently demonstrates the internal architecture of the main duct and the extent of IPMN (Intraductal Papillary Mucinous Neoplasms) better than ERCP. (ACG-GL)

Biliary strictures: Approximately 15% of biliary strictures in the western world are benign. 80% are related to previous surgery, usually an injury during gallbladder surgery. After liver transplantation anastomotic strictures usually develop 3-6 months after surgery. Rare causes of stricture formation include infectious agents such as TB, parasites and viruses. Other etiologies include recurrent pyogenic cholangitis, Mirizzi syndrome with external compression of the bile duct by an inflamed gallbladder, blunt trauma and an even smaller number of strictures of unknown etiology also occur.

PSC (primary sclerosing cholangitis): The American College of Gastroenterology recommends MRCP as the preferred modality over endoscopic retrograde cholangiopancreatography ERCP) to establish a diagnosis of PSC. Liver biopsy to make the diagnosis is reserved for patients with unexplained cholestatic liver function tests and normal cholangiograms suspected of having small duct PSC (Lindor, 2015). Although direct cholangiography is more sensitive, it has been nearly replaced by the non invasive MRCP technique. Neither liver histology nor cholangiography alone will reliably reflect the severity of the disease. They must be used together with symptoms, physical findings, blood tests, and imaging or upper endoscopy tests that indicate the presence and severity of portal hypertension (Griffin, 2012).
REFERENCES


INTRODUCTION:
Smoking-related lung cancer is the leading cause of cancer deaths in both men and women in the United States. Treatment for most lung cancer is focused on surgery which is usually curative only when the tumors are very small. Screening for early lung cancer with sputum cytology and chest x-rays has not been successful in reducing deaths from lung cancer. However, in 2011 a large, prospective, multicenter trial was published that showed CT Chest screening identified early cancers better than other approaches and reduced the death rate from lung cancer. In 2014, the United States Preventive Service Task Force (USPSTF) recommended annual low dose CT Chest screening (CPT code G0297) for people with current or recent past smoking histories.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR LOW DOSE CT FOR LUNG CANCER SCREENING:

For annual lung cancer screening:
The use of low-dose, non-contrast spiral (helical) multi-detector CT imaging as a screening technique for lung cancer is considered medically necessary ONLY when used to screen for lung cancer for certain high-risk, asymptomatic individuals when ALL of the following criteria are met (USPSTF, 2013):

- Individual is between 55-80 years of age; AND
- There is at least a 30 pack-year history of cigarette smoking; AND
- If the individual is a former smoker, that individual had quit smoking within the previous 15 years.

ADDITIONAL INFORMATION:
Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.

REFERENCES
CPT Codes: S8042

IMPORTANT NOTE:

Low Field MRI services are not considered to be medically necessary, are not approvable for payment, and cannot be approved.

ADDITIONAL INFORMATION:

MRI scanners with a field strength of greater than 1.0 Tesla (T) are considered high field. The typical high field MRI units in clinical practice range between 1.0 – 3.0 Tesla. In October 2017 the FDA cleared the first 7 T MRI units. The definition of mid and low field MRI is more variable with mid field units having a lower field strength range of 0.3 to 0.5 and an upper limit under 1.0 T. Low field units have field strengths below 0.3 to 0.2 T. The major disadvantage of low field strength MRI relative to higher field scanners is lower signal to noise ratios, less homogeneity in the magnetic field, lower detection of calcification, hemorrhage or gadolinium enhancement. Lee et al showed that low field (<0.5 T) units were effective in evaluating medial meniscal, anterior cruciate ligament, and rotator cuff tears but not effective for evaluating lateral meniscal tears, osteochondral defects, or shoulder superior labrum-anterior posterior (SLAP) ligament complex pathology (Lee 2013, 2014).
REFERENCES


EXPANDED CARDIAC GUIDELINES

33225 – Cardiac Resynchronization Therapy (CRT)

CPT Codes: 33221, 33224, 33225, 33231

INTRODUCTION

(Epstein 2012; Brignole 2013; Russo 2013; Yancy 2013; Ponikowski 2016)

➢ Cardiac resynchronization therapy (CRT), which paces two ventricular sites in rapid sequence, also known as biventricular pacing, improves coordination of ventricular contraction in the presence of a wide QRS complex in the setting of systolic heart failure.

➢ CRT improves cardiac function and quality of life, and it decreases cardiac events and mortality among appropriately chosen patients. The improved survival in patients with CRT is greater than that provided by ICD insertion alone.

➢ Guiding principles in the consideration of CRT:

  • NYHA class is an important qualifying factor, with candidacy ranging from New York Heart Association (NYHA) class I to ambulatory NYHA class IV (See Additional information for NYHA class descriptions)

  • Bundle branch block/intraventricular conduction delay should be persistent, not rate-related (Russo 2013)

  • Guideline directed medical therapy (GDMT) should have been in place continuously for at least 3 months (Epstein 2012; Yancy 2013; Ponikowski 2016), unless a non-elective permanent pacemaker and/or ICD is indicated prior to completion of the 3 months, and CRT would have been likely required even after 3 months of GDMT. Otherwise, recovery of left ventricular ejection fraction (LVEF) from myocardial infarction (40 days) and reversible causes (e.g. ischemia) should be allowed (Katsumoto 2014; Marine 2018) (See Additional Information section regarding GDMT definition).

  • The patient should have expected survival with reasonably good functional status for more than a year (Epstein 2012; Ponikowski 2016; Hernandez-Madrid 2018; Khairy 2014).

  • If CRT is indicated, use of an ICD with CRT should be considered (Epstein 2012), and biventricular pacing should occur nearly 100% the time (Yancy 2013, Ponikowski 2016).

  • There are no accepted guidelines for CRT in the pediatric population (Motonaga 2014). Available guidelines are extensions of adult indications.

  • Elective CRT generator replacement indicators support generator change (Russo 2013).
**Indications for Cardiac Resynchronization Therapy (CRT)**

( Epstein 2012; Brignole 2013; Yancy 2013; Ponikowski 2016; Russo 2013; Adelstein 2018)

- LVEF $\leq 35\%$, sinus rhythm, left bundle branch block (LBBB) with a QRS $\geq 130$ ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT (guideline-directed medical therapy) (Ponikowski 2016; Adelstein 2018).
- LVEF $\leq 35\%$, sinus rhythm, a non-LBBB pattern with a QRS duration $\geq 130$ ms, and NYHA III or ambulatory class IV symptoms on GDMT (Epstein 2012; Yancy 2013; Ponikowski 2016).
- Atrial fibrillation and LVEF $\leq 35\%$ on GDMT if:
  1. the patient requires ventricular pacing or otherwise meets CRT criteria (as with sinus rhythm)
  2. AV nodal ablation or pharmacologic rate control allows nearly 100% ventricular pacing with CRT, or else the patient is expected to return to sinus rhythm (Yancy 2013).
- LVEF $< 50\%$ with heart failure (HF) on GDMT, regardless of NYHA class, when patient will require new ventricular pacing that would be $\geq 40\%$ (Brignole 2013; Yancy 2013; Ponikowski 2016; Adelstein 2018; Curtis 2013)
- LVEF $< 50\%$ with HF, with worsening HF, despite GDMT, subsequent to implantation of a conventional pacemaker or ICD that is pacing $\geq 40\%$ (Ponikowski 201; Adelstein 2018; Curtis 2013)
- LVEF $\leq 30\%$, ischemic etiology of HF, sinus rhythm, LBBB with a QRS duration $\geq 150$ ms, and NYHA class I symptoms on GDMT
- LVEF $< 35\%$, sinus rhythm, a non-LBBB pattern with a QRS duration $\geq 150$ ms, and NYHA class II on GDMT

**NOT Indications for Cardiac Resynchronization Therapy (CRT)**

- NYHA class I or II symptoms and non-LBBB pattern with QRS duration $< 150$ ms (Epstein 2012)
- Comorbidities and/or frailty expected to limit survival with good functional capacity to $< 1$ year.

**Indications for CRT in Adult Congenital Heart Disease**

(Hernandez-Madrid 2018; Khairy 2014)

- Systemic LVEF $\leq 35\%$, sinus rhythm, wide QRS complex $\geq 120$ ms with complete left bundle branch block QRS morphology (spontaneous or paced) and NYHA function Class II—ambulatory IV.
- Systemic ventricle, regardless of ejection fraction (EF), intrinsic narrow QRS complex, NYHA function Class I—ambulatory IV and undergoing new device placement or replacement with anticipated requirement for significant ($\geq 40\%$) ventricular pacing (single site pacing from the systemic ventricular apex or mid-lateral wall may be considered as alternative).
- Systemic right ventricle (RV) with an EF $\leq 35\%$, NYHA function Class II—ambulatory IV, and wide QRS complex $\geq 150$ ms with a complete right bundle branch block QRS morphology (spontaneous or paced).
- Single ventricle with an EF $\leq 35\%$, NYHA function Class II—ambulatory IV and wide QRS complex $\geq 150$ ms due to intraventricular conduction delay causing either a complete right or left bundle branch block QRS morphology (spontaneous or paced).
- Systemic RV with an EF $\geq 35\%$, **sinus rhythm**, wide QRS complex (120—149 ms) with complete right bundle branch block QRS morphology (spontaneous or paced) and NYHA function Class II—ambulatory IV (Hernandez-Madrid 2018).
• Single ventricle with an EF ≥ 35%, **sinus rhythm**, wide QRS complex (120–149 ms) due to intraventricular conduction delay causing either a complete right or left bundle branch block QRS morphology (spontaneous or paced) and NYHA function Class II—ambulatory IV (Hernandez-Madrid 2018).

• Cardiac surgery (especially if thoracotomy access is needed for lead implantation) with an intrinsic or paced QRS duration ≥ 150 ms, complete bundle branch block morphology ipsilateral to the systemic ventricle (left or right), NYHA class I - ambulatory IV, and progressive systolic systemic ventricular dysfunction and/or dilatation or expectation of such development regardless of the ejection fraction value, especially if epicardial access is required to implement CRT.

• Systemic RV and significant tricuspid valve regurgitation without a specific EF limit, NYHA function Class I—ambulatory IV, wide QRS complex ≥ 150 ms with a complete right bundle branch block QRS morphology (spontaneous or paced) undergoing surgery for significant tricuspid valve regurgitation.

• Severe subpulmonary RV dysfunction and dilatation despite interventions to decrease RV volume overload (as in Tetralogy of Fallot), NYHA function Class II—ambulatory IV and wide QRS complex > 150 ms due to a complete right bundle branch block.

• Selected adults with CHD, NYHA class IV, and severe systemic ventricular dysfunction in an attempt to delay or avert cardiac transplantation or mechanical support.

### NOT an Indication for CRT in Adult Congenital Heart Disease

- CRT is not indicated in patients with a narrow QRS complex (<120 ms) without major electrical activation delay within the failing ventricle.
- CRT is not indicated for patients whose co-morbidities and/or frailty limit survival with good functional capacity to less than 1 year.

### Exemption for < 3 Months GDMT

**Indications for CRT as the Appropriate Pacing Modality in Special Situations**
(Marine 2018; Katsumoto 2014; Russo 2013)

- Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or a non-elective pacemaker, either initial or replacement, and based upon the low likelihood of improvement in symptoms and adequate recovery of LVEF, despite less than 3 months GDMT for heart failure or < 40 days post myocardial infarction, criteria for CRT are otherwise met.*

*Based on ICD status, in a setting that would warrant CRT as the appropriate pacing modality. This enables avoidance of a second implantation procedure within less than 3 months.

### ADDITIONAL INFORMATION

#### NYHA Class Definitions
(Russo 2013; Colucci 2018)

- **Class I**: No limitation of functional activity or only at levels of exertion that would limit normal individuals (patient can carry 24 pounds up 8 stairs, play basketball, and shovel soil).
- **Class II**: Slight limitation of activity. Fatigue, palpitation, or dyspnea with moderate exercise (patient able to dance, garden, walk 4 MPH on level ground, and have sexual intercourse).
- **Class III**: Marked limitation of activity. Fatigue, palpitation, or dyspnea with minimal activity (patient able to shower, make bed, bowl or golf, dress, and walk 2.5 MPH on level).
• Class IV: Severe limitation of activity. Symptoms even at rest, worse with activity (patient unable to comfortably perform any significant activity).
• Ambulatory Class IV: Class IV heart failure with:
  - no active acute coronary syndrome,
  - no inotropes, AND
  - on GDMT.

**Heart Block Definitions**  
(Epstein 2012)

• First Degree: All atrial beats are conducted to the ventricles, but with a delay of > 200 ms.
• Second Degree: Intermittent failure of conduction of single beats from atrium to ventricles.
  - Type I: Conducted beats have variable conduction times from atrium to ventricles.
  - Type II: Conducted beats have uniform conduction times from atrium to ventricles.
  - Advanced: Two or more consecutive non-conducted beats (premature atrial beats might not normally be conducted).
• Third Degree: No atrial beats are conducted from atrium to ventricle

**Guideline Directed (or Optimal) Medical Therapy in Heart Failure**  
(Yancy 2013; Yancy 2017)

  - Angiotensin converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
  - Beta blocker (might be less critical in permanent atrial fibrillation, still recommended) (Kotecha 2017)
  - Addition of loop diuretic for all NYHA class II – IV patients
  - Addition of hydralazine and nitrate for persistently symptomatic African Americans
  - Addition of an aldosterone antagonist, provided eGFR is > 30 ml/min and K+ < 5.0
  - Not required for consideration of CRT: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm. Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of ivabradine.
<table>
<thead>
<tr>
<th>Age group</th>
<th>Respiratory rate</th>
<th>Heart rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (1st-99th percentile)</td>
<td>Median (1st-99th percentile)</td>
</tr>
<tr>
<td>0 to 3 months</td>
<td>43 (25-66)</td>
<td>143 (107-181); term newborn at birth: 127 (90-164)</td>
</tr>
<tr>
<td>3 to 6 months</td>
<td>41 (24-64)</td>
<td>140 (104-175)</td>
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<tr>
<td>6 to 9 months</td>
<td>39 (23-61)</td>
<td>134 (98-168)</td>
</tr>
<tr>
<td>9 to 12 months</td>
<td>37 (22-58)</td>
<td>128 (93-161)</td>
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<tr>
<td>12 to 18 months</td>
<td>35 (21-53)</td>
<td>123 (88-156)</td>
</tr>
<tr>
<td>18 to 24 months</td>
<td>31 (19-46)</td>
<td>116 (82-149)</td>
</tr>
<tr>
<td>2 to 3 years</td>
<td>28 (18-38)</td>
<td>110 (76-142)</td>
</tr>
<tr>
<td>3 to 4 years</td>
<td>25 (17-33)</td>
<td>104 (70-136)</td>
</tr>
<tr>
<td>4 to 6 years</td>
<td>23 (17-29)</td>
<td>98 (65-131)</td>
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<tr>
<td>6 to 8 years</td>
<td>21 (16-27)</td>
<td>91 (59-123)</td>
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<tr>
<td>8 to 12 years</td>
<td>19 (14-25)</td>
<td>84 (52-115)</td>
</tr>
<tr>
<td>12 to 15 years</td>
<td>18 (12-23)</td>
<td>78 (47-108)</td>
</tr>
<tr>
<td>15 to 18 years</td>
<td>16 (11-22)</td>
<td>73 (43-104)</td>
</tr>
</tbody>
</table>

* The respiratory and heart rates provided are based upon measurements in awake, healthy infants and children at rest. Many clinical findings besides the actual vital sign measurement must be taken into account when determining whether a specific vital sign is normal in an individual patient. Values for heart rate or respiratory rate that fall within normal limits for age may still represent abnormal findings that are caused by underlying disease in a particular infant or child (Fleming 2011; Fleegler, 2018).
**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE-I</td>
<td>Angiotensin converting enzyme inhibitor</td>
</tr>
<tr>
<td>ARNI</td>
<td>combined angiotensin receptor inhibitor and neprilysin inhibitor</td>
</tr>
<tr>
<td>AV</td>
<td>Atrioventricular</td>
</tr>
<tr>
<td>CAD</td>
<td>Coronary artery disease, same as ischemic heart disease</td>
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<tr>
<td>CHF</td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>CRT</td>
<td>Cardiac resynchronization therapy (also known as biventricular pacing)</td>
</tr>
<tr>
<td>CHD</td>
<td>Congenital heart disease</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<tr>
<td>eGFR</td>
<td>Estimated glomerular filtration rate</td>
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<tr>
<td>EPS</td>
<td>Electrophysiologic Study</td>
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<tr>
<td>GDMT</td>
<td>Guideline-Directed Medical Therapy</td>
</tr>
<tr>
<td>HF</td>
<td>Heart Failure</td>
</tr>
<tr>
<td>HRS</td>
<td>Heart Rhythm Society</td>
</tr>
<tr>
<td>HV</td>
<td>His-ventricular</td>
</tr>
<tr>
<td>ICD</td>
<td>Implantable cardioverter-defibrillator</td>
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<tr>
<td>LBBB</td>
<td>left bundle-branch block</td>
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<tr>
<td>LV</td>
<td>Left ventricular/left ventricle</td>
</tr>
<tr>
<td>LVEF</td>
<td>Left ventricular ejection fraction</td>
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<tr>
<td>MI</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>ms</td>
<td>milliseonds</td>
</tr>
<tr>
<td>NYHA</td>
<td>New York Heart Association</td>
</tr>
<tr>
<td>STEMI</td>
<td>ST-elevation Myocardial Infarction</td>
</tr>
<tr>
<td>SND</td>
<td>Sinus node dysfunction</td>
</tr>
<tr>
<td>VT</td>
<td>Ventricular tachycardia</td>
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</tbody>
</table>
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CPT Codes: 33230, 33240, 33249, 33262, 33263

INTRODUCTION

(The-Khatib 2017; Priori 2015; Ganz 2018; Russo 2013; Epstein 2012; Yancy 2013; Ponikowski 2016; Shen 2017)

➢ The implantable cardioverter defibrillator (ICD) has become valuable in the management of patients with ventricular arrhythmias (VA) capable of causing syncope, cardiac arrest, and sudden cardiac death (SCD), in either one of two scenarios:
  o Secondary prevention of SCD due to previous ventricular arrhythmic events
  o Primary prevention in patients at high risk for SCD due to ventricular arrhythmia

➢ Patient eligibility for an ICD presumes all of the following:
  o Anticipated reasonable quality of life for ≥ 1 year post implantation, with consideration of age and comorbidities, although age alone is not a contraindication (Katsumoto 2017)
  o Patient’s ability to live with a shock-delivering device that requires management
  o Absence of a completely reversible cause that led to VA for which an ICD is being considered (see Additional Information section on reversible causes) (Marine 2018a)
  o Completion of ≥ 3 months of guideline directed medical therapy (GDMT) for heart failure (HF) in most, but not all, cases of primary prevention, unless a supervening indication for non-elective pacemaker implantation or ICD generator replacement arises (to avoid second implantation procedure) (see Additional Information section for definition of GDMT)
  o ICD indications are present in the vast majority of scenarios in which cardiac resynchronization therapy (CRT) is appropriate
  o Sustained VT is defined as having duration > 30 seconds or requiring termination due to hemodynamic compromise in < 30 seconds
  o Elective replacement indicators support generator change if there is anticipated reasonable quality of life for ≥ 1 year (issues pertaining to reduction in VA risk associated with improved LVEF and/or absence of VA remain unresolved) (Al-Khatib 2017; Russo 2013)

➢ Guidelines for the pediatric population are extrapolated from the adult population, due to a lack of relevant trials (Brugada 2013; Priori 2015)

INDICATIONS FOR ICD INSERTION

(The-Khatib 2017; Priori 2015; Ganz 2018; Russo 2013; Epstein 2012; Yancy 2013; Ponikowski 2016; Shen 2017)

General, Secondary Prevention of VT/VT/SCA

(The-Khatib 2017; Priori 2015; Ganz 2018)
- Patients with ventricular fibrillation (VF) or hemodynamically non-tolerated ventricular tachycardia (VT) after evaluation of etiology of event and exclusion of completely reversible causes (e.g. occurrence of myocardial infarction < 48 hours ago can often be considered a completely reversible cause; also see Ischemic Heart Disease section below) (O’Gara 2013).
- Spontaneous VT lasting > 30 seconds in patients with structural or ischemic heart disease (CAD) or with channelopathies, whether hemodynamically stable or unstable (Ganz 2018).
- Post resuscitation from sudden cardiac arrest due to coronary artery spasm (Montalescot 2013).

**Ischemic Heart Disease (CAD)**
(Al-Khatib 2017, Priori 2015, Ganz 2018, Russo 2013)

- Sustained VT (> 30 s or with hemodynamic non-tolerance)
- Syncope of undetermined origin, in ischemic heart disease or with prior myocardial infarction (MI), with either one of:
  - hemodynamically significant sustained monomorphic VT induced at electrophysiological study
  - LVEF ≤35%
- LVEF ≤35% due to ischemic heart disease or prior MI, NYHA class II or III, despite GDMT, and at least 40 days post-MI and at least 90 days post-revascularization
- LVEF ≤30% due to ischemic heart disease or prior MI, NYHA class I despite GDMT, and at least 40 days post-MI and at least 90 days post-revascularization (Al-Khatib 2017; Ganz 2018; Russo 2013)
- Non-sustained VT due to prior MI, LVEF ≤40%, and inducible sustained VT or inducible VF at electrophysiological study. Non-sustained ventricular tachycardia (NSVT) should have been ≥4 full days post MI or post coronary revascularization (Russo 2013)
- Newly found LVEF < 50% with VF or polymorphic VT < 48 hours post MI, NSVT ≥4 days later, and inducible VT or VF ≥4 days post complete coronary revascularization (Russo 2013)
- Newly found LVEF ≤35% with VF or polymorphic VT < 48 hours post MI, and not amenable to complete coronary revascularization (Russo 2013)
- VF or hemodynamically unstable VT < 48 hours following elective coronary revascularization, without evidence of acute coronary occlusion, provoking infarct, or any other clearly reversible cause (Russo 2013)

**Nonischemic cardiomyopathy (NICM)**
(Al-Khatib 2017)

- Sustained VT (> 30 s or with hemodynamic non-tolerance)
- Syncope in NICM (nonischemic cardiomyopathy) that is presumed to be due to ventricular arrhythmia, given the weak correlation between VT or VF inducibility and mortality
- NICM with LVEF ≤35% and NYHA functional Class I, II, or III, despite GDMT, and at least 90 days (or 3 months) after diagnosis of dilated cardiomyopathy (DCM).
- NICM due to a Lamin A/C mutation, who have ≥2 risk factors from the following list:
  a. NSVT
  b. LVEF < 45%
  c. Nonmissense mutation
d. male sex

- In borderline uncertain indications for ICD in NICM, late gadolinium enhancement on cardiovascular magnetic resonance (CMR) provides evidence of mid wall fibrosis, indicating a higher risk for cardiac arrest and SCD. (Al-Khatib 2017; Halliday 2017; Kuruvilla 2014)
- Peripartum cardiomyopathy with LVEF ≤ 35% that persists > 3 months postpartum despite 3 months of GDMT. (Russo 2013)
- Familial dilated cardiomyopathy with LVEF > 35%, with family history associated with SCD OR with a LMNA mutation (Russo 2013; Hershberger 2018)

**Advanced Heart Failure & Transplantation**
(Al-Khatib 2017; Priori 2015)

- **In NYHA class IV and/or using inotropes**, awaiting transplantation or an LVAD, either non-hospitalized or planning imminent discharge, without other qualifying ICD criteria met (Al-Khatib 2017; Priori 2015; Russo 2013)
- **In a patient with an LVAD**, sustained ventricular arrhythmias (Al-Khatib 2017)
- **Severe allograft vasculopathy**, with severe LV dysfunction, with expected survival ≥1 year (Al-Khatib 2017)
- In NYHA ambulatory class IV, with appropriately indicated CRT implantation (see Additional Information section for definition of ambulatory NYHA class IV)

**Myocardial Diseases**

- **Giant cell myocarditis** with (Al-Khatib 2017; Priori 2015):
  a. VF or hemodynamically unstable VT, even if early in the course, OR
  b. Requires a pacemaker

- **Chronic Chagas cardiomyopathy** for one of the following (Priori 2015; Marin-Neto 2018):
  a. Cardiac arrest or sustained VT
  b. Ejection fraction < 40%

- **Cardiac Sarcoidosis** for one of the following (Al-Khatib 2017; Shen 2017; Priori 2015):
  a. Sustained VT or sudden cardiac arrest, even if early in the course
  b. LVEF ≤ 35%
  c. LVEF > 35% with inducible sustained ventricular arrhythmia
  d. Syncope
  e. Scar on CMR or positron emission tomography (PET)
  f. Require a permanent pacemaker, even if transient (Blankstein 2018)

- **Neuromuscular Disorders** for one of the following (Al-Khatib 2017):
  o Primary and secondary prevention as for NICM (Priori 2016)
  o Emery-Dreifuss or limb-girdle type I-B muscular dystrophy with progressive cardiac muscle involvement
  o Type 1 myotonic dystrophy (Steinert Disease) with an indication for a permanent pacemaker

- **Hypertrophic cardiomyopathy** (HCM) with ≥ 1 major risk factors for SCD (Al-Khatib 2017; Maron 2018; Shen 2017; Epstein 2012):
  a. Prior sudden cardiac arrest (SCA) due to VT or VF
b. Sustained VT with syncope or hemodynamic compromise

c. Maximum LV wall thickness ≥ 30 mm

d. SCD ≥ 1 first degree relatives, presumably caused by HCM

e. ≥ 1 episodes of unexplained syncope within the preceding 6 months

f. NSVT

g. Abnormal BP response to exercise in patients < 40 yr
   i. BP rise < 20 mm Hg or fall of > 20 from exercise peak during ongoing exercise

h. Borderline evidence of the above risk factors plus one of the following:
   i. End stage HCM with LVEF < 50%
   ii. Left ventricular apical aneurysm
   iii. age < 30 years old
   iv. Late gadolinium enhancement on CMR ≥ 15%
   v. Marked left ventricular outflow tract (LVOT) gradient (at least ≥ 50 mm Hg peak at rest)
   vi. Syncope > 5 years ago

i. Only if the above method is not helpful, the ESC HCM Risk-SCD Calculator can be used, according to the limitations on the web page (O’Mahoney 2017): Available at: [http://www.doc2do.com/hcm/webHCM.html](http://www.doc2do.com/hcm/webHCM.html)

**Arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C)** and ≥ 1 of the following risk factors for SCD:
(Al-Khatib 2017; Shen 2017; McKenna 2018; Calkins 2017; Epstein 2012)

a. Resuscitated cardiac arrest

b. Sustained VT

c. Right or left ventricular ejection fraction < 35%

d. Syncope with documented or presumed/suspected ventricular arrhythmia

e. Electrocardiographic abnormalities such as any one of the following:
   i. T wave inversion in V1 to V3 during sinus rhythm
   ii. Frequent premature ventricular contractions (PVCs) (e.g. > 30/hour)
   iii. Nonsustained VT
   iv. Positive electrophysiologic study (EPS) for sustained VT
   v. High risk genotypes or multiple mutations

   o Borderline evidence of the above risk factors plus one of the following:
     i. male sex
     ii. extensive/severe involvement/dilation of the right or left ventricle
     iii. continued vigorous exertion

**Channelopathies**

- **Congenital long QT syndrome** with one of the following (Al-Khatib 2017; Zimethaum 2018; Priori 2015; Goldenberg 2008; Schwartz 2012; Epstein 2012; Schwartz 2012) [Diagnosis based upon the Schwartz score, if in question (see Additional Information section) (Schwartz 2011; Schwartz 2018)]:
  o Cardiac arrest
  o Sustained VT or recurrent syncope despite optimal beta blocker (or with beta blocker intolerance/noncompliance)
  o QTc > 500 ms on a beta blocker (Al-Khatib 2017)
  o Jervell and Lange-Nielson syndrome
  o Strong family history of SCD
• High risk genotype

- **Brugada syndrome** with one of the following:
  (Al-Khatib 2017; Priori 2015; Katsumoto 2017; Epstein 2012)
  a. Cardiac arrest
  b. Sustained ventricular arrhythmia
  c. Syncope with a spontaneous Brugada type I electrocardiogram (ECG)

- **Catecholaminergic polymorphic VT** with one of the following (Al-Khatib 2017; Buxton 2018; Epstein 2012; Russo 2013):
  a. Cardiac arrest
  b. Syncope or sustained VT while receiving optimal dosing of beta blockers
  c. Inducible VT or VF

- **Early Repolarization or Short QT Syndrome** with one of the following (Al-Khatib 2017; Priori 2015):
  a. Cardiac arrest
  b. Sustained ventricular arrhythmia

- **Idiopathic Polymorphic VT/VF** with one of the following (Al-Khatib 2017):
  a. Cardiac arrest due to polymorphic VT or VF
  b. Idiopathic VF (Russo 2013; Priori 2015)
  c. First degree relative with SCD (Russo 2013)

**Miscellaneous**

- **Unexplained syncope following appropriate thorough evaluation** with one of the following:
  a. Advanced structural heart disease (Epstein 2012)
  b. Hypertensive heart disease with LVH and LVEF ≤ 35% (Russo 2013)

**Adult & Pediatric Congenital (Structural) Heart Disease (ACHD)**
  Main references: (Khairy 2014; Hernandez-Madrid 2018)
  Secondary references: (Al-Khatib 2017; Priori 2015; Brugada 2013; Shen 2017)

- Cardiac arrest due to VF or hemodynamically unstable VT after evaluation to define the cause of the event and exclusion of a completely reversible etiology.

- Spontaneous symptomatic sustained VT, after undergoing hemodynamic and EP evaluation (hemodynamics impact arrhythmia risk and require optimization). Catheter ablation or surgery may offer a reasonable alternative or adjunct to ICD.

- Systemic LVEF ≤ 35%, biventricular physiology, and NYHA class II or III on GDMT.

- Tetralogy of Fallot with one of the following (Al-Khatib 2017; Shen 2017):
  o Spontaneous sustained VT
  o Inducible monomorphic or polymorphic sustained VT or VF
  o Multiple risks from the following list:
    ▪ Left ventricular dysfunction
    ▪ NSVT
    ▪ QRS duration ≥ 180 ms
• Extensive right ventricular scarring

Single or systemic right ventricular ejection fraction (RVEF) < 35%, in the presence of an additional risk factor such as:
  o NSVT
  o Unexplained syncope
  o NYHA class II or III, despite GDMT (Al-Khatib 2017; Priori 2015)
  o QRS duration ≥ 140 ms
  o Severe systemic AV valve regurgitation

Syncope of unknown origin in the presence of either advanced ventricular dysfunction (EF < 35%) or marked hypertrophy or inducible sustained VT or VF (Al-Khatib 2017; Shen 2017)

Syncope and moderate or complex congenital heart disease (CHD), with high clinical suspicion of ventricular arrhythmia despite thorough invasive and non-invasive evaluation not defining a cause

Non-hospitalized patients with CHD awaiting heart transplantation

Left ventricular noncompaction that meets same indications as NICM, including a familial history of SCD (Connolly 2018; Russo 2018).

ICD NOT Recommended in CHD

Patients with less than 1 year of expected survival, even if they otherwise meet ICD implantation criteria. Incessant VT or VF.

Significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up.

NYHA Class IV symptoms with drug-refractory congestive heart failure and who are not eligible for cardiac transplantation, ventricular assist device, or cardiac resynchronization therapy defibrillator (CRT-D).

Advanced pulmonary vascular disease/Eisenmenger syndrome - generally not considered candidates for ICD therapy.

Exemptions

Indications for ICD with an Appropriate Pacing Modality in Special Situations

(Marine 2018b; Katsumoto 2014; Russo 2013) *

• ICD criteria met, and elevated troponin is deemed to not be due to a myocardial infarction (although troponin elevation can also be secondary to VT or VF, requiring judgment) (Al-Khatib 2017).
• ICD criteria met, except for myocardial infarction within 40 days or revascularization within 3 months, but a non-elective permanent pacemaker (new or replacement) is required, and recovery of left ventricular function to LVEF > 35% is uncertain or not expected (Russo 2013).**
• ICD criteria met, except NICM or ischemic cardiomyopathy has not had 3 months’ time for LVEF to improve on medical therapy, a non-elective permanent pacemaker is required, and recovery of LVEF is uncertain or not expected.**
• Pre-existing ICD (with or without pre-existing CRT) requiring non-elective generator replacement within <40 days post myocardial infarction or < 3 months post revascularization restrictions.**
• Patient met primary prevention criteria for an ICD prior to coronary revascularization, and it is unlikely that LVEF will recover to > 35% despite a 90 day wait (Katsumoto 2014).
• Listed for transplantation or received a LVAD within 3 months of revascularization, but not within 40 days of myocardial infarction (Katsumoto 2014).

* With these ICD indications, CRT would sometimes be the appropriate pacing modality. CRT is highly likely to be the appropriate modality when > 40% rhythm requires pacing.
** These indications enable avoidance of a second implantation procedure within less than 3 months.

ADDITIONAL INFORMATION

General
(Al-Khatib 2017; Priori 2015; Ganz 2018; Russo 2013; Epstein 2012; Yancy 2013; Ponikowski 2016; Shen 2017)

Implantable cardioverter defibrillators (ICDs) are indicated for the treatment of life-threatening ventricular tachycardia and ventricular fibrillation. An ICD system includes a pulse generator and one or more leads. ICDs are indicated both for patients who have survived life threatening rhythm disturbances (secondary prevention) and for those who are at risk for them (primary prevention).

• An ICD continually monitors heart rhythm. If a rapid rhythm is detected, the device delivers electrical therapy directly to the heart muscle in order to terminate the rapid rhythm and restore a normal heart rhythm. There are two types of therapy that can be delivered:
  o Rapid pacing, which is painless, is often effective in terminating ventricular tachycardia.
  o High-voltage shocks, which are painful to the patient, are necessary for ventricular fibrillation and also for instances where rapid pacing has failed to correct ventricular tachycardia.

• In addition, all ICDs have pacing capability, and they deliver pacing therapy for slow heart rhythms (bradycardia).

• The parameters defining limits for pacing therapy and for tachycardia therapy are programmable using noninvasive radio signals on all available ICDs.

• Waiting Period is an important issue in the timing of ICD insertion for primary prevention. This has resulted from guidelines and payment policies, predominantly on the part of CMS, which mirror the inclusion criteria of published primary and secondary prevention trials. For example, most primary prevention trials have excluded patients with recent coronary revascularization (under 3 months or 90 days) or recent myocardial infarction (under 40 days). Studies of patients who have received ICDs early after myocardial infarction have not demonstrated a mortality benefit.
  o Most guidelines recommend waiting periods that are reasonable and appropriate, but there are certain clinical scenarios in which exemptions might be required. For example, a patient with a longstanding cardiomyopathy, who is a candidate for an ICD, might have a small non-revascularized non-ST-elevation myocardial infarction (STEMI). This patient’s LVEF will certainly not improve over the next 40 days, and withholding an ICD makes little sense.
  o This scenario would be rendered even more problematic if the patient required a non-elective pacemaker, since waiting 40 days post myocardial infarction to upgrade a pacemaker to an ICD would subject the patient (and payer) to two procedures instead of one. Therefore, these guidelines adhere to the current waiting periods but also provide an opportunity to request exemptions where patient benefit is clearly documented (see “Exemptions” section above).

Reversible Causes of Ventricular Arrhythmia
(Marine 2018a)
In some survivors of SCA or sustained VT, a transient or reversible cause (e.g. acute myocardial ischemia, electrolyte disturbances, medication-related proarrhythmia) can be identified which is thought to have been the cause. Initial treatment should be directed at the underlying disorder. However, prior to concluding that the VA was entirely due to a reversible cause, a thorough evaluation should be performed, for which electrophysiologic consultation might be required. As opposed to completely reversible causes, a reversible condition might be only a precipitant of ventricular arrhythmia in a patient who is otherwise predisposed and therefore considered high risk for recurrence, especially in the context of possible recurrence of precipitating factors. A prime example is a patient who presents with VF and is found to have mild hypokalemia, in which case it is generally not appropriate to assign the entirety of the cause of the ventricular arrhythmia to the low potassium level alone.

Correction of a reversible cause of SCA or sustained VT is most likely to be adequate in one of several settings:

- **Polymorphic VT or VF that is preceded by clear evidence of myocardial ischemia or acute myocardial infarction within the past 48 hours** - In such cases, revascularization is often adequate for the purpose of reducing the risk of SCD. However, some of these patients will later qualify for a primary prevention ICD due to severe left ventricular systolic dysfunction or HF. Guideline-directed medical therapy should be applied, and follow-up evaluation with a cardiologist soon after discharge should be arranged for additional risk stratification. A repeat evaluation of LV function is recommended >40 days post-MI and >90 days after revascularization to determine if the patient qualifies for ICD implantation based on consideration for primary prevention indications.

An important caveat is that **sustained monomorphic VT** in the setting of prior myocardial infarction is typically due to scar-related (substrate) re-entry and is not due to the occurrence of ischemia. Thus, in patients with stable CAD and sustained monomorphic VT, coronary revascularization alone is considered an ineffective therapy to prevent such recurrent VT.

- **Polymorphic VT in the setting of acquired QT prolongation** - Withdrawal of the offending drug and avoidance of other QT prolonging medications may be adequate to reduce the risk of SCD.

- **VF in the setting of Wolff-Parkinson-White syndrome in patients with a structurally normal heart** – These patients are adequately treated with catheter ablation of the accessory pathway.

- **Idiopathic monomorphic VT in the setting of a structurally normal heart** – Such patients are usually adequately treated with medical therapy or catheter ablation (see VA in Structurally Normal Hearts, below).

- **VT/VF occurring in the setting of drug overdose** – Examples include cocaine, amphetamines, digoxin, tricyclic antidepressants, and antiarrhythmic drugs.

In **most other cases**, life-threatening ventricular arrhythmias should **not** be attributed solely to a reversible disorder, and patients should be managed according to guidelines for secondary prevention.

**Ventricular Arrhythmias in Structurally Normal Hearts**

Sustained VT is uncommon in patients with structurally normal hearts. In patients with structurally normal hearts, an ICD is generally **not** recommended in patients with monomorphic VT. When there are substantial symptoms (or adverse effect on LVEF or sustained VT) these patients can be treated with medical therapy or, more often, catheter ablation. An ICD would not be required since the risk of sudden cardiac death is typically low, especially following successful catheter ablation (e.g. atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, RV or LV outflow tract VT, idiopathic VT, or...
fascicular VT in the absence of structural heart disease) (Ganz 2018; Al-Khatib 2017; Dukkipati 2017a; Callans 2018).

Reduced LVEF deemed solely due to a high burden of ventricular ectopy (PVCs, VT), comprising > 10% of QRS complexes, is considered a reversible cause for the reduced LVEF. When ablation can eradicate the ventricular ectopy and restore LVEF > 35%, an ICD would not be indicated; it should be considered if the LVEF remains ≤ 35% (Dukkipati a&b 2017).

Some polymorphic VT or VF in structurally normal hearts can be treated with ablation of the triggering PVC, e.g. catecholaminergic polymorphic VT/VF, idiopathic VF, Congenital Long QT Syndrome, Brugada Syndrome, and Early Repolarization Syndrome. In Brugada patients, the substrate of the VF can often be ablated by an epicardial approach. Generally, an ICD is still required in this group of patients with polymorphic VT or VF (given the complexity, any decision to avoid an ICD implant following such potential VA cures by ablation in structurally normal hearts is beyond the scope of this guideline) (Dukkipati a&b 2017).

**Wearable Cardioverter Defibrillator (WCD)**

The WCD will require additional clinical trials to determine its optimal place in the treatment of ventricular arrhythmia, since to date, only one randomized clinical trial, VEST, had been presented orally at the American College of Cardiology meeting in March, 2018. The WCD is addressed in a separate document.

**Unanswered Questions**

Additional issues need to be addressed with respect to vulnerability to SCD. While ventricular arrhythmia within the first 48 hours post myocardial infarction might not qualify for longer term risk that warrants an ICD, the presence of sustained monomorphic VT (as opposed to polymorphic VT or VF) in that time frame bespeaks underlying substrate for chronic risk of recurrence of the sustained monomorphic VT, in which case either an ICD versus WCD plus watchful waiting and/or EPS testing/ablation might prove helpful. Further study is necessary (Liang 2014).

**NYHA Class Definitions**

(Russo 2013; Colucci 2018)

- **Class I:** No limitation of functional activity or only at levels of exertion that would limit normal individuals (patient can carry 24 pounds up 8 stairs, play basketball, and shovel soil).
- **Class II:** Slight limitation of activity. Fatigue, palpitation, or dyspnea with moderate exercise (patient able to dance, garden, walk 4 MPH on level ground, and have sexual intercourse).
- **Class III:** Marked limitation of activity. Fatigue, palpitation, or dyspnea with minimal activity (patient able to shower, make bed, bowl or golf, dress, and walk 2.5 MPH on level ground).
- **Class IV:** Severe limitation of activity. Symptoms even at rest, worse with activity (patient unable to comfortably perform any significant activity).
- **Ambulatory Class IV:** Class IV heart failure with: 1) no active acute coronary syndrome; 2) no inotropes; and 3) on GDMT.

**Heart Block Definitions**
• First Degree: All atrial beats are conducted to the ventricles, but with a delay of > 200ms.
• Second Degree: Intermittent failure of conduction of single beats from atrium to ventricles.
  o Type I: Conducted beats have variable conduction times from atrium to ventricles.
  o Type II: Conducted beats have uniform conduction times from atrium to ventricles.
  o Advanced: Two or more consecutive non-conducted beats (premature atrial beats might not normally be conducted).
• Third Degree: No atrial beats are conducted from atrium to ventricle

Guideline Directed (or Optimal) Medical Therapy for Heart Failure
(Yancy 2013; Yancy 2017)

• Angiotensin converting enzyme (ACE-I), angiotensin receptor blockers (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
• Beta blocker (might be less critical in permanent atrial fibrillation, still recommended) (Kotecha 2017).
• Addition of loop diuretic for all NYHA class II – IV patients
• Addition of hydralazine and nitrate for persistently symptomatic African Americans
• Addition of an aldosterone antagonist, provided eGFR is > 30 ml/mi
• n and K+ < 5.0
• Not required for consideration of ICD: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm. Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of ivabradine.

Schwartz score diagnostic criteria for long QT syndrome (LQTS) (Schwartz 2011)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electrocardiographic findings</strong></td>
<td></td>
</tr>
<tr>
<td>QTc¶</td>
<td></td>
</tr>
<tr>
<td>▪ ≥480 ms</td>
<td>3</td>
</tr>
<tr>
<td>▪ 460 to 479 ms</td>
<td>2</td>
</tr>
<tr>
<td>▪ 450 to 459 ms (in males)</td>
<td>1</td>
</tr>
<tr>
<td>QTc¶ fourth minute of recovery from exercise stress test ≥480 ms</td>
<td>1</td>
</tr>
<tr>
<td>Torsades de pointesΔ</td>
<td>2</td>
</tr>
<tr>
<td>T wave alternans</td>
<td>1</td>
</tr>
<tr>
<td>Notched T wave in 3 leads</td>
<td>1</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---</td>
</tr>
<tr>
<td>Low heart rate for age◊</td>
<td>0.5</td>
</tr>
</tbody>
</table>

**Clinical history**

<table>
<thead>
<tr>
<th>SyncopeΔ</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ With stress</td>
</tr>
<tr>
<td>▪ Without stress</td>
</tr>
</tbody>
</table>

| Congenital deafness | 0.5 |

**Family history**

<table>
<thead>
<tr>
<th>Family members with definite LQTS§</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexplained sudden cardiac death below age 30 among immediate family members§</td>
<td>0.5</td>
</tr>
</tbody>
</table>

**SCORE:**

- ≤1 point = low probability of long QT syndrome (LQTS).
- 1.5 to 3 points = intermediate probability of LQTS, requires addition of genotyping to further classify risk as low or high.
- ≥3.5 points = high probability of LQTS.

* In the absence of medications or disorders known to affect these electrocardiographic features.
¶ QTc calculated by Bazett’s formula where QTc = QT/√RR.
Δ Mutually exclusive.
◊ Resting heart rate below the second percentile for age.
§ The same family member cannot be counted in A and B.

**Abbreviations**

- ACE-I: Angiotensin converting enzyme inhibitor
- ACHD: Adult congenital heart disease
- ARNI: Combined angiotensin receptor inhibitor and neprilysin inhibitor
- ARVD/C: Arrhythmogenic right ventricular dysplasia/cardiomyopathy
- AV: Atrioventricular
- CAD: Coronary artery disease, same as ischemic heart disease
- CHD: Congenital heart disease
- CHF: Congestive heart failure
- CRT: Cardiac resynchronization therapy
- CRT-D: Cardiac resynchronization therapy ICD system
- DCM: Dilated cardiomyopathy
- ECG: Electrocardiogram
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPS</td>
<td>Electrophysiologic Study</td>
</tr>
<tr>
<td>GDMT</td>
<td>Guideline-Directed Medical Therapy</td>
</tr>
<tr>
<td>HCM</td>
<td>Hypertrophic cardiomyopathy</td>
</tr>
<tr>
<td>HF</td>
<td>Heart failure</td>
</tr>
<tr>
<td>HRS</td>
<td>Heart Rhythm Society</td>
</tr>
<tr>
<td>HV</td>
<td>His-ventricle</td>
</tr>
<tr>
<td>ICD</td>
<td>Implantable cardioverter-defibrillator</td>
</tr>
<tr>
<td>LBBB</td>
<td>Left bundle-branch block</td>
</tr>
<tr>
<td>LV</td>
<td>Left ventricular/left ventricle</td>
</tr>
<tr>
<td>LVAD</td>
<td>Left ventricular assist device, mechanical heart</td>
</tr>
<tr>
<td>LVEF</td>
<td>Left ventricular ejection fraction</td>
</tr>
<tr>
<td>MI</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>ms</td>
<td>Milliseconds</td>
</tr>
<tr>
<td>NICM</td>
<td>Nonischemic cardiomyopathy</td>
</tr>
<tr>
<td>NYHA</td>
<td>New York Heart Association</td>
</tr>
<tr>
<td>RV</td>
<td>Right ventricular/right ventricle</td>
</tr>
<tr>
<td>STEMI</td>
<td>ST-elevation myocardial infarction</td>
</tr>
<tr>
<td>SND</td>
<td>Sinus node dysfunction</td>
</tr>
<tr>
<td>VT</td>
<td>Ventricular tachycardia</td>
</tr>
<tr>
<td>VF</td>
<td>Ventricular fibrillation</td>
</tr>
</tbody>
</table>
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CPT Codes: 33206, 33207, 33208, 33212, 33213, 33214, 33227, 33228

INTRODUCTION
(Epstein 2013; Hayes 2018)

➢ Pacemaker implantation generally serves to address bradycardias, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.

➢ Guidelines for the pediatric and congenital heart disease population are provided in the latter portion of this guideline.

➢ This guideline is not intended to cover the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines.

➢ Elective generator replacement indicators support generator change.

ADULT INDICATIONS FOR PACEMAKERS
(Epstein 2013; Hayes 2018)
(Excludes transient causes, such as unnecessary medication, temporary metabolic and inflammatory conditions, etc.)

Sinus Node Dysfunction

- Documented symptomatic sinus bradycardia, including frequent sinus pauses that produce symptoms
- Symptomatic chronotropic incompetence, documented by stress test or electrocardiography (ECG) recording data
- Symptomatic sinus bradycardia that results from required medication
- Heart rate less than 40, in the waking state, when a clear association between significant symptoms consistent with bradycardia and the actual presence of bradycardia has not been documented.
- Syncope of unexplained origin when clinically significant abnormalities of sinus node function are discovered (e.g. an asymptomatic ventricular pause > 6 s) or provoked by electrophysiologic study (EPS), such as a prolonged sinus node recovery time (Brignole 2013).
- Symptomatic sinus bradycardia (< 60 bpm), which includes syncope, near-syncope, dizziness, lethargy, congestive heart failure (CHF), fatigue, or dyspnea, whether spontaneous or as a result of clinically required medications or procedures (e.g. medical or catheter treatment for atrial fibrillation) that slow the heart rate, when symptoms can clearly be attributed to bradycardia (Brignole 2013).
- Ischemia-related life threatening bradyarrhythmias, when coronary spasm presents a poor or uncertain response to medical therapy (Montalescot 2013).

NOT Indicated for Sinus Node Dysfunction:
• Asymptomatic.
• Symptoms in the absence of bradycardia.
• Bradycardia resulting from nonessential drug therapy.

**Acquired Third-Degree and Advanced Second-Degree Atrioventricular (AV) Block:** (See definition of advanced atrioventricular (AV) Block in Additional Information section.)

• Persistent third-degree (complete) AV block, with or without symptoms
• Advanced second degree AV block at any anatomic level associated with bradycardia with symptoms (including heart failure) or ventricular arrhythmias presumed to be due to AV block
• Persistent third degree AV block or advanced second degree AV block that is due to clinically necessary medication
• In atrial fibrillation, while awake, pauses in heartbeat ≥ 5 seconds with or without symptoms
• In sinus rhythm (with AV block) and while awake, pauses in heartbeat ≥ 3 seconds or heart rates less than 40 beats per minute or an escape rhythm below the AV node, with or without symptoms
• Following catheter ablation of the AV junction
• Associated with neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy
• Exercise-induced third degree AV block without myocardial ischemia

**NOT Indicated for Acquired Third-Degree and Advanced Second-Degree Atrioventricular Block:**

• AV block is expected to resolve and is unlikely to recur (e.g. drug toxicity, Lyme disease, or transient increases in vagal tone or during hypoxia in sleep apnea syndrome) and without symptoms
• AV block secondary to nonessential drug therapy

**First- and Second-Degree AV Block**

• Symptomatic bradycardia associated with second-degree AV block at any level of conduction, either Mobitz I or II, including patients on required medication
• Mobitz Type II second-degree AV block, with or without symptoms
• Second-degree AV block associated with a wide QRS, including isolated right bundle branch block, or if due to EP-documented infra-His conduction prolongation
• First- or second-degree AV block with “pacemaker syndrome” symptoms or hemodynamic compromise (i.e. hypotension, syncope, or pulmonary edema, particularly if PR > 0.30 s) (Brignole 2013)
• First or second degree AV block in neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy
• AV block due to drug use and/or drug toxicity AND block is expected to recur after drug withdrawal
• Exercise-induced second degree heart block without myocardial ischemia

**NOT Indicated for Other Presentations of First- and Second-Degree AV Block:**

• AV block is expected to resolve and is unlikely to recur (e.g. drug toxicity, Lyme disease, or transient increases in vagal tone or during hypoxia in sleep apnea syndrome) and without symptoms
• AV Block secondary to nonessential drug therapy
Chronic Bifascicular Block

- Type II second-degree AV block, advanced second-degree AV block (see definitions section) or intermittent third-degree AV block
- Alternating bundle-branch block
- Syncope and bifascicular block when other likely causes have been excluded, specifically ventricular tachycardia
- Electrophysiologic study (EPS) documentation of an H-V interval ≥100 milliseconds, even in asymptomatic patients
- Electrophysiologic study (EPS) documentation of non-physiological, pacing-induced infra-His block
- In neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy with bifascicular block or any fascicular block
- In bundle branch block with syncope and documentation of an HV interval > 70 ms (Brignole 2013)

**NOT Indicated for Permanent Pacing for Chronic Bifascicular Block:**
- Asymptomatic fascicular block without AV block
- Asymptomatic fascicular block with first-degree AV block

**After the Acute Phase of Myocardial Infarction**
(UM usually not required due to inpatient status)

- Persistent second- or third-degree AV block after ST-elevation myocardial infarction (STEMI).
- Transient second- or third-degree AV block below the AV node after STEMI. If the site of block is uncertain, electrophysiologic study (EPS) may be necessary.

**NOT Indicated for Permanent Pacing After the Acute Phase of Myocardial Infarction:**
- Bradyarrhythmia secondary to nonessential drug therapy.
- Transient AV block without intraventricular conduction defects.
- Transient AV block with isolated left anterior fascicular block.
- New bundle-branch block or fascicular block without AV block.
- Asymptomatic first-degree AV block with bundle-branch or fascicular block.

**Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope**

- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induces ventricular asystole ≥3 seconds.
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) of 3 seconds or longer.
- Neurocardiogenic syncope associated with bradycardia occurring spontaneously or at the time of tilt-table testing.

**NOT Indicated for Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope:**
- Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms.
• Situational neurocardiogenic syncope in which avoidance behavior is effective and preferred.

Following Cardiac Transplantation, Cardiac Surgery and Transcatheter Intervention
(UM usually not required due to inpatient status.)

• Persistent inappropriate or symptomatic bradycardia not expected to resolve, such as one of the following (Brignole 2013):
  o Third degree AV block with low escape rate > 48 hours postoperative
  o All other AV Block, after a 5-7 day wait for improvement
  o 5 days - 3 weeks wait for sinus node dysfunction (SND) to improve after surgery and transplantation.
• Prolonged bradycardia limiting rehabilitation or discharge post transplantation.
• Syncope after transplantation even when bradyarrhythmia has not been documented.

NOT Indicated for Pacing following Cardiac Transplantation:
• Bradycardia secondary to nonessential drug therapy.

Antitachycardia Pacing
(Pacing to Terminate Tachycardia)

• Symptomatic recurrent supraventricular tachycardia documented to be pacing terminated in the setting of failed catheter ablation and/or drug treatment (intolerance included).

NOT Indicated for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardia:
• Presence of an accessory pathway with capacity for rapid anterograde conduction.

Tachycardia Prevention

• Sustained pause-dependent ventricular tachycardia (VT), with or without QT prolongation.
• Type 3 congenital long-QT syndrome (ICD frequently preferred) (Zimetbaum 2018)
• For management of paroxysmal atrial fibrillation only when other indications for pacing are present (Passman 2018, January 2014)

NOT Indicated for Pacing to Prevent Tachycardia:
• Ventricular ectopy without sustained VT in the absence of the long-QT syndrome.
• Reversible, e.g., drug-related, Torsade de Pointes VT.

Hypertrophic Cardiomyopathy

• Symptomatic hypertrophic cardiomyopathy and hemodynamically significant resting (peak > 30 mm Hg) or provoked (peak > 50 mm Hg) LV outflow tract gradient, refractory to medical therapy, and suboptimal candidates for septal reduction therapy (including high risk for developing heart block post procedure) (Marin 2018).

NOT Indicated for Pacing in Patients with Hypertrophic Cardiomyopathy:
• Asymptomatic OR symptoms controlled on medical therapy.
• Without significant LV outflow tract obstruction.
Cardiac Sarcoidosis & Giant Cell Myocarditis

- Transient or permanent high degree or complete AV block (with additional recommendation to include ICD) (Blankstein 2018, Priori 2015)

Pediatric and Congenital Heart Disease Pacing Indications
(Epstein 2013; Brignole 2013; Brugada 2013, Silva 2018);

Children, Adolescents (<19 years), and Patients with Congenital Heart Disease

Sinus Bradycardia

- SND with symptomatic age- and activity-inappropriate bradycardia. The definition of bradycardia varies with the patient’s age and expected heart rate. For normal heart rates by age, please see the table in the Additional information section. (Correlation does not need to be completely conclusive) (Hernandez-Madrid 2018).
- Sinus bradycardia with complex congenital heart disease AND a resting heart rate < 40 bpm OR pauses in ventricular rate >3 seconds.
- Congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony (e.g. PR interval ≥ 0.30s)
- Asymptomatic sinus bradycardia following biventricular repair of congenital heart disease with an awake resting heart rate < 40 bpm or pauses in ventricular rate > 3 seconds.

Bradycardia-Tachycardia

- Bradycardia-tachycardia syndrome, when symptoms and bradycardia correlate (correlation does not need to be completely conclusive) (Brignole 2013; Hernandez-Madrid 2018).
- Congenital heart disease (CHD) and sinus node dysfunction (SND) or junctional bradycardia, for the prevention of recurrent episodes of intra-atrial reentrant tachycardia (IART), with SND or junctional bradycardia either intrinsic or secondary to necessary anti-arrhythmic treatment, when catheter ablation is not possible. Devices with atrial antitachycardia pacing are preferred. (Brugada 2013; Brignole 2013; Khairy 2014)
- Permanent pacing is reasonable in adults with complex CHD and an awake resting heart rate (sinus or junctional) <40 bpm or ventricular pauses >3 seconds. A device with antitachycardia pacing may be considered if the underlying anatomic substrate carries a high likelihood of developing IART (Khairy 2014)

AV Block

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output.
- Advanced second degree AV block ((inadequate literature on asymptomatic Mobitz type II or prolonged HV interval in children, but it would appear reasonable when condition is permanent) (Brignole 2013; Silva 2018).
• Postoperative advanced second- or third-degree AV block that is expected to be permanent or that persists ≥ 7 days after cardiac surgery.
• Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, prolonged QT interval, low cardiac output, or ventricular dysfunction (Hernandez-Madrid 2018).
• Congenital third-degree AV block in the infant with a ventricular rate <55 bpm or with congenital heart disease and a ventricular rate <70 bpm.
• Congenital third-degree AV block after age 1 year with an average heart rate <50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence.
• Unexplained syncope after prior congenital heart surgery complicated by transient complete heart block, with residual fascicular block after a careful evaluation to exclude other causes of syncope.
• Transient postoperative third-degree AV block that reverts to sinus rhythm with residual bifascicular block.
• Permanent pacemaker implantation may be considered for congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS complex and normal ventricular function.
• Permanent pacing is reasonable in adults with congenital complete AV block and an average daytime resting heart rate < 50 bpm (Khairy 2014).
• Any degree AV block in neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy. (Epstein 2013; Brugada 2013)

Ventricular Tachyarrhythmia-Related

• Sustained, pause-dependent Ventricular tachycardia (VT), with QT prolongation, if ICD is not indicated (Epstein 2013; Hernandez-Madrid 2018).
• Type 3 congenital long-QT syndrome (ICD frequently preferred) (Zimetbaum 2018).

NOT Indicated for Pacing in Children, Adolescents, and Patients with Congenital Heart Disease

• Asymptomatic transient postoperative AV block with return of normal AV conduction.
• Asymptomatic bifascicular block +/-first-degree AV block after surgery for congenital heart disease in the absence of prior transient complete AV block.
• Asymptomatic Mobitz type I second-degree AV block.
• Asymptomatic sinus bradycardia with the longest RR interval < 3 seconds and a minimum heart rate > 40 bpm.
• Asymptomatic sinus bradycardia in a healthy child (Silva 2018)
• Bradycardia secondary to nonessential drug therapy.

ADDITIONAL INFORMATION

General
A pacemaker system is composed of a pulse generator and one or more leads. The pulse generator is implanted under the skin, usually below one of the collarbones (clavicles). It contains a battery, a microprocessor that governs timing and function, and a radio antenna to allow for noninvasive interrogation and reprogramming. The leads are insulated cables that conduct electricity from the pulse generator to the heart. Leads are most commonly inserted into a vein and then advanced under fluoroscopy (X-ray guidance) to within one or more heart chambers. The leads are fastened within the chambers to the heart muscle using either hooks or retractable/extendable screws, which are built into
their tips. Timed electrical impulses are delivered from the pulse generator via the leads to the heart, where stimulation results in heart muscle contraction.

The most recent guidelines stress that asymptomatic bradycardia rarely qualifies as an indication for pacemaker insertion. However, there are some asymptomatic bradycardic rhythms for which pacemaker insertion is indicated because they present a risk of injury or death. Thus, there are also a small number of situations in which the ECG or an invasive EPS can reveal evidence of specific disease in the cardiac electrical system that warrants pacemaker insertion in the absence of symptoms. Guidelines are fairly specific and technical in these instances.

In the case of dilated cardiomyopathy, near-simultaneous stimulation of both ventricles, referred to as cardiac resynchronization therapy (CRT) has been demonstrated to improve cardiac performance and quality of life and to decrease cardiac event rates and mortality, usually among symptomatic patients with systolic heart failure and a wide QRS complex. Device implantation requires the insertion of leads that pace both the right and left ventricles, most commonly with a coronary sinus lead for the LV pacing. The majority of these patients have a CRT device with ICD function as well (CRT-D). (See separate guidelines for ICD and CRT.)

**Heart Block Definitions**

( Epstein 2013)

- **First Degree:** All sinus or atrial beats are conducted to the ventricles, but with a delay (PR interval of > 200ms).
- **Second Degree:** Intermittent failure of conduction of single beats from atrium to ventricles.
  - (Mobitz) Type I: Conducted beats have variable conduction times from atrium to ventricles.
  - (Mobitz) Type II: Conducted beats have uniform conduction times from atrium to ventricles.
  - Advanced or high degree: Two or more consecutive non-conducted sinus or (non-premature) atrial beats.
- **Third Degree:** No atrial beats are conducted from atrium to ventricle

**Pediatric respiratory rate and heart rate by age**

<table>
<thead>
<tr>
<th>Age group</th>
<th>Respiratory rate</th>
<th>Heart rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Median</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>(1st-99th percentile)</strong></td>
<td><strong>Median</strong></td>
</tr>
<tr>
<td>0 to 3 months</td>
<td>43 (25-66)</td>
<td>143 (107-181); term newborn at birth: 127 (90-164)</td>
</tr>
<tr>
<td>3 to 6 months</td>
<td>41 (24-64)</td>
<td>140 (104-175)</td>
</tr>
<tr>
<td>6 to 9 months</td>
<td>39 (23-61)</td>
<td>134 (98-168)</td>
</tr>
<tr>
<td>9 to 12 months</td>
<td>37 (22-58)</td>
<td>128 (93-161)</td>
</tr>
<tr>
<td>12 to 18 months</td>
<td>35 (21-53)</td>
<td>123 (88-156)</td>
</tr>
<tr>
<td>18 to 24 months</td>
<td>31 (19-46)</td>
<td>116 (82-149)</td>
</tr>
<tr>
<td>Age Range</td>
<td>Heart Rate (BPM)</td>
<td>Respiratory Rate (RR)</td>
</tr>
<tr>
<td>-----------------</td>
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</tr>
<tr>
<td>2 to 3 years</td>
<td>28 (18-38)</td>
<td>110 (76-142)</td>
</tr>
<tr>
<td>3 to 4 years</td>
<td>25 (17-33)</td>
<td>104 (70-136)</td>
</tr>
<tr>
<td>4 to 6 years</td>
<td>23 (17-29)</td>
<td>98 (65-131)</td>
</tr>
<tr>
<td>6 to 8 years</td>
<td>21 (16-27)</td>
<td>91 (59-123)</td>
</tr>
<tr>
<td>8 to 12 years</td>
<td>19 (14-25)</td>
<td>84 (52-115)</td>
</tr>
<tr>
<td>12 to 15 years</td>
<td>18 (12-23)</td>
<td>78 (47-108)</td>
</tr>
<tr>
<td>15 to 18 years</td>
<td>16 (11-22)</td>
<td>73 (43-104)</td>
</tr>
</tbody>
</table>

* The respiratory and heart rates provided are based upon measurements in awake, healthy infants and children at rest. Many clinical findings besides the actual vital sign measurement must be taken into account when determining whether a specific vital sign is normal in an individual patient. Values for heart rate or respiratory rate that fall within normal limits for age may still represent abnormal findings that are caused by underlying disease in a particular infant or child. (Fleming 2011; Fleegler, 2018)

**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AV</td>
<td>Atrioventricular</td>
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<tr>
<td>CHF</td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>CRT</td>
<td>Cardiac resynchronization therapy (same as biventricular pacing)</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<tr>
<td>EPS</td>
<td>Electrophysiologic Study</td>
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<tr>
<td>GDMT</td>
<td>Guideline-Directed Medical Therapy</td>
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<tr>
<td>HRS</td>
<td>Heart Rhythm Society</td>
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<tr>
<td>HV</td>
<td>His-ventricular</td>
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<tr>
<td>ICD</td>
<td>Implantable cardioverter-defibrillator</td>
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<tr>
<td>LBBB</td>
<td>Left bundle-branch block</td>
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<tr>
<td>LV</td>
<td>Left ventricular/left ventricle</td>
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<tr>
<td>LVEF</td>
<td>Left ventricular ejection fraction</td>
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<tr>
<td>MI</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>ms</td>
<td>Milliseconds</td>
</tr>
<tr>
<td>s</td>
<td>Seconds</td>
</tr>
<tr>
<td>STEMI</td>
<td>ST-elevation Myocardial Infarction</td>
</tr>
<tr>
<td>SND</td>
<td>Sinus node dysfunction</td>
</tr>
<tr>
<td>VT</td>
<td>Ventricular tachycardia</td>
</tr>
</tbody>
</table>
REFERENCES


Fleegler E. Pediatric advanced life support (PALS). UpToDate, Waltham, MA. Available at: https://www.uptodate.com/contents/pediatric-advanced-life-support-pals Retrieved May 31, 2018


INTRODUCTION

➢ Transthoracic echocardiography (TTE) uses ultrasound to image the complex structures of the heart in a real time format, providing 2-dimensional, cross sectional images.

➢ The addition of Doppler ultrasound derives hemodynamic data from flow velocity versus time measurements, as well as from color coded two dimensional representations of flow velocities.

➢ TTE’s safety and versatility in examining cardiac structure, function, and hemodynamics lends to its utility for numerous indications in children and adults.

➢ TEE (transesophageal echocardiography) widens the scope of utility for echocardiographic imaging, and its indications are covered in a separate guideline.

ADULT PATIENTS

Indications for pediatric patients follow the section for adult patients.

Indications for Transthoracic Echocardiography (TTE)
(Douglas 2011)

General Evaluation of Cardiac Structure and Function

Suspected Cardiac Etiology

• Symptoms or conditions potentially related to suspected cardiac etiology including, but not limited to, chest pain, shortness of breath, palpitations, TIA, stroke, or peripheral embolic event

• Respiratory failure or hypoxemia of uncertain etiology if cardiac structural or myocardial disease is a consideration

• Prior testing that is concerning for heart disease or structural abnormality including but not limited to ECG, chest X-ray, baseline scout images from stress echocardiography, or cardiac biomarkers

Arrhythmias

• Frequent VPCs or exercise-induced VPCs

• Atrial fibrillation, SVT, or VT

Presyncope/Syncope (Shen 2017; Benditt 2018; Doherty 2017)

• When clinical rationale supports a suspicion of structural or potentially structurally associated arrhythmic heart disease, i.e. a diagnosis known to cause such symptoms

Perioperative Evaluation (Fleischer 2014; Lentine 2012; Cowie 2010)

• Preoperative left ventricular function assessment in patients who are candidates for kidney or liver transplantation: TTE might identify pulmonary hypertension and/or intrapulmonary arteriovenous shunt in candidates for liver transplantation

• Re-evaluation (<1 yr) in patients with moderate or severe aortic stenosis, who will be subjected to increased hemodynamic demands (e.g. noncardiac surgery, pregnancy)
• Evaluation of patients prior to noncardiac surgery with clinically suspected moderate or greater degrees of valvular stenosis or regurgitation if there has been either
  o No prior echo within 1 year
  OR
  o There has been a significant change in clinical status or physical examination since the last evaluation.

**Pulmonary Hypertension**

• Evaluation of suspected pulmonary hypertension including evaluation of right ventricular function and estimated pulmonary artery pressure
• Evaluation of pulmonary embolism patients with respect to right ventricular function and pulmonary hypertension, with intent to risk stratify and initiate appropriate therapy (Saric 2016).
• Routine surveillance (≥1 y) of known pulmonary hypertension without change in clinical status or cardiac exam
• Re-evaluation of known pulmonary hypertension if there is a change in clinical status or cardiac exam, or to guide therapy
• Surveillance for pulmonary hypertension during chemotherapy with dasatinib, every 3 months during and again at completion of therapy, and as required for subsequent symptoms or signs of pulmonary hypertension (Zamorano 2016).

**Evaluation of Valvular Function**

(Christopher 2017, Nishimura 2014)

**INITIAL Evaluation of Valvular Function in an Asymptomatic Patient**

• Asymptomatic patient with unexplained heart murmur or abnormal heart sounds, with reasonable suspicion of valvular heart disease
• Continuous heart murmur (Warnes 2008)
• History of rheumatic heart disease
• Known systemic or acquired disease associated with valvular heart disease (Examples: Ankylosing spondylitis, Marfan’s, Turner’s, history tertiary syphilis, Ehlers Danlos or Loeys-Dietz syndromes, etc.) (Hiratzka 2010)
• First degree family member has history of bicuspid aortic valve (Warnes 2008)
• Patient with Turner syndrome, for evaluation of bicuspid aortic valve, as well as coarctation of the aorta and aortic root dilation
• Exposure to medications that could result in development of valvular heart disease (Examples: The prior use of the diet drug fenfluramine/phentermine, marketed as Fen Phen, and or dexfenfluramine alone, can cause aortic or mitral regurgitation. Bengluorex is another culprit diet drug. Ergot derivatives used for migraine, such as ergotamine and methysergide are a group. Bromocriptine (another ergot derivative) can cause valvular problems. Parkinson medications, such as pergolide and cabergoline are another group, both removed from the US market. Also, prior radiation to the heart valves can cause valvular disease. The vast majority of the disease is valvular regurgitation, mainly aortic, mitral, and tricuspid. There have even been reports of Ecstasy causing valvular regurgitation, but that appears to be less clear.)

**Murmur or Click**

• Initial evaluation when there is a reasonable suspicion of valvular or structural heart disease
• Re-evaluation of known valvular heart disease with a change in clinical status or cardiac exam, or to guide therapy

**Native Valvular Stenosis**
- Routine surveillance (≥3 yr) of bicuspid aortic valve, aortic sclerosis, or mild valvular stenosis, without a change in clinical status or cardiac exam
- Routine surveillance (≥1 yr) of moderate stenosis without a change in clinical status or cardiac exam
- Re-evaluation (<1 yr) in patients with moderate or severe aortic stenosis, who will be subjected to increased hemodynamic demands (e.g. noncardiac surgery, pregnancy)
- Re-evaluation of an asymptomatic patient with severe aortic stenosis 6-12 months without change in clinical status or cardiac exam
- Re-evaluation after control of hypertension in low flow – low gradient severe aortic stenosis with preserved ejection fraction
- In asymptomatic young adults, annual TTE for aortic stenosis with mean Doppler gradient > 30 mm Hg or peak instantaneous gradient >50 mm Hg, and every 2 years for patients with lesser gradients (Warnes 2008)
- In asymptomatic patient with pulmonic stenosis, with peak instantaneous gradient < 30 mm Hg, follow up TTE at 5 year intervals (Warnes 2008)
- In asymptomatic patient with pulmonic stenosis, with peak instantaneous gradient > 30 mm Hg, follow up TTE at 2-5 year intervals(Warnes 2008)

<table>
<thead>
<tr>
<th>Native Valvular Regurgitation With TTE (aLancellotti 2013)</th>
</tr>
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<tbody>
<tr>
<td>• Routine surveillance (≥1 yr) of moderate valvular regurgitation without change in clinical status or cardiac exam</td>
</tr>
<tr>
<td>• Re-evaluation of asymptomatic patient (6-12 months) with severe aortic regurgitation with preserved ejection fraction and normal left ventricular size</td>
</tr>
<tr>
<td>• Re-evaluation of asymptomatic patient (6-12 months) with severe mitral regurgitation</td>
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<table>
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<tr>
<th>Prosthetic Valves With TTE</th>
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<tbody>
<tr>
<td>• Initial postoperative evaluation of prosthetic valve for establishment of baseline, typically 6 weeks to 3 months postoperative.</td>
</tr>
<tr>
<td>• Routine surveillance (≥3 y after valve implantation) of prosthetic valve if no known or suspected valve dysfunction</td>
</tr>
<tr>
<td>• Evaluation of prosthetic valve with suspected dysfunction or a change in clinical status or cardiac exam</td>
</tr>
<tr>
<td>• Re-evaluation of known prosthetic valve dysfunction when it would change management or guide therapy</td>
</tr>
<tr>
<td>• Evaluation prior to pregnancy in patients with a prosthetic valve and no echocardiography within the past year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infective Endocarditis (Native or Prosthetic Valves) With TTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Initial evaluation of suspected infective endocarditis with positive blood cultures or a new murmur</td>
</tr>
<tr>
<td>• Re-evaluation of infective endocarditis at high risk for progression or complication or with a change in clinical status or cardiac exam, or when findings might change management</td>
</tr>
<tr>
<td>• Re-evaluation of prior TTE/TEE finding for interval change (e.g. resolution of vegetation after antibiotic therapy) when a change in therapy is anticipated or under consideration</td>
</tr>
<tr>
<td>• Re-evaluation of patient with infective endocarditis at high risk of progression of complication (e.g., extensive infective tissue/large vegetation on initial echocardiogram, or staphylococcal, enterococcal, or fungal infections) in the absence of clinical change</td>
</tr>
</tbody>
</table>

Transcatheter Valvular Intervention
• Transcatheter Aortic Valve Replacement (TAVR), one of the following:
  (Otto 2017; Doherty 2017)
  • For pre-TAVR evaluation: Assessment of number cusps and degree of calcification
  • Post TAVR at 30 days (6 weeks to 3 months also acceptable) and annually
  • Post TAVR evaluation: Assessment of aortic regurgitation when there is suspicion of valvular
dysfunction (<30 days)
  • Post TAVR evaluation: Assessment of stroke with suspicion of valve dysfunction or thrombus

• Percutaneous Mitral Valve Repair, one of the following:
  (Doherty 2017)
  o Determination of patient eligibility
  o Reassessment for degree of MR and left ventricular function (pre-discharge, at 1, 6, and 12
  months, and then annually to 5 yr)

Additional Interventions or Noncardiac Procedures
• Guidance of and evaluation for percutaneous noncoronary cardiac procedures including but not
limited to pericardiocentesis, septal ablation, right ventricular biopsy, cardiac valvular and
structural interventions, radiofrequency ablation, or LVAD optimization or weaning
  (Wunderlich 2018; Porter 2015).
• Periprocedural cardiac monitoring of noncardiac procedures posing substantial hemodynamic or
ischemic risk, procedures requiring fluid resuscitation, etc., when it can assist management
  (Porter 2015).

Intracardiac and Extracardiac Structures
• Suspected cardiac mass (Saric 2016)
• Suspected cardiovascular source of embolus (Saric 2016)
• Suspected pericardial conditions
• Re-evaluation of known pericardial effusion to guide management or therapy

Thoracic Aortic Disease
In the absence of recent computed tomography (CT) or cardiovascular magnetic resonance (CMR),
which are preferred for imaging beyond the proximal ascending aorta
  (Hiratzka 2010; Hiratzka 2016; Erbel 2014; Schiller 2017; Wright a&b 2018; Woo a&b 2018; Svensson
2013’ Bhave 2018)
  (See table in Additional Information for top normal size of the thoracic aorta.)
• Screening first degree relatives of individuals with a history of thoracic aortic aneurysm (defined
as ≥ 50% above normal) or dissection or an associated high risk mutation in common.
• Screening second degree relative of a patient with thoracic aortic aneurysm, when the first
degree relative has aortic dilation, aneurysm, or dissection.
• Six month follow up after initial finding of a dilated thoracic aorta, for assessment of rate of
  change
• Annual follow up of enlarged thoracic aorta that is above top normal for age, gender, and size up
to 4.4 cm
• Biannual (twice/yr) follow up of enlarged aortic root ≥ 4.5 cm or showing growth rate ≥ 0.5
cm/year
• Evaluation of the ascending aorta in the setting of a known or suspected connective tissue
disease or genetic condition that predisposes to aortic aneurysm or dissection (e.g., Marfan
syndrome, Ehlers Danlos or Loeys-Dietz syndromes,)
• At time of diagnosis of Marfan’s syndrome and 6 months thereafter for growth rate assessment,
followed by annual imaging, increased to biannual (twice yearly) if diameter >=4.5 or expanding
>= 0.5 cm/yr
• Evaluation of aortic root in patient with Turner syndrome, along with aortic valve and coarctation evaluation, with normal results followed up at 5-10 years with repeat TTE, with abnormalities followed annually.

• Re-evaluation of known ascending aortic dilation or history of aortic dissection to establish a baseline rate of expansion (at 6 months from last assessment) or when the rate of expansion is excessive (repeat at 6 months)

• Re-evaluation of known ascending aortic dilation or history of aortic dissection with a change in clinical status or cardiac exam or when findings may alter management or therapy

• Re-evaluation (<1 y, generally twice a year) of the size and morphology of the aortic sinuses and ascending aorta in patients with a bicuspid AV and an ascending aortic diameter >4 cm with 1 of the following:
  1. Aortic diameter >4.5 cm
  2. Rapid rate of change in aortic diameter when an annual growth rate of ≥0.5 cm is suspected.
  3. Family history (first-degree relative) of aortic dissection

• Evaluation of a ruptured sinus of Valsalva aneurysm and resultant shunting

• Follow up post aortic medical treatment:
  o Acute dissection: Discharge, 1 month, 6 months, then annually
  o Chronic dissection: Discharge, years 1, 2, and 3.

• Follow up post either root repair or AVR plus ascending aortic root/arch repair:
  Discharge and annual

---

**Hypertension, Heart Failure, or Cardiomyopathy**

**Hypertension**

• Initial evaluation of suspected hypertensive heart disease

**Heart Failure & LV Function (Nagueh 2016; Yancy 2013; Patel 2013)**

• Initial evaluation of known or suspected heart failure (HF) (systolic or diastolic) based on symptoms, signs, or abnormal test results

• Re-evaluation of known HF (systolic or diastolic) with a change in clinical status or cardiac exam without a clear precipitating change in medication or diet

• Prior to cardiotoxic chemotherapy, and subsequently for monitoring and follow up. (See Cardio-Oncology section under the Additional Information section.)

• Left ventricular function assessment at baseline prior to initiation of radiation to the anterior or left chest, at 5 years post initiation, and every 5 years thereafter (Lancellotti 2013b)

• Assessment in patients with a history of prior myocardial infarction and unknown left ventricular function.

• Re-evaluation of known HF (systolic or diastolic) when essential to guide therapy

• Worsening in ventricular arrhythmias, including after implantable cardioverter defibrillator (ICD) placement (Patel 2013)

• Unimproved heart failure symptoms in the first 6 months after cardiac resynchronization therapy (CRT initiation (Patel 2013)

---

**Device Candidacy (Pacemaker, ICD, or CRT)**
- Initial evaluation or re-evaluation after revascularization (≥ 3 months or 90 days) and/or myocardial infarction (≥ 40 days) and/or 3 months of optimal medical therapy to determine candidacy for device therapy and/or to determine optimal choice of device (Al-Khatib 2017)
- Initial evaluation for CRT device optimization after implantation
- Known implanted pacing device with symptoms possibly due to device complication or suboptimal pacing device settings

### Ventricular Assist Devices (VADs) and Cardiac Transplantation

(Stainback 2015)

- To determine candidacy for ventricular assist device
- Optimization of ventricular assist device settings and assessment of response post device
- Re-evaluation for signs/symptoms suggestive of ventricular assist device-related complications
- Assessment of alterations in valvular function post assist device, particularly aortic regurgitation.
- Assessment for myocardial recovery post assist device
- Monitoring for rejection in a cardiac transplant recipient
- **Follow up of transplanted heart patients’ allograft with TTE:**
  - Every 3 months during the first year,
  - Every 6 months during the second year.
  - Alternatively, after each endomyocardial biopsy (Badano 2015)

- Cardiac structure and function evaluation in a potential heart donor

### Cardiomyopathies

(Yancy 2013)

- Initial evaluation of known or suspected cardiomyopathy (e.g., restrictive, infiltrative, dilated, hypertrophic, or genetic cardiomyopathy)
- Re-evaluation of known cardiomyopathy with a change in clinical status or cardiac exam or to guide therapy and manage post transplantation or post ventricular assist device (VAD) patients
- Screening evaluation for structure and function in first-degree relatives of a patient with an inherited cardiomyopathy
- Assessment of peripartum cardiomyopathy at onset and 3 months, then at 6 month intervals for minimum two years, longer if required for surveillance during and after trial of weaning medication, with additional follow up of 2 years after weaning trial completed. Follow up as needed, including for intended or actual recurrent pregnancy. (Tsang 2018; Hilfiker-Kleiner 2015)

### Adult Congenital Heart Disease

(Warnes 2008; Baumgartner 2010)

- Initial evaluation of known or suspected adult congenital heart disease
- Known adult congenital heart disease with a change in clinical status or cardiac exam
- Re-evaluation to guide therapy in known adult congenital heart disease.
- Evaluation of asymptomatic patients following repair of Atrial Septal Defect (ASD), Patent Foramen Ovale (PFO), Ventricular Septal Defect (VSD) or Patent Ductus Arteriosus (PDA), approvable within the first year following correction
- Routine surveillance (≥1 yr) of adult congenital heart disease following incomplete or palliative repair with residual structural or hemodynamic abnormal, even without a change in clinical status or exam.
- Asymptomatic, small ASD (<10 mm) shunt with normal right ventricular size, TTE follow up at 2 year intervals, more frequently for larger shunts with normal right ventricle
- Follow up after device closure of shunts, TTE at 24 hours, 2 month, 6 months, 1 year intervals thereafter.
- Asymptomatic small coronary arteriovenous fistula, TTE every 3 years
- After arterial switch repair of d-transposition of the great arteries, TTE at least every 2 years
• In congenitally corrected transposition of the great arteries, TTE every 1-2 years.

PEDIATRIC PATIENTS
(PATIENTS UNDER THE AGE OF 18)

Indications for an Initial Transthoracic Echocardiography (TTE)
(Campbell 2014)

• Hypertension.

• Palpitations, if one:
  o EKG is markedly abnormal
  o Family history at age <50 of either:
    ▪ sudden cardiac arrest or
    ▪ death, pacemaker, or ICD
  o History or family history of cardiomyopathy

• Chest pain, if one of:
  o Exertional
  o Abnormal EKG
  o Family history with unexplained sudden death or cardiomyopathy
  o Associated features of the presentation are suspicious for cardiac origin (e.g. rheumatic fever, endocarditis)

• Syncope, if any one of:
  o History, exam, and/or EKG provide suspicion of structural heart disease
  o Exertional, especially mid exertional due to high correlation with structural heart disease and/or arrhythmic disorder
  o Unexplained post exertional
  o Family history at age < 50 of either one:
    ▪ sudden cardiac death/arrest or
    ▪ a pacemaker or ICD
  o There is a family history of cardiomyopathy

• Presyncope, when all apply:
(Salerno 2018; Anderson 2016; Cote 2001; Shen 2017)
  o When recurrent and well documented
  o With good documentation that neither neutrally mediated syncope (NMS) nor orthostasis is the etiology
  o When structural or arrhythmia related structural heart disease is a suspected cause
  o **Without** prior echocardiographic diagnosis during the course of the current clinical status

• Signs and/or symptoms of heart failure, including, but not limited to any one of:
  o Respiratory distress
  o Poor peripheral pulses
  o Feeding difficulty
  o Decreased urine output
  o Edema
- Hepatomegaly

- Abnormal physical findings, including any one of:
  - Clicks, snaps, or gallops
  - Fixed and/or abnormally split S2
  - Decreased pulses.
  - Central cyanosis without explanation.

- Arrhythmia, if one of:
  - Supraventricular tachycardia
  - Ventricular tachycardia
  - Frequent premature ventricular contractions (PVCs) (≥ 10% of beats/24 hours)

- Murmur
  - Pathologic sounding or harsh murmur, diastolic murmur, or continuous murmur, present in such a way as to have a reasonable belief that congenital heart disease might be present
  - An otherwise innocent murmur, but in the presence of signs, symptoms, or findings of cardiovascular disease

- Abnormal basic data, including any one of:
  - Clearly abnormal electrocardiogram (ECG)
  - Desaturation on pulse oximetry, with concern for cardiac cause
  - Abnormal cardiac structure on a chest x-ray

- Suspected pulmonary hypertension

- Patients with prosthetic valves

- Signs and symptoms of endocarditis, including either one of:
  - In the absence of positive blood cultures, including all patients with an indwelling catheter who present with unexplained fever
  - Positive blood cultures suggestive of infective endocarditis.

- Thromboembolic Related, either one:
  - Patients on anticoagulants, when required to evaluate for thrombus
  - Thromboembolic events or stroke (Saric 2016)

- Systemic hematologic diseases that are associated with cardiac findings, either one:
  - Sickle cell disease
  - HIV infection

- Oncologic Therapy, any one:
  - Cardiotoxic chemotherapy, before or following exposure
  - Radiation therapy to chest, before and long term follow up (Lancellotti 2013) (See Cardio-Oncology section under Additional Information section)

- Inflammatory & Autoimmune, any one:
  - Suspected Rheumatic Fever
  - Systemic lupus erythematosus
• Takayasu Arteritis
• Kawasaki Disease (Newburger 2004)

• Suspicion of Structural Disease, any one:
  o Premature birth where there is suspicion of a Patent Ductus Arteriosus.
  o Adopted children for whom there is a suspicion of congenital heart disease (e.g. HCM), based on physical or clinical findings when there is a lack of family history information.
  o Vascular Ring, based upon either one:
    ▪ Difficulty breathing with stridor and eating solid foods that might suggest a vascular ring
    ▪ Abnormal barium swallow or bronchoscopy suggesting a vascular ring
  o Ventricular pre-excitation with no clinical or Holter findings to suggest an arrhythmia, but with suspicion of Ebstein’s anomaly, Tumors, HCM or clinical signs of heart failure

• Genetic & Syndrome Related, any one:
  o Genotype positive for cardiomyopathy, family history of hypertrophic cardiomyopathy, other heritable cardiomyopathy, genetic disorder at high risk for cardiovascular involvement, heritable pulmonary arterial hypertension
  o Syndromic patients with a known syndrome associated with congenital or acquired heart disease (Down’s syndrome, Noonan’s syndrome, 22Q deficiency syndrome, William’s syndrome, Trisomy Thirteen, Trisomy Eighteen, Allagille syndrome, chromosomal abnormality associated with cardiovascular disease, abnormal viscera, or cardiac situs).
  o Known or suspected connective tissue diseases that are associated with congenital or acquired heart disease. (e.g. Marfan’s, Loeys-Dietz)
  o Known or suspected muscular dystrophies associated with congenital heart disease.
  o Mitochondrial or metabolic storage disease (e.g. Fabry’s disease)
  o Patients with a first degree relative who is known to have a genetic acquisition, such as cardiomyopathies (hypertrophic, dilated, arrhythmogenic right ventricular dysplasia, restrictive, left ventricular noncompaction).

• Maternal-Fetal Related, any one:
  o Maternal infection during pregnancy or delivery with potential fetal/neonatal cardiac sequelae
  o Maternal phenylketonuria
  o Suspected cardiovascular abnormality on fetal echocardiogram

• Previously normal echocardiogram with either one:
  o A change in cardiovascular status
  o A new family history suggestive of heritable heart disease

Indications for Follow-up Echocardiography in Pediatric Patients
(Davey 2004)

General Indications for Postoperative/Post-Procedure Pediatric Patients:
• Upon first outpatient visit, to establish the patient’s new hemodynamic baseline, and assess for potential complications such as pericardial effusions, residual shunts, obstruction at the site of repair, patency of surgical shunts, etc.
• On subsequent visits as needed to monitor as medications are weaned or to evaluate need for further surgical intervention.
Specific Indications for Follow-Up Echocardiograms in Pediatric Patients:

- Congenital Heart Disease (CHD) with a change in clinical status.
- Kawasaki Disease, upon diagnosis, two weeks later and 4 to 6 weeks later. If any coronary abnormalities are present, echocardiograms may need to be more frequent as clinically indicated. (Newburger 2004)
- Valvular regurgitation that is more than mild in asymptomatic child may require annual echocardiogram to assess chamber size and progressive regurgitation.
- Valvular stenosis: (Peak Doppler [mm Hg]: Mild < 40, Moderate 40-60, Severe >60)
  - Pulmonic Stenosis (PS): (Peng 2018)
    - Mild to moderate PS in an infant up to 1-2 year: repeat at 2 weeks and 6 weeks to assess for increasing gradient as PVR drops.
    - Mild stenosis post infancy (6 weeks): every 6 months until age 2 years, and
      - If the gradient regresses to < 25 mm Hg, reduce follow up to every 5 years.
      - If the gradient remains 25-40 after one year, follow up in one year and then every 3 years, if stable
    - Moderate stenosis post infancy (6 weeks): every 1-2 years
    - Post intervention for severe: every year for two years, then every 3-5 years, if stable; also depends on result of valvuloplasty
  - Aortic Stenosis (AS): (Aortic regurgitation rarely alone, usually with aortic stenosis) (Brown 2018)
    (Mean Gradients [mm Hg] mild < 25, moderate 25-40, severe > 40)
    - Mild AS in an infant: every 6 months, or more depending on the patient’s clinical status and rate of progression.
    - Moderate AS in an infant: every 1-3 months to assess for progression and indication for valvuloplasty.
    - Mild in an asymptomatic child: every 1-2 years to assess for progression of stenosis
    - Moderate AS in an asymptomatic child: at least every 6-12 months to assess for progressive stenosis, left ventricular hypertrophy, post-stenotic dilation.
    - In asymptomatic adolescents, annual TTE for aortic stenosis with mean Doppler gradient > 30 mm Hg or peak instantaneous gradient >50 mm Hg, and every 2 years for patients with lesser gradients. (Warnes 2008)
  - Aortic valve prosthesis (Brown 2018)
    - Mechanical: every 6-12 months
    - Bioprosthetic: every 3-6 months
  - Mitral Stenosis (MS):
    - MS from Rheumatic Heart Disease on no meds with no symptoms may require an annual echocardiogram.
    - MS with CHF on medications may require an echocardiogram every three to 6 months.
  - Tricuspid Stenosis (TS):
    - A rare indication that would be based on the patient’s course of treatment and clinical symptoms.
- Shunt lesions:
  - Ventricular Septal Defect (VSD): (Fulton 2018)
    (Pulmonary to systemic shunt ratio: small < 1.5, moderate 1.5-2.0, large > 2.0) (Oakley 2008)
    - Infants with VSD: repeat echocardiogram at 2 weeks and 6 weeks to assess for increasing shunt as the PVR drops.
    - Small VSD: annual echocardiogram to assess for associated lesions depending on location of defect, i.e. aortic regurgitation, development of DCRV (double chambered right ventricle); after 6 months, if the murmur is gone repeat echo is not necessary, if otherwise stable.
• Moderate to large VSD, asymptomatic: Close follow up in response to patient’s clinical status, to assess for LV dilation, mitral regurgitation, and associated lesions: if after one year, there is no pulmonary hypertension or left ventricular dilation, echo can be performed every 2 years, if stable.
  o Atrial Septal Defect (ASD): (Vick 2018)
    ▪ Moderate to large secundum ASD (≥ 3 mm or shunt ≥ 1.5:1) and all primum, sinus venosus, and coronary sinus ASDs, at 6 months intervals to assess for progressive RV dilation, tricuspid regurgitation.
    ▪ Small secundum (<3mm and shunt < 1.5: 1) ASD: every 1-3 years, depending on age of patient.

NOT INDICATED unless there is treating physician input during a peer-to-peer discussion that supports the need for an echocardiogram.
  • Chest pain that changes with inspiration.
  • Clear Orthostatic Hypotension.
  • Chest pain that increases upon palpation.
  • High cholesterol/triglycerides in children who have no other indication for an echocardiogram.
  • Isolated prolonged QT syndrome with no clinical or Holter evidence of an arrhythmia or other physical findings.

NOT INDICATED:
  • Attention Deficit Disorder with no other relevant findings.
  • A sports physical with normal history, physical and ECG.
  • Parental request as the sole reason for an echocardiogram.
  • All patients with a 1st degree relative with an inherited form of cardiomyopathy where the patient has been definitively excluded by genetic testing.

ADDITIONAL INFORMATION

I. Imaging Surveillance for Cardiotoxic Chemotherapy
   (Plana 2014; Zamorano 2016; Maleszewski 2018; Herrmann 2014)

**TTE is the method of choice** for the evaluation of patients before, during, and after cancer therapy. Ideally accuracy prefers that 3D and global longitudinal strain (GLS) are part of the exam, and serum troponin (Tn) should also be measured. However, GLS and Tn might not have been performed, in which case determinations might need to be made with LVEF only. **Serum troponin (Tn) and GLS abnormalities constitute an abnormal assessment of LV function, because their abnormalities frequently herald an imminent fall in LVEF**. (Plana 2014; Zamorano 2016)

**CMR** is recommended when TTE has been unreliable and/or candidacy for cardiotoxic chemotherapy based upon LVEF is questionable (Plana 2014) (MUGA can also be considered when TTE is inadequate and CMR is not available).

**MUGA** is accurate and reproducible, but lacks information about pericardium and valves, incurs repeated radiation exposure, and is inaccurate during an irregular cardiac rhythm (Plana 2014).

**Surveillance guidelines** are somewhat complex, possibly beyond the scope of this guideline, especially in patients with additional risk factors for LV dysfunction (Herrmann 2014). As with all guidelines, adequate information for complex decisions might be impractical to acquire. However, if the reader requires more rigorous recommendations, they are summarized concisely in the table below.

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TTE Surveillance Strategy for Cardiotoxic Chemotherapy (Optional Information)


<table>
<thead>
<tr>
<th>Suspected/Detected LV Status at Baseline, During, or After Completion of Therapy (LVEF is minimum information, GLS and Tn can reveal early LV dysfunction prior to LVEF)</th>
<th>Type I Anthracyclines: Doxorubicin, Epirubicin, Idarubicin Mitoxantrone (Asnani 2018)</th>
<th>Type II Trastuzumab, Labatinib, Pertuzumab, Sorafenib, Sunitinib, Bevacizumab, Bortezomib **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal: EF is ≥ 55%, troponin is negative, <em>and</em> global longitudinal strain (GLS) &gt; lower limit of normal*</td>
<td>Normal assessment: Assess after a cumulative dose &gt; 200mg/M² (or its anthracycline equivalent) <em>and</em> prior to each additional 50 mg/M², <em>and</em> at completion of therapy, and 6 months later, <em>and</em> for cumulative dose &gt; 300 mg/M² include assessment at 1 year and at 5 years post completion of therapy. (Zamorano 2016)</td>
<td>Normal assessment: Assess every 3 months during therapy <em>and</em> at 6 months post completion of therapy</td>
</tr>
<tr>
<td>Abnormal: any <em>one</em> of:</td>
<td>Abnormal assessment: Assess after every cycle, <em>and</em> reassess for verification 2-3 weeks later if a drop in LV function has been detected/suspected; assess 6 months post completion of therapy, followed by re­assessment every 6 months until stable, <em>and</em> for cumulative dose &gt; 300 mg/M² include assessment at 1 year <em>and</em> 5 years post completion of therapy. (Zamorano 2016)</td>
<td>Abnormal assessment: Assess after every cycle, <em>and</em> reassess for verification 2-3 weeks later if a drop in LV function has been detected /suspected; assess 6 months post completion of therapy, <em>and</em> if still not stable re­assess every 6 months until stable.</td>
</tr>
<tr>
<td>- GLS reduced ≥ 10-15% below normal (about 20 is normal*, labs vary)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Troponin positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- LVEF started &lt; 55%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- During therapy LVEF drops below 55% AND ≥ 5 points for a symptomatic/≥10 points for an asymptomatic patient. (Maleszewski 2018)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* GLS of (negative) 20 is generally normal, but individual labs vary. (Collier 2017)
** Imatinib, rarely cardiotoxic, does not require surveillance of LV function. (Floyd 2018)

II. Aortic Root Disease

(Hiratzka 2010; Erbel 2014; Schiller 2017; Wright a&b 2018; Woo a&b 2018; Svensson 2013; Doherty 2017; Bhave 2018)

Indications for aortic root disease in this document are further explained in the section below:

- In asymptomatic stable patients with aortic dilation:
1. All 3 modalities of imaging, computed tomography (CT), magnetic resonance imaging (MRI), Echocardiography (TTE and TEE) appear to be reasonable alternatives for the diagnosis and surveillance of aortic pathology with 3 caveats:
   - TTE accuracy is limited to the aortic valve, aortic root, and proximal ascending aorta, so that conditions requiring evaluation of more distal portions are better imaged with CT or MRI. TEE's invasive nature and weak visualization of the distal ascending aorta, proximal arch, and abdominal aorta make it suboptimal as well. TTE might be satisfactory for surveillance in pathology with greatest prominence localized to the proximal ascending aorta (in bicuspid aortic valve disease or when prior CT or MRI showed the most dilated portion of the aorta to be visible on TTE), until its dimensions approach surgical indications, at which time more precise or comprehensive imaging with CT and MRI might be more appropriate.
   - MRI is recommended for Loeys Dietz, Ehlers-Danlos, and certain other noted genetic mutations, wherein surgical intervention is recommended at 4.2 cm.
   - While still usable for degenerative aortic dilation, echocardiography appears less favorable than CT or MRI for this indication.
   - CT and MRI were recommended for postoperative evaluation and periodic follow up. Echocardiography was not a noted recommendation for this category.

2. The flow diagram from the 2010 ACC Thoracic Aortic Disease Guideline gives reasonable recommendations for surveillance of degenerative aortic root disease, with annual imaging for enlargement above normal up to 4.4 cm, biannual for 4.5-5.4 or more cm (surgical intervention notwithstanding). See Table below for age, gender, and body size determined upper limits of normal for the thoracic aorta, ascending and descending:
An aneurysm is defined as >50% greater than top normal. (Cikach 2018; Hiratzka 2010)

It would be reasonable to allow echocardiography as a less favorable alternative to CT and MRI, based upon the judgement of the ordering physician and local expertise with imaging. (The definition of a thoracic aortic aneurysm is dilation of at least 50% above the normal) (Cikach 2018; Hiratzka 2010).

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>BSA (m²)</th>
<th>Ascending aorta (mm)</th>
<th>Descending aorta (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Women (n = 1,147)</td>
<td>Men (n = 1,805)</td>
</tr>
<tr>
<td>&lt; 45</td>
<td>&lt; 1.70</td>
<td>33.8</td>
<td>33.0</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>34.4</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>35.0</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.1</td>
<td>NA</td>
<td>38.3</td>
</tr>
<tr>
<td>45–54</td>
<td>&lt; 1.70</td>
<td>35.2</td>
<td>38.6</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>37.2</td>
<td>38.1</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>38.9</td>
<td>39.7</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.1</td>
<td>40.6</td>
<td>40.6</td>
</tr>
<tr>
<td>55–64</td>
<td>&lt; 1.70</td>
<td>36.9</td>
<td>36.3</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>37.0</td>
<td>39.7</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>39.0</td>
<td>41.2</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.1</td>
<td>42.0</td>
<td>43.1</td>
</tr>
<tr>
<td>≥ 65</td>
<td>&lt; 1.70</td>
<td>37.5</td>
<td>38.5</td>
</tr>
<tr>
<td></td>
<td>1.70–1.89</td>
<td>39.2</td>
<td>41.0</td>
</tr>
<tr>
<td></td>
<td>1.90–2.09</td>
<td>42.7</td>
<td>42.2</td>
</tr>
<tr>
<td></td>
<td>&gt; 2.1</td>
<td>NA</td>
<td>42.4</td>
</tr>
</tbody>
</table>

*Upper limits of normal are 2 standard deviations above the mean. Not calculated if there were fewer than 6 patients in a group.

BSA = body surface area; NA = not available

(Table from Wolak 2008, as adapted by Cikach 2018)

An aneurysm is defined as ≥50% greater than top normal. (Cikach 2018; Hiratzka 2010)

3. An echocardiogram is recommended at the time of diagnosis of Marfan syndrome to determine the aortic root and ascending aortic diameters and 6 months thereafter to determine the rate of enlargement of the aorta. Subsequently, patients with Marfan’s require annual imaging, with increase to biannual imaging at a diameter of 4.5 cm or when > 0.5 cm/yr expansion has been noted.

4. Patients with bicuspid aortic valve and aortic dilation over 4.0 cm require annual imaging. This would increase to biannual imaging in the event of any one of the additional conditions: diameter > 4.5 cm, rapid rate of change 0.5 cm/yr, or a family history of a first degree relative with aortic
dissection.

5. Patients with Loeys-Dietz syndrome or a confirmed genetic mutation known to predispose to aortic aneurysms and aortic dissections (TGFBR1, TGFBR2, FBN1, ACTA2, or MYH11) should undergo **complete aortic imaging** at initial diagnosis and 6 months thereafter to establish if enlargement is occurring. MRI is recommended in this setting.

6. Patients with Loeys-Dietz syndrome should have yearly **magnetic resonance imaging** from the cerebrovascular circulation to the pelvis.

7. Patients with Turner syndrome should undergo imaging of the heart and aorta for evidence of bicuspid aortic valve, coarctation of the aorta, or dilatation of the ascending thoracic aorta. If initial imaging is normal and there are no risk factors for aortic dissection, repeat imaging should be performed every 5 to 10 years or if otherwise clinically indicated. If abnormalities exist, annual imaging or otherwise appropriate follow-up imaging should be done.

8. Computed tomographic imaging or magnetic resonance imaging of the thoracic aorta is reasonable after a Type A or B aortic dissection or after prophylactic repair of the aortic root/ascending aorta.

9. Echocardiography is the primary modality for evaluation of the sinus of Valsalva aneurysms and associated shunting secondary to rupture (Schiller 2018).

10. Computed tomographic imaging or magnetic resonance imaging of the aorta is reasonable at 1, 3, 6, and 12 months post un-operated dissection and, if stable, annually thereafter so that any threatening enlargement requiring surgery/intervention can be detected in a timely fashion.

11. Postoperative surveillance recommendations are taken from the 2010 ACC Thoracic Aortic Disease Guideline: See Table below (Hiratzka 2010)
### III. General Information on TTE

(Douglas 2011; Campbell 2014; Nishimura 2014; Doherty 2017)

#### Frequency of Echocardiography Studies

- Judgement required, based upon:
  - Stability or change in patient symptoms, exam, lab, and/or X-ray data
  - Stability of underlying condition being followed
  - Likelihood of repeat test affecting management
  - Specifics for cardio-oncology, valvular disease, etc.

Examples of non-approvable repeat imaging:

---

**Table 17. Suggested Follow-Up of Aortic Pathologies After Repair or Treatment**

<table>
<thead>
<tr>
<th>Pathology</th>
<th>Interval</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dissection</td>
<td>Before discharge, 1 mo, 6 mo, yearly</td>
<td>CT or MR, chest plus abdomen TTE</td>
</tr>
<tr>
<td>Chronic dissection</td>
<td>Before discharge, 1 y, 2 to 3 y</td>
<td>CT or MR, chest plus abdomen TTE</td>
</tr>
<tr>
<td>Aortic root repair</td>
<td>Before discharge, yearly</td>
<td>TTE</td>
</tr>
<tr>
<td>AVR plus ascending</td>
<td>Before discharge, yearly</td>
<td>TTE</td>
</tr>
<tr>
<td>Aortic arch</td>
<td>Before discharge, 1 y, 2 to 3 y</td>
<td>CT or MR, chest plus abdomen</td>
</tr>
<tr>
<td>Thoracic aortic stent</td>
<td>Before discharge, 1 mo, 2 mo, 6 mo, yearly Or 30 days*</td>
<td>CXR, CT, chest plus abdomen</td>
</tr>
<tr>
<td>Acute IMH/PAU</td>
<td>Before discharge, 1 mo, 3 mo, 6 mo, yearly</td>
<td>CT or MR, chest plus abdomen</td>
</tr>
</tbody>
</table>

*US Food and Drug Administration stent graft studies usually required before discharge or at 30-day CT scan to detect endovascular leaks. If there is concern about a leak, a predischarge study is recommended; however, the risk of renal injury should be borne in mind. All patients should be receiving beta blockers after surgery or medically managed aortic dissection, if tolerated. Adapted from Erbel et al (539).

AVR indicates aortic valve replacement; CT, computed tomographic imaging; CXR, chest x-ray; IMH, intramural hematoma; MR, magnetic resonance imaging; PAU, penetrating atherosclerotic ulcer; and TTE, transthoracic echocardiography.

(Table from Hiratzka 2010)
• For same imaging test less than 52 weeks apart unless specific guideline criteria states otherwise.

• For different imaging tests of same anatomical structure but different imaging type less than six (6) weeks ago (i.e. CT, MRI and currently requesting echocardiogram) unless specific guideline criteria states otherwise, and/or there is approval following high level review.

• Additional images from same type of study (e.g. due to poor quality).

**Pediatric Post-Operative Patients**

Congenital heart disease, which requires surgical palliation, is, by its very nature, quite varied. No written consensus criteria currently exists for monitoring post-operative patients, but rather is based upon the clinical experience and training of the Pediatric Cardiologists caring for the patient. Criteria for performing an echocardiogram in the out-patient setting will vary greatly based upon whether the patient has a complex lesion, which must be repaired in stages, had post-operative complications, or is on medications which will be weaned over the ensuing weeks.

**Murmurs**

A harsh murmur, diastolic murmur, or continuous murmur would be an indication for an echocardiogram. Soft systolic murmurs and vibratory murmurs in general would not be indications for an echocardiogram. There is an important caveat in regards to age. Existent literature suggests that young children particularly under the age of three can have what appear to be unremarkable murmurs that result in organic heart disease even when examined by experts. Great leeway should therefore be given when echocardiograms are performed under the age of 3 years.

**TTE Accuracy**

In general, transthoracic echocardiography (TTE) is adequate for diagnosing infective endocarditis (IE) and for identifying vegetations when image quality is good. Contemporary TTE has improved the diagnostic accuracy of IE with enhanced image quality; it may reduce the need for TEE. However, accuracy may be reduced because of technical difficulties like obesity, chronic obstructive pulmonary disease, chest-wall deformities etc. Furthermore, the higher resolution of TEE can provide superior visualization of smaller vegetations.

**TTE versus TEE**

Specific situations where transesophageal echocardiography (TEE) is preferred over TTE and may be an appropriate initial study for evaluation of prosthetic device, suspected peri-annular complications, children with complex congenital cardiac lesions, selected patients with Staphylococcus aureus bacteremia, etc. Visualization of left atrial thrombus is far superior with TEE, which is the recommended strategy.

**Abbreviations**

- **ASD**: atrial septal defect
- **CABG**: coronary artery bypass grafting surgery
- **CAD**: coronary artery disease
- **CMR**: cardiovascular magnetic resonance
- **CRT**: cardiac resynchronization therapy
- **CT**: computed tomography
- **ECG**: electrocardiogram
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLS</td>
<td>global longitudinal strain (measure of left ventricular function)</td>
</tr>
<tr>
<td>HCM</td>
<td>hypertrophic cardiomyopathy</td>
</tr>
<tr>
<td>HF</td>
<td>heart failure</td>
</tr>
<tr>
<td>ICD</td>
<td>implantable cardioverter-defibrillator</td>
</tr>
<tr>
<td>LV</td>
<td>left ventricular</td>
</tr>
<tr>
<td>LVEF</td>
<td>left ventricular ejection fraction</td>
</tr>
<tr>
<td>MI</td>
<td>myocardial infarction</td>
</tr>
<tr>
<td>PDA</td>
<td>patent ductus arteriosus</td>
</tr>
<tr>
<td>PFO</td>
<td>patent foramen ovale</td>
</tr>
<tr>
<td>SVT</td>
<td>supraventricular tachycardia</td>
</tr>
<tr>
<td>TAVR</td>
<td>transcatheter aortic valve replacement</td>
</tr>
<tr>
<td>TEE</td>
<td>transesophageal echocardiogram</td>
</tr>
<tr>
<td>TIA</td>
<td>transient ischemic attack</td>
</tr>
<tr>
<td>Tn</td>
<td>troponin</td>
</tr>
<tr>
<td>TTE</td>
<td>transthoracic echocardiogram</td>
</tr>
<tr>
<td>VPC</td>
<td>ventricular premature contraction</td>
</tr>
<tr>
<td>VSD</td>
<td>ventricular septal defect</td>
</tr>
<tr>
<td>VT</td>
<td>ventricular tachycardia</td>
</tr>
</tbody>
</table>
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INTRODUCTION

➢ Transesophageal echocardiography (TEE) enables cardiac ultrasonic imaging from within the esophagus, which provides a window for enhanced quality images as well as additional views, beyond that acquired by standard transthoracic echocardiography (TTE).

➢ TEE can be used as a complement to TTE or as a superior alternative, depending upon the clinical scenario.

INDICATIONS FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)
(Ayres 2005; Douglas 2011; Hahn 2013; Flachskampf 2014; Manning, 2018)

**TEE as Initial or Supplemental Test—General Uses**

- Use of TEE after nondiagnostic TTE or when there is a high likelihood of a nondiagnostic TTE due to patient characteristics or inadequate visualization of relevant structures, such as valvular heart disease, prosthetic valve dysfunction, left atrial thrombus, patent foramen ovale, atrial baffles post Fontan, Senning, or Mustard procedures, etc. (Ogbara 2011; Flachskampf 2014; Lancellotti 2013)

- Re-evaluation of prior TEE finding for interval change (e.g., resolution of thrombus after anticoagulation, resolution of vegetation after antibiotic therapy) when a change in therapy is would be based upon the findings

Any ONE of the following for procedural and surgical guidance, especially when TEE is superior or complimentary to TTE (Thys 2010; Porter 2015):

- Guidance during percutaneous/transcatheter noncoronary cardiac interventions including but not limited to closure device placement, left atrial appendage closure, ASD closure, radiofrequency ablation, and percutaneous valve procedures (Flachskampf 2014).

- For intraoperative noncoronary cardiac repair, including, but not limited to, valve repair, congenital defect repair, unanticipated findings or complications of cardiac surgery requiring intraoperative imaging.

- Suspected acute aortic pathology including but not limited to dissection/transsection when computed tomography angiogram (CTA) and magnetic resonance imaging (MRI) are either not available or not conclusive or not thought to be the optimal first imaging test for clinical reasons (Bhave 2018).

- Dilated aortic sinuses or ascending aorta or a bicuspid aortic valve (stages A and B), to evaluate the presence and severity of AR, when TTE is inadequate.

**TEE as Initial or Supplemental Test—Valvular Disease (Nishimura 2014; Doherty 2017)**

Evaluation of valvular structure, native and prosthetic, and function to assess suitability for, and assist in planning of, an intervention
- Evaluation of the mean mitral gradient and pulmonary artery pressure in mitral stenosis, when there is a discrepancy between resting Doppler echocardiographic findings and clinical symptoms or signs, exercise stress echocardiography is not possible, **AND** TTE is inadequate

- Discordance between clinical assessment and TTE assessment of the severity of MR
- Discordance between clinical assessment and TTE assessment of the severity of AR
- To diagnose infective endocarditis and cardiac complications of infective endocarditis, with a moderate or high pretest probability (e.g., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device)
- Re-evaluation of infective endocarditis (IE) in a patient with a change in clinical status or cardiac examination (e.g., new murmur, embolism, persistent fever, heart failure (HF), abscess, or atrioventricular heart block (Saric 2016)
- Re-evaluation of IE if the patient is at high risk for progression/complications or for other potential treatment-altering changes, when TTE is inadequate.

### TEE as Initial or Supplemental Test—Embolic Event

Evaluation of suspected cardiac mass, tumor, or thrombus, or for evaluation of potential cardiac source of embolism when there is no identified noncardiac source (Saric 2016)

### TEE as Initial Test—Atrial Fibrillation/Flutter

Evaluation to facilitate clinical decision making with regards to anticoagulation, cardioversion, and/or radiofrequency ablation

### TAVR (Transcatheter Aortic Valve Replacement/Repair) (Doherty 2017, Otto 2017)

- Accurate pre-procedural assessment of annular size and shape, number of cusps, and degree of calcification, when computed tomography (CT) cannot be performed (i.e. limited role)
- Pre-, peri- and post procedural assessment of degree of aortic regurgitation (including valvular and paravalvular) with suspicion of valve dysfunction, if TTE is inadequate
- Intraprocedural guidance of TAVR or paravalvular leak closure (Thys 2010; Porter 2015; Flachskampf 2014)
- Assessment of post procedural stroke with suspicion of valve dysfunction, if TTE is inadequate

### Percutaneous/Transcatheter Mitral Valve Repair/Replacement (Doherty 2017)

- Determination of patient eligibility for procedures such as PMBV, TMVR, edge-to-edge repair, artificial chord implantation, annuloplasty, PVML closure
- Pre-procedural evaluation for TMVR, mitral annuloplasty, or PVML closure can be performed in addition to CT imaging (Wunderlich 2018)
- Exclude the presence of intracardiac mass, thrombus, or vegetation prior to (within 3 days) the procedure
- Intraprocedural guidance of transcatheter mitral valve repair or replacement (Thys 2010; Porter 2015; Flachskampf 2014)

### Left Ventricular Assist Devices (Stainback 2015)

- Preoperative evaluation for suitability, intraoperative monitoring during placement, and immediate postoperative evaluation of function
ADDITIONAL INFORMATION

Frequency of Echocardiography Studies

- Judgement required, based upon:
  - Stability or change in patient symptoms, exam, lab, and/or X ray data
  - Stability of underlying condition being followed
  - Likelihood of repeat test affecting management

Examples of non-approvable repeat imaging:

- For same imaging test less than 52 weeks (1 year) apart unless specific guideline criteria states otherwise.

- For different imaging tests of same anatomical structure but different imaging type less than six (6) weeks ago (for example, a recent CT or MRI and currently requesting echocardiogram), unless specific guideline criteria states otherwise, and/or there is approval following high level review.

- Additional images from same type of study (e.g. due to poor quality).

Abbreviations

AR  aortic regurgitation
CABG  coronary artery bypass grafting surgery
CAD  coronary artery disease
CMR  cardiovascular magnetic resonance
CT  computed tomography
ECG  electrocardiogram
HF  heart failure
LV  left ventricular
MI  myocardial infarction
MR  mitral regurgitation
PBMV  percutaneous balloon mitral valvuloplasty
PVML  paravalvular mitral leak
RV  right ventricle
TEE  transesophageal echocardiography
TIA  transient ischemic attack
TTE  transthoracic echocardiography
TMVR  transcatheter mitral valve replacement
TR  tricuspid regurgitation
REFERENCES


CPT Codes: 93350, 93351, +93320, +93321, +93325, +93352

Introduction

➢ Stress echocardiography (SE) refers to ultrasound imaging of the heart during exercise electrocardiography (ECG) testing, during which visualized wall motion abnormalities can provide evidence of significant coronary artery disease (CAD).

➢ While drug-induced stress with dobutamine can be a legitimate alternative to exercise stress testing in patients who are unable to exercise, this guideline does not require use of this modality for practical reasons with rare noted exceptions. Hence, reference in this document to SE almost always refers to exercise stress echocardiography.

➢ Although SE provides comparable accuracy without radiation relative to myocardial perfusion imaging (MPI), scenarios which do not permit safe and effective use of SE might be better suited for alternative stress imaging with MPI, rarely cardiovascular magnetic resonance imaging (CMR) or positron emission tomography (PET), and in some cases, non-stress imaging such as coronary computed tomography angiography (CCTA) (Askew 2018; Douglas 2011; Metz 2007; Einstein 2012; Fazel 2011; Fleischmann 1998; Heijenbrok-Kal 2007; Hirschfeld 2018; Marwick 2003; Pellikka 2007; Schinkel 2003; Scott-Moncrieff 2011; Sicari 2008; Sicari 2017; Yao 2003; Zhang 2014).

➢ Scenarios that support MPI over SE are detailed in the Additional Information section and include:
  (Henzlova 2016; Askew 2018; Wolk 2013)
  • Poor quality echocardiographic images
  • Inability to exercise
  • Specific comorbidities
  • ECG-related wall motion abnormalities.
  • Elevated coronary risk

➢ CAD stenosis ≥ 50% is considered clinically significant or obstructive CAD, where CAD and ischemic heart disease (IHD) are symptoms. Hemodynamically or functionally significant CAD means the degree of stenosis is severe enough to cause ischemia. This is discussed in more detail in the Additional Information section (Fihn 2012; Wolk 2013; Montalescot 2013; Gerber 2018; Tobis 2007).

➢ Stable patients without known CAD fall into 2 categories:
  (Fihn 2012; Wolk 2013; Montalescot 2013)
  ➢ Asymptomatic patients, for whom Global Risk of CAD events can be determined from coronary risk factors using calculators available online. (see Part III in the Additional Information section)

  ➢ Symptomatic patients, for whom we estimate the Pretest Probability that their chest-related symptoms are due to clinically significant (≥ 50%) CAD (see below):
The 3 Types of Chest Pain or Discomfort

- **Typical Angina (Definite)** is defined as including all 3 of these characteristics:
  1) Substernal chest pain or discomfort with characteristic quality and duration
  2) Provoked by exertion or emotional stress
  3) Relieved by rest and/or nitroglycerine

- **Atypical Angina (Probable)** has only 2 of the above characteristics

- **Nonanginal Chest Pain/Discomfort** has only 0-1 of the above characteristics

Once the type of chest pain has been established from the medical record, the Pretest Probability of obstructive CAD is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability:

(Wolk 2013; Fihn 2012)

**Diamond Forrester Table**

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Gender</th>
<th>Typical/Definite Angina Pectoris</th>
<th>Atypical/Probable Angina Pectoris</th>
<th>Nonanginal Chest Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;=39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>40–49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td>&gt;=60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
</tbody>
</table>

- **Very low**: < 5% pretest probability of CAD, usually not requiring stress evaluation (Fihn 2012)
- **Low**: 5-10% pretest probability of CAD
- **Intermediate**: 10% - 90% pretest probability of CAD
- **High**: > 90% pretest probability of CAD

**INDICATIONS for STRESS ECHO**

(Fihn 2012; Wolk 2013; Montalescot 2013; Pellikka 2007; Marwick 2003; Sicari 2008; Sicari 2017; Douglas 2011; Yao 2003)

**Suspected CAD**

(Without known history of CAD)

1. **Symptomatic patients without known CAD**
   - Low pretest probability, if ECG is uninterpretable AND patient can exercise.
   - Intermediate pretest probability
• High pretest probability
• Repeat testing in patient with recurrent symptomatic presentation and negative result over 2 years ago
• Repeat testing in patient with new or worse symptoms and negative result at least one year ago

2. Asymptomatic patients without known CAD:

• Previously unevaluated ECG evidence of possible myocardial ischemia such as substantial ischemic ST segment or T wave abnormalities
• Previously unevaluated pathologic Q waves or wall motion abnormality (evidence of prior myocardial infarction)
• Unevaluated complete left bundle branch block
• Following radiation therapy to the anterior or left chest, at 5 years post inception of radiation and every 5 years thereafter (Lancellotti 2013)

3. Incomplete or inconclusive CAD evaluation within the past 2 years, without known CAD:

• Exercise stress ECG with low risk Duke treadmill score but patient’s current symptoms indicate an intermediate or high pretest probability, which should include stress imaging
• Exercise stress ECG with intermediate Duke treadmill score
• Inconclusive/borderline CCTA (e.g. 40-70% lesions)
• An indeterminate (equivocal, borderline, or discordant) evaluation by prior stress imaging (MPI or CMR) within the past 2 years, in patients for whom a noninvasive approach is preferable to proceeding to invasive coronary arteriography (e.g. a patient presenting with unclear symptoms, ECG and imaging discordant, but with severe contrast allergy or chronic kidney disease.)

**Known Major Vessel CAD**
(Patel 2017)

• Validated concern for a previous acute coronary syndrome without subsequent invasive or non-invasive coronary evaluation

• Follow up SE at 2-year intervals is approvable, if it will affect consideration of coronary revascularization (initial or additional), in patients with one of the following:
  o History of silent ischemia with severe unrevascularized CAD and revascularization could be feasible (Deedwania 2018)
  o History of severe unrevascularized major multivessel CAD, without major wall motion abnormality, and revascularization could be feasible.

• Ischemia assessment following inconclusive findings of invasive coronary arteriography or CCTA, for the purpose of assessing extent of ischemia and need for additional medical, interventional, or surgical therapy

• Myocardial viability testing by low dose dobutamine stress echocardiography (myocardial perfusion imaging at rest is equally approvable) prior to coronary revascularization is reasonable in patients with left ventricular ejection fraction (LVEF) ≤ 50%, if it could significantly alter the revascularization strategy. (Patel 2013; Yancy 2013).
• New or worsening symptoms of ischemia in the absence of an acute coronary syndrome, unless the most current stress imaging study would warrant invasive coronary arteriography instead (e.g. History of high risk stress test without subsequent invasive coronary arteriography might warrant invasive coronary angiography) (Patel 2012).

• De novo heart failure (HF) patients who have known CAD, even without angina, unless the patient is not eligible for revascularization of any kind, or unless invasive coronary arteriography is immediately planned (Yancy 2013).

Special Diagnostic Conditions, Requiring Coronary Evaluation

• Newly diagnosed systolic or diastolic HF, when invasive coronary angiography is not immediately planned, especially when symptoms or signs of ischemia are present or suspected (SE diversion not required) (Yancy 2013, Patel 2013, Fihn 2012).
• Newly found wall motion abnormality (Colucci 2018)
• Ventricular arrhythmias:
  o Sustained ventricular tachycardia (VT) >100 bpm, ventricular fibrillation (VF), or exercise induced ventricular tachycardia (VT), when invasive coronary arteriography is not the initially required test (Al-Khatib 2018, in press)
  o Nonsustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, without known cause or associated cardiac pathology, when an exercise ECG has shown an intermediate risk Duke Score or an exercise ECG could not be performed (Zimetbaum 2018)
  o Frequent premature ventricular contractions (PVCs) ≥ 30/hour, or any PVC on a 12 lead ECG, without known cause or associated cardiac pathology, when an exercise ECG has shown an intermediate risk Duke Score OR an exercise ECG is not feasible due to inability to exercise or due to an uninterpretable ECG (Cha 2012, Manolis 2018)
• Prior to Class IC antiarrhythmic drug initiation in intermediate and high global risk patients (Kumar 2018)
• Assessment of hemodynamic significance of known
  o Anomalous coronary arteries (Grani 2017),
  o Muscle bridging of a coronary artery (perform with exercise stress) (Sorajja 2018), OR
  o Coronary aneurysms in Kawasaki’s disease (Newburger 2018)

Chronic Valvular Disease
Evaluation with Inclusion of Doppler
(Nishimura 2014; Doherty 2017; Baumgartner 2017; Steiner 2017)

• Low dose dobutamine SE for the evaluation of aortic stenosis and flow (contractile) reserve in symptomatic patients with severe aortic stenosis by calculated valve area, low flow (stroke volume ≤ 35mL/square M) /low gradient (mean < 40 mm Hg or Doppler <4 M/sec), and ejection fraction < 50%  (Contractile reserve is > 20% rise in stroke volume with dobutamine).
• Exercise echo Doppler evaluation for mitral stenosis when there is a discrepancy between resting Doppler and clinical signs or symptoms.
• Exercise echo Doppler evaluation for primary (also known as prolapse, degenerative, unrelated to wall motion abnormality, etc.) mitral regurgitation (MR) if there is:
• Discrepancy between exertional symptoms and severity of MR at rest
  OR
• Need to distinguish moderate from severe MR in the asymptomatic patient

• Evaluation of secondary MR (also known as ischemic, related to wall motion abnormality or left ventricular dilation in cardiomyopathy, etc.), with respect to establishing an ischemic etiology

Prior to Elective Noncardiac Surgery
(Fleischer 2014; Patel 2015)

• Patients who have no other indication for a non-invasive coronary evaluation, but are referred for preoperative cardiac evaluation, are eligible for SE, based upon cardiac risk ≥1%, if all 4 criteria are met:
  o Surgery is supra-inguinal vascular, intrathoracic, or intra-abdominal.
  AND
  o The patient has at least one of these additional cardiac complication risk factors:
    ▪ Ischemic Heart Disease
    ▪ History of stroke or trans ischemic attack (TIA)
    ▪ History of congestive heart failure (CHF) or ejection fraction ≤ 35%
    ▪ Insulin-requiring diabetes mellitus
    ▪ Creatinine ≥ 2.0 mg/dl
    AND
  o The patient has limited functional capacity (< 4 metabolic equivalents) such as one of the following:
    ▪ Cannot take care of their ADLs or ambulate
    ▪ Cannot walk 2 blocks on level ground
    ▪ Cannot climb 1 flight of stairs
    ▪ Cannot vacuum, dust, do dishes, sweep, or carry small grocery bag
    AND
  o There has been no non-invasive coronary testing within one year, and the result of such a test would be likely to substantially alter therapy and/or preclude proceeding with the intended surgery

• Planning for solid organ transplantation is an indication for preoperative dobutamine SE, if there has not been a conclusive stress evaluation within the past year (Lentine 2012):
  o In a patient with poor or unknown functional capacity (4 metabolic equivalents, as characterized under preoperative evaluation for noncardiac surgery section above) (Wolk 2013)
  OR
  o In a patient with ≥ 3 of the following (Lentine 2012):
    • Age > 60
    • Smoking
    • Hypertension
- Dyslipidemia
- Left ventricular hypertrophy
- > 1 year on dialysis (for renal transplant patients)
- Diabetes mellitus
- Prior cardiovascular disease

- When the above risk calculators prove inadequate, and cardiac risk could be ≥ 1%, the American College of Surgeons NSQIP Cardiac Risk Calculator can be used as a less validated alternative. It is available at http://www.surgicalriskcalculator.com/miorcardiacarrest, with an application download required.

**POST CARDIAC TRANSPLANTATION**
Dobutamine SE recommended, not exercise SE
(Gustafsson 2016)

- During the first five years post cardiac transplantation, patients with glomerular filtration rates less than 40 mL/min/1.73 body surface area (BSA), or who otherwise should not undergo annual invasive coronary arteriography, are appropriate for annual SE.
- After the first five years post cardiac transplantation:
  - Patients considered at low risk for transplant vasculopathy (i.e., with normal invasive coronary arteriography) can have annual SE,
  - Patients with transplant coronary vasculopathy can have annual SE, if the risk of annual invasive coronary arteriography is not acceptable (i.e. high risk of contrast nephropathy).

**ADDITIONAL INFORMATION**
(Fihn 2012; Wolk 2013; Montalescot 2013)

**I. Scenarios that support MPI over SE**
(Henzlova 2016; Askew 2018)

**I. Poor Quality Echo Image**
- Obesity with body mass index (BMI) over 40 or poor acoustic imaging window

**II. Inability to Exercise**
- Physical infirmities precluding a reasonable ability to exercise for at least 3 full minutes of Bruce protocol
- The patient has limited functional capacity (< 4 metabolic equivalents) **such as one** of the following:
  - Cannot take care of their activities of daily living (ADLs) or ambulate
  - Cannot walk 2 blocks on level ground
  - Cannot climb 1 flight of stairs
  - Cannot vacuum, dust, do dishes, sweep, or carry a small grocery bag
• Patients who cannot walk up a single flight of stairs at even a slow pace or perform ADLs based upon documented limitations

III. Comorbidity Related
• Prior cardiac surgery (coronary artery bypass graft or valvular), CHF with left ventricular ejection fraction ≤ 40%
• Severe chronic obstructive pulmonary disease with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
• Poorly controlled hypertension, with systolic BP > 180 or Diastolic BP > 120
• Medical instability or serious acute illness, where maximal exercise is not recommended or appropriate (e.g. acute myocarditis or pericarditis, active infective endocarditis, acute aortic dissection, etc.)
• Resting wall motion abnormalities that would make exercise SE interpretation difficult, which includes left bundle branch block
• More than moderate valvular heart disease, when coronary data, not valvular hemodynamics, are required

IV. ECG Related Uninterpretable Wall Motion
• Pacemaker or ICD
• Poorly controlled atrial fibrillation/ectopy
• Frequent ectopy, irregular rhythm
• Ventricular pre-excitation (e.g. Wolff Parkinson White)
• Complete LBBB (SE doable, but more difficult to interpret)

V. Risk Related
• High pretest probability in suspected CAD
• Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs
• Patients with prior coronary revascularization
• Arrhythmia risk with exercise and provocation of arrhythmia not required for test
• LVEF < 40%

II. ECG Stress Test Alone versus Stress Testing with Imaging
Prominent scenarios suitable for an ECG stress test WITHOUT imaging (i.e. exercise treadmill ECG test) are inferred from the guidelines presented above, often (but not always) requiring that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate AND has an interpretable ECG for ischemia during exercise (Wolk 2013):
• The (symptomatic) low pretest probability patient who is able to exercise and has an interpretable ECG
• The (asymptomatic) high global risk patient who is able to exercise and has an interpretable ECG
• The patient who is under evaluation for exercise induced arrhythmia (or long QT interval evaluation when the resting QTc is normal), and coronary artery disease is not suspected (Al-Khatib 2017)
• The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription.

Duke Exercise ECG Treadmill Score calculates risk from ECG treadmill alone:
• The equation for calculating the Duke treadmill score (DTS) is: \( DTS = \text{exercise time in minutes} \times (5 \\times \text{ST deviation in mm or 0.1 mV increments}) - (4 \times \text{exercise angina score}) \), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.

• The score typically ranges from -25 to +15. These values correspond to low-risk (with a score of \( \geq +5 \)), intermediate risk (with scores ranging from -10 to +4), and high-risk (with a score of \( \leq -11 \)) categories.

An uninterpretable baseline ECG includes (Fihn 2012):

• Abnormalities of ST segment depression of 0.1 mV (1 mm with conventional calibration) or more
• Ischemic looking T wave inversions of at least 0.25 mV (2.5 mm with conventional calibration)
• ECG findings of probable or definite LVH, WPW, a ventricular paced rhythm, or left bundle branch block
• Digitalis use or hypokalemia
• Resting HR under 50 bpm on a beta blocker and an anticipated suboptimal workload (e.g. rate-pressure product less than 20-25K) could render inconclusive result
• Prior false positive stress ECG

III. Global Risk of Cardiovascular Disease

Global risk of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to asymptomatic patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging (Douglas 2018). There are rare exemptions, such as patients requiring a I-C antiarrhythmic drug, who might require coronary risk stratification prior to initiation of the drug, when global risk is moderate or high.

• CAD Risk—Low
  10-year absolute coronary or cardiovascular risk less than 10%.

• CAD Risk—Moderate
  10-year absolute coronary or cardiovascular risk between 10% and 20%.

• CAD Risk—High
  10-year absolute coronary or cardiovascular risk of greater than 20%.

Links to Global Cardiovascular Risk Calculators*

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

(D’Agostino 2008; Ridker 2007; McClelland 2015; Goff 2014)

<table>
<thead>
<tr>
<th>Risk Calculator</th>
<th>Link to Online Calculator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reynolds Risk Score</td>
<td><a href="http://www.reynoldsriskscore.org/">http://www.reynoldsriskscore.org/</a></td>
</tr>
<tr>
<td>---------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Can use if no diabetes Unique for use of family history</td>
<td></td>
</tr>
<tr>
<td>Pooled Cohort Equation</td>
<td><a href="http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example">http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example</a></td>
</tr>
<tr>
<td>MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk</td>
<td><a href="https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx">https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx</a></td>
</tr>
</tbody>
</table>

**IV. Definitions of Coronary Artery Disease**

(Fihn 2012; Montalescot 2013; Patel 2017; Mintz 2016 Tobis 2007)

1. Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and refers to cross sectional narrowing when IVUS (intravascular ultrasound) is the method of determination.

2. Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a **risk stratification** tool. Its incorporation into Global Risk can be achieved by using the MESA risk calculator.

3. Stenoses ≥ 50% are considered obstructive coronary artery disease (also referred to as clinically significant), while stenoses ≤ 50% are considered nonobstructive coronary artery disease (Gerber 2018).

4. Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
   i. Suggested by percentage diameter stenosis ≥ 70% by angiography; borderline lesions are 40-70% (Fihn 2012, Tobis 2007)
   ii. For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross sectional area on IVUS ≤ 6 square mm (Fihn 2012, Mintz 2016)
   iii. FFR (fractional flow reserve) ≤ 0.80 for a major vessel (Mintz 2016)
   iv. Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree

5. A major vessel is a coronary vessel that would typically be substantial enough for revascularization, if indicated. Lesser forms of coronary artery disease would be labeled as “limited” and not major (i.e. A 50% lesion in a tiny septal or modest size mid PDA would be limited obstructive coronary artery disease.)

6. Microvascular ischemic coronary artery disease, as might be described by a normal FFR (fractional flow reserve) above 0.80 with a reduced CFR (coronary flow reserve less than 2.5), has not otherwise been addressed in this manuscript, because it is very rarely an issue in compliance determinations. However, it would constitute a form of ischemic heart disease.

7. FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow. Newer iterations such as iFR (instantaneous wave free ratio) might supersede basic FFR technology in the near future.

8. New technology is evolving that estimates FFR from CCTA images. This is covered under the separate NIA Guideline for FFR-CT.
V. Anginal Equivalent

Development of an anginal equivalent (e.g. shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g. dyspnea due to lung disease, fatigue due to anemia, etc.), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent (Moya 2009, Shen 2017, Fihn 2012).

VI. Peripheral Arterial Disease/Cerebrovascular Disease

Arterial vascular disease below the renal arteries is generally referred to as peripheral arterial disease, when the ankle brachial index is < 0.9 or there is at least 50% vessel diameter narrowing on ultrasound or angiography (Hussain 2018).

Cerebrovascular disease generally refers to a history of TIA or stroke, or cerebrovascular lesions that put the patient at considerable risk for stroke (Caplan 2018).

There is no evidence to demonstrate that screening all patients with peripheral arterial disease for asymptomatic atherosclerosis in other arterial beds improves clinical outcome. Intensive treatment of risk factors through guideline directed medical therapy is the principal method for preventing adverse cardiovascular ischemic events secondary to atherosclerotic disease in other arterial beds (Gerhard-Herman 2016).

Abbreviations

AAD  antiarrhythmic drug
ADLs  activities of daily living
BSA  body surface area in square meters
CAD  coronary artery disease
ECG  electrocardiogram
FFR  fractional flow reserve
LBBB  left bundle-branch block
LVEF  left ventricular ejection fraction
LVH  left ventricular hypertrophy
MI  myocardial infarction
MET  estimated metabolic equivalent of exercise
MPI  myocardial perfusion imaging
PFT  pulmonary function test
PVCs  premature ventricular contractions
SE  stress echocardiography
VT  Ventricular tachycardia
VF  Ventricular fibrillation
WPW  Wolf Parkinson White
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INTRODUCTION

➢ Heart Catheterization is an invasive angiographic procedure used to evaluate the presence and extent of coronary artery disease (CAD).

➢ In addition to angiography, it can also include ventriculography, aortography, acquisition of hemodynamic data, measurement of cardiac output, detection and quantification of shunts and flows, intravascular ultrasound (IVUS), and fractional flow reserve (FFR)/ instantaneous wave free ratio (iFR) determination of a lesion’s hemodynamic severity.

➢ This guideline applies to patients with a stable clinical presentation, not to those with acute coronary syndromes or acute valvular scenarios, who frequently manifest imminent need for catheter-based or surgical intervention.

➢ In stable patients, prior to a recommendation for cardiac catheterization, preliminary evaluation with non-invasive cardiac testing is usually indicated.

➢ CAD stenosis $\geq 50\%$ is considered clinically significant or obstructive CAD (CAD and IHD [ischemic heart disease] mean the same thing. Hemodynamically or functionally significant CAD means the degree of stenosis is severe enough to cause ischemia. This is discussed in more detail in the Additional Information section) (Fihn 2012; Wolk 2013; Montalescot 2013; Gerber 2018; Tobis 2007).

INDICATIONS FOR INVASIVE CORONARY ARTERIOGRAPHY

(Patel 2012; Fihn 2012; Fihn 2014; Patel 2017; Wolk 2013)

Acute

• Reasonable documentation of acute coronary syndrome, which exempts it from this guideline.

Symptoms and Non-invasive Testing

• Based upon symptoms of ischemia, without known CAD, and with one of the following:
  
  o A high pretest probability of clinically significant coronary artery disease (See Additional Information section) (Wolk 2013; Patel 2012)
  
  o Patients with suspected symptomatic CAD, who cannot undergo stress testing or coronary computed tomographic angiography (CCTA), when there is a high likelihood that the findings will affect therapy (Fihn 2012; Fihn 2014; Montalescot 2013)

Noninvasive testing for CAD showing any of the following, which have not yet been addressed:
▪ Exercise electrocardiogram (ECG) stress test with Duke Score ≤ negative 11, ST segment elevation, hypotension, exercise induced ventricular tachycardia (VT), or several minutes of ST segment depression post exercise (Patel 2012)
▪ Stress imaging with high risk findings (see Additional Information section)
▪ Stress imaging with intermediate risk (see Additional Information section) in a patient with one of the following
  • Symptoms consistent with CAD (Patel 2012)
  • Ejection fraction > 50% and unsatisfactory quality of life due to angina (Fihn 2012)
  • Ejection fraction < 50% (Fihn 2012)
▪ Discordant, equivocal, or inconclusive non-invasive evaluation in symptomatic patients, such as one of the following scenarios with appropriate stress imaging: (Wolk 2013; Montalescot 2013; Patel 2012)
  • Low risk stress imaging with ongoing symptoms of ischemia (Patel 2012)
  • Low risk stress imaging with high risk stress ECG response or stress induced typical angina (Patel 2012)
  • Equivocal/uninterpretable/inconclusive stress imaging due to issues of attenuation or other problems with interpretability (Patel 2012, Fihn 2012)
    o Otherwise appropriate noninvasive testing is inadequate or contraindicated
    o Moderate or greater sized area of infarction (≥ 5% myocardium), but limited or no ischemia (<5% myocardium), in a patient with symptoms of ischemia (Patel 2012)
▪ CCTA findings, not yet addressed: (Patel 2012; Patel 2017; Fihn 2012)
  o In appropriately chosen symptomatic patient for CCTA, with one of:
    ▪ One vessel CAD with ≥ 70% stenosis
    ▪ Moderate CAD stenosis (50% to 69% stenosis) in ≥ 2 arteries on CCTA
    ▪ Stenosis ≥ 30% with FFR-CT < 0.8. (Douglas 2016)
      OR
  o In any patient, with evidence of ≥ 50% left main lesion
▪ Evaluation of patients with known major vessel CAD, with or without prior revascularization, who are amenable to, and candidates for, coronary revascularization or more aggressive coronary management of:
  o New, worsening, or limiting symptoms with non-invasive findings that are intermediate or high risk (Patel 2012)
  o New, worsening, or limiting symptoms, with reasonable suspicion of cardiac origin, despite optimal antianginal therapy (beta blocker and one additional antianginal medication, or necessary alternatives, as tolerated by side effects and vital signs), with non-invasive findings that are low risk (Fihn 2012; Fihn 2014; Patel 2012)
  o New, worsening, or limiting symptoms, with a history of prior unrevascularized significant or severe CAD, and the patient is eligible for coronary revascularization. (Fihn 2012; Fihn 2014)
  o Patients with suspected symptomatic CAD, who cannot undergo stress testing or CCTA, when there is a high likelihood that the findings will affect therapy (Fihn 2012; Fihn 2014; Montalescot 2013)
  o Asymptomatic or controlled symptoms, with unevaluated high risk non-invasive findings (Patel 2012)
Heart Failure and Left Ventricular Dysfunction/Abnormality

- New heart failure/ cardiomyopathy/wall motion abnormality, in patients who would be eligible for coronary revascularization or more aggressive coronary management:
  (Yancy 2013; Wolk 2013; Patel 2012; Patel 2013; Fihn 2012)
  
  o Newly recognized reduction in ejection fraction to ≤40%, with one of the following:
    - Any coronary risk factors, including age >45 in men, >55 in women
    - Symptoms or signs of ischemia
    - Evidence of ischemia (or hibernating myocardium) on non-invasive testing or ECG
    - Known history of significant CAD
  
  o Newly recognized reduction in ejection fraction to 41-49% and one of following:
    - Symptoms of or signs of ischemia
    - Evidence of ischemia on non-invasive testing or ECG
    - Known history of significant CAD
  
  o Symptomatic from HF and/or ischemia with new, unexplained, (> 5%) significant wall motion abnormality and normal ejection fraction (Patel 2012, Fihn 2012)
  
  o Structural abnormality (severe secondary MR or a VSD) with reason to suspect ischemic origin
  
  o Deterioration in clinical status of heart failure or cardiomyopathy requiring invasive evaluation for guidance and/or alteration in therapy, with reasonable likelihood and candidacy for coronary revascularization
  
  o Clarification of the diagnosis of myocarditis versus acute/subacute coronary syndrome  (Cooper 2018)
  
  o When non-invasive coronary evaluation has been nondiagnostic or has not been feasible, and reasonable likelihood of CAD has been provided (Colucci 2018)
  
  o Diastolic heart failure, when symptoms, signs, or stress imaging provide evidence of contributory ischemia.  (Borlaug 2018)

Ventricular Arrhythmias

- Ventricular Arrhythmias, without otherwise known explanatory diagnosis:
  
  o Following recovery from unexplained sudden cardiac arrest. (Al-Khatib 2017)
  
  o Significant ventricular arrhythmia such as sustained VT or VF (Patel 2012)
  
  o Exercise-induced nonsustained VT in a patient at significant risk for CAD, based upon signs or symptoms of ischemia  (Patel 2012)

Prior to Non-Coronary Intervention and Cardiac Surgery

- Evaluation of coronary anatomy, with consideration of coronary revascularization, prior to cardiac surgical or transcatheter interventions (upon cardiac valves, great vessels/thoracic aorta, congenital disease, pericardial disease) in patients with any of the following:
  
  o Symptoms of angina
  
  o Objective evidence of ischemia
  
  o Decreased LV systolic function (EF < 50%)
  
  o History of CAD
  
  o Coronary risk factors, including men > 40 and postmenopausal women
  
  o Non-invasive data that is inconclusive or showing evidence of ischemia or clinically significant CAD (≥ 50% or FFR-CT ≤ 0.8) (Douglas 2016)
Chronic severe secondary mitral regurgitation
 Requirement for more detailed assessment of coronary anomalies prior to aortic valve homograft surgery
 Requirement for better assessment of the origin of the coronary arteries than non-invasive data could provide, when prior to a pulmonary autograft (Ross procedure) or root procedure

**Indications Post Cardiac Transplantation**
(Gustafsson 2018)

- Assessment for allograft vasculopathy on an annual basis for the first 5 years, followed by annual assessment in those with evidence of documented allograft vasculopathy, renal function permitting; estimated glomerular filtration rate (eGFR) ≥30 to 40 mL/min/1.73 square meter body surface area
- Assessment of change in clinical status, any one of the following:
  - Left ventricular dysfunction that has developed, but is not explained by graft dysfunction
  - Symptoms of angina/myocardial ischemia
  - Non-invasive findings of ischemia
- Annual assessment following diagnosis of allograft vasculopathy

**Special Indications for Hemodynamic Assessment**

- Indications for angiographic and/or hemodynamic assessment of valvular function (Doherty 2017; Patel 2012)
  - Assessment of bioprosthetic valve when transthoracic echocardiography (TTE) and transesophageal electrocardiography (TEE) were inadequate, and cardiac magnetic resonance (CMR) and cardiac computed tomography (CCT) are not available
  - Assessment of mechanical valve prostheses when TTE and TEE are inadequate, CCT is not available, and fluoroscopy is not sufficient
  - Discordance between non-invasive data and clinical impression of severity of valvular disease
  - Evaluation of indeterminate shunt anatomy or shunt flows/ratio

- Indications for Hemodynamic Assessment Only (Patel 2012)
  - Assessment of pericardial hemodynamics and distinction from restrictive physiology
  - Assessment of pulmonary hypertension and when non-invasive data provides inadequate information for its management
  - Assessment of pulmonary hypertension response to intravenous drug therapy.
  - Assessment of hemodynamics in heart failure, valvular disease, or cardiomyopathy, when
    - Non-invasive data is discordant or conflicts with the clinical presentation
    - Non-invasive data is inadequate for clinical management

**ADDITIONAL INFORMATION**

**Angina Symptoms**
Persistent symptoms indicative of CAD can include chest discomfort, arm or jaw symptoms thought to be ischemia related, and symptoms considered an anginal equivalent.

**Anginal Equivalent**
Development of an anginal equivalent (e.g. shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g. dyspnea due to lung
disease, fatigue due to anemia, etc.), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT or CTA, and/or pulmonary function tests (PFTs) when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope by itself is not considered an anginal equivalent (Moya 2009; Shen 2017; Fihn 2012).

The Three Types of Chest Pain or Discomfort and Pretest Probability of CAD

- **Typical Angina (Definite)** is defined as including all 3 characteristics:
  1) Substernal chest pain or discomfort with characteristic quality and duration
  2) Provoked by exertion or emotional stress
  3) Relieved by rest and/or nitroglycerine

- **Atypical Angina (Probable)** has only 2 of the above characteristics

- **Nonanginal Chest Pain/Discomfort** has only 0-1 of the above characteristics

- Once the type of chest pain has been established from the medical record, the Pretest Probability of obstructive CAD is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability (Wolk 2013; Fihn 2012).

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Gender</th>
<th>Typical/Definite Angina Pectoris</th>
<th>Atypical/Probable Angina Pectoris</th>
<th>Nonanginal Chest Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;=39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>40–49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
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<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td>&gt;=60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
</tr>
</tbody>
</table>

- **Very low**: < 5% pretest probability of CAD, usually not requiring stress evaluation
- **Low**: 5-10% pretest probability of CAD
- **Intermediate**: 10% - 90% pretest probability of CAD
- **High**: > 90% pretest probability of CAD
  (Fihn 2012)

**Coronary Risk Categories Derived from Non-invasive Testing**
  (Fihn 2012; Patel 2017)

**High risk (>3% annual death or MI)**
1. Severe resting left ventricular (LV) dysfunction (LVEF < 35%) not readily explained by noncoronary causes
2. Resting perfusion abnormalities ≥10% of the myocardium in patients without prior history or evidence of myocardial infarction (MI)
3. Stress ECG findings including ≥2 mm of ST-segment depression at low workload or persisting into recovery, exercise-induced ST-segment elevation, or exercise-induced ventricular tachycardia (VT)/ventricular fibrillation (VF)
4. Severe stress-induced left ventricular (LV) dysfunction (peak exercise LVEF <45% or drop in LVEF with stress ≥10%)
5. Stress-induced perfusion abnormalities encumbering ≥10% myocardium or stress segmental scores indicating multiple vascular territories with abnormalities
6. Stress-induced LV dilation
7. Inducible wall motion abnormality (involving >2 segments or 2 coronary beds)
8. Wall motion abnormality developing at low dose of dobutamine (#10 mg/kg/min) or at a low heart rate (<120 beats/min)
9. Coronary artery calcium (CAC) score >400 Agatston units (only for use in primary prevention, not for heart cath decision making) (Patel 2012; Fihn 2012; Montalescot 2013; Goff 2014)
10. Multivessel obstructive CAD (≥ 70% stenosis) or left main stenosis (≥ 50% stenosis) on CCTA

Intermediate risk (1% to 3% annual death or MI)
1. Mild/moderate resting LV dysfunction (LVEF 35% to 49%) not readily explained by noncoronary causes
2. Resting perfusion abnormalities in 5% to 9.9% of the myocardium in patients without a history or prior evidence of MI
3. ≥1 mm of ST-segment depression occurring with exertional symptoms
4. Stress-induced perfusion abnormalities encumbering 5% to 9.9% of the myocardium or stress segmental scores (in multiple segments) indicating 1 vascular territory with abnormalities but without LV dilation
5. Small wall motion abnormality involving 1 to 2 segments and only 1 coronary bed
6. CAC score 100 to 399 Agatston units (only for use in primary prevention, not for heart cath decision making) (Patel 2012; Fihn 2012; Montalescot 2013; Goff 2014)
7. One vessel CAD with ≥ 70% stenosis or moderate CAD stenosis (50% to 69% stenosis) in ≥ 2 arteries on CCTA

Low risk (<1% annual death or MI)
1. Low-risk treadmill score (score ≥5) or no new ST segment changes or exercise-induced chest pain symptoms; when achieving maximal levels of exercise
2. Normal or small myocardial perfusion defect at rest or with stress encumbering <5% of the myocardium (Note: Although the published data are limited, patients with these findings will probably not be at low risk in the presence of either a high-risk treadmill score or severe resting LV dysfunction (LVEF <35%)
3. Normal stress or no change of limited resting wall motion abnormalities during stress
4. CAC score <100 Agatston units (only for use in primary prevention, not for heart cath decision making) (Patel 2012; Fihn 2012; Montalescot 2013; Goff 2014)
5. No coronary stenosis >50% on CCTA
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAC</td>
<td>coronary artery calcium</td>
</tr>
<tr>
<td>CAD</td>
<td>coronary artery disease</td>
</tr>
<tr>
<td>CCT</td>
<td>cardiac computed tomography</td>
</tr>
<tr>
<td>CCTA</td>
<td>coronary computed tomographic angiography</td>
</tr>
<tr>
<td>CMR</td>
<td>cardiac magnetic resonance</td>
</tr>
<tr>
<td>LV</td>
<td>left ventricular</td>
</tr>
<tr>
<td>LVEF</td>
<td>left ventricular ejection fraction</td>
</tr>
<tr>
<td>MI</td>
<td>myocardial infarction</td>
</tr>
<tr>
<td>MR</td>
<td>mitral regurgitation</td>
</tr>
<tr>
<td>TAVR</td>
<td>transcatheater aortic valve replacement</td>
</tr>
<tr>
<td>TTE</td>
<td>transthoracic echocardiography</td>
</tr>
<tr>
<td>TEE</td>
<td>transesophageal echocardiography</td>
</tr>
<tr>
<td>VT</td>
<td>ventricular tachycardia</td>
</tr>
<tr>
<td>VF</td>
<td>ventricular fibrillation</td>
</tr>
</tbody>
</table>

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Proprietary

Page 487 of 927
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Gustafsson F. Diagnosis and prognosis of cardiac allograft vasculopathy. UpToDate. Waltham, MA; March, 2018. Available at: http://www.uptodate.com/contents/diagnosis-and-prognosis-of-cardiac-allograft-vasculopathy?source=machineLearning&search=transplant+vasculopathy+follow+up&selectedTitle=1~7E150&sectionRank=1&anchor=H12357202#H12357202 Retrieved May 1, 2018


CPT Codes:
- Anterior Cervical Decompression with Fusion - Single Level** (ACDF) 22548, 22551, 22554
- Anterior Cervical Decompression with Fusion - Multiple Level** (ACDF) 22548, 22551, 22554, +22552, +22585
- Cervical Posterior Decompression with Fusion - Multiple Levels** 22590, 22595, 22600, +22614
- Cervical Posterior Decompression with Fusion - Single Level** 22590, 22595, 22600
- Cervical Artificial Disc – Single Level 22856, 22861, 22864
- Cervical Artificial Disc – Two Levels (**0375T is not a covered service and is not reimbursable) 22858, 0098T, 0095T
- Cervical Posterior Decompression (without fusion) 63001, 63015, 63020, 63040, 63045, 63050, 63051, +63035, +63043, +63048,
- Cervical Anterior Decompression (without fusion) 63075, +63076

OVERVIEW:
This guideline outlines the key surgical treatments and indications for common cervical spinal disorders and is a consensus document based upon the best available evidence. Spine surgery is a complex area of medicine, and this document breaks out the clinical indications by surgical type. Operative treatment is indicated only when the natural history of an operatively treatable problem is better than the natural history of the problem without operative treatment. Choice of surgical approach is based on anatomy, the patient's pathology, and the surgeon's experience and preference. All operative interventions must be based on a positive correlation with clinical findings, the natural history of the disease, the clinical course, and diagnostic tests or imaging results.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR CERVICAL SPINE SURGERY:
I. Anterior Cervical Decompression with Fusion (ACDF) - Single Level
   1) Anterior cervical discectomy and fusion with either a bone bank allograft or autograft with or without plating is the standard approach anteriorly and is most commonly used for disc herniation. The following criteria must be met*:
      a) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with spinal cord compression - immediate surgical evaluation is indicated (AAOS, 2013; Bono, 2011; Cunningham, 2010; Holly, 2009; Matz, 2009a; Matz, 2009b; Matz, 2009d; Matz, 2009e; Mummaneni, 2009; Tetreault, 2013; Yalamanchili, 2012; Zhu, 2013). Symptoms may include:
i) upper extremity weakness
ii) unsteady gait related to myelopathy/balance or generalized lower extremity weakness
iii) disturbance with coordination
iv) hyperreflexia
v) Hoffmann sign
vi) positive Babinski sign and/or clonus

OR

b) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with evidence of spinal cord or nerve root compression on Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) imaging. Immediate surgical evaluation is indicated. (Bono, 2011; Matz, 2009b; Tetreault, 2013).

OR

c) When All of the following criteria are met (Bono, 2011; Nikolaidis, 2010):

   i) Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity; AND

   ii) Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least 6 weeks of appropriate conservative treatment; AND

   iii) Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:

       (1) Analgesics, steroids, and/or NSAIDs

       (2) Structured program of physical therapy

       (3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician

       (4) Epidural steroid injections and or selective nerve root block; AND

   iv) Imaging studies confirm the presence of spinal cord or spinal nerve root compression (disc herniation or foraminal stenosis) at the level corresponding with the clinical findings (Bono, 2011). Imaging studies may include:

       (1) MRI (preferred study for assessing cervical spine soft tissue); OR

       (2) CT with or without myelography—indicated in patients in whom MRI is contraindicated; preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI).

2) *Cervical spine decompression with fusion as first-line treatment without conservative care measures in the following clinical cases (Matz, 2009b; Tetreault, 2013; Zhu, 2013; White, 1987):

   a) As outlined above for myelopathy or progressive neurological deficit scenarios.

   b) Significant spinal cord or nerve root compression due to tumor, infection or trauma.
c) Fracture or instability on radiographic films measuring:
   i) Sagittal plane angulation of greater than 11 degrees at a single interspace or greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction; OR
   ii) Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

3) Not Recommended (Nikolaidis, 2010; van Middelkoop, 2012):
   a) In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
   b) In cases of neck pain alone, without neurological deficits, and no evidence of significant spinal nerve root or cord compression on MRI or CT. See V. Cervical Fusion for Treatment of Axial Neck Pain Criteria

II. Anterior Cervical Decompression with Fusion (ACDF) - Multiple Level

1) Anterior cervical discectomy and fusion with either a bone bank allograft or autograft with or without plating is the standard approach anteriorly and is most commonly used for disc herniation. The following criteria must be met:*
   a) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with worsening spinal cord compression - immediate surgical evaluation is indicated (AAOS, 2013; Bono, 2011; Cunningham, 2010; Holly, 2009; Matz, 2009a; Matz, 2009b; Matz, 2009d; Matz, 2009e; Mummaneni, 2009; Tetreault, 2013; Yalamanchili, 2012; Zhu, 2013). Symptoms may include:
      i) upper extremity weakness
      ii) unsteady gait related to myelopathy/balance or generalized lower extremity weakness
      iii) disturbance with coordination
      iv) hyperreflexia
      v) Hoffmann sign
      vi) positive Babinski sign and or clonus
   OR
   b) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with corresponding evidence of spinal cord or nerve root compression on an MRI or CT scan images - immediate surgical evaluation is indicated (Bono, 2011; Matz, 2009b; Tetreault, 2013).
   OR
   c) When ALL of the following criteria are met (Bono, 2011; Nikolaidis, 2010):
      i) Cervical radiculopathy or myelopathy due to ruptured disc, spondylosis, spinal instability, or deformity; AND
      ii) Persistent or recurrent pain/symptoms with functional limitations that are unresponsive to at least 6 weeks of conservative treatment; AND
      iii) Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:
         (1) Analgesics, steroids, and/or NSAIDs
(2) Structured program of physical therapy
(3) Structured home exercise program prescribed by a physical therapist,
    chiropractic provider or physician
(4) Epidural steroid injections and or selective nerve root block;

**AND**

iv) Imaging studies confirm the presence of spinal cord or spinal nerve root compression
    (disc herniation or foraminal stenosis) at multiple levels corresponding with the clinical
    findings. Imaging studies may include any of the following (Bono 2011):
    (1) MRI (preferred study for assessing cervical spine soft tissue): OR
    (2) CT with or without myelography - indicated in patients in whom MRI is
        contraindicated; preferred for examining bony structures, or in patients presenting
        with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal
        compression not seen on MRI)

2) **Cervical spine decompression with fusion performed as first-line treatment without
    conservative care measures in the following clinical cases** (Matz, 2009b; Tetreault, 2013; White,
    1987; Zhu, 2013):
   a) As outlined above for myelopathy or progressive neurological deficit scenarios.
   b) Significant spinal cord or nerve root compression due to tumor, infection or trauma.
   c) Fracture or instability on radiographic films measuring:
      i) Sagittal plan angulation of greater than 11 degrees at a single interspace or greater
         than 3.5mm anterior subluxation in association with radicular/cord dysfunction; OR
      ii) Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an
          adult and 5 mm in a child.

3) **Not Recommended** (Nikolaidis, 2010; van Middelkoop, 2012):
   a) In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
   b) In cases of neck pain alone, without neurological deficits, and no evidence of significant
      spinal nerve root or cord compression on MRI or CT.  *See V. Cervical Fusion for Treatment
      of Axial Neck Pain Criteria.*

### III. Cervical Posterior Decompression with Fusion - Single Level

1) **Surgical indications for cervical spine stenosis/cervical spondylotic myelopathy (CSM) must meet
   the following criteria***:

   a) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits
      consistent with worsening spinal cord compression - immediate surgical evaluation is indicated
      (AAOS, 2013; Anderson, 2007; Cunningham, 2010; Holly, 2009; Matz, 2009d; Mummaneni,
      2009; Tetreault, 2013; Yalamanchili, 2012; Zhu, 2013). Symptoms may include:
         i) upper extremity weakness
         ii) unsteady gait related to myelopathy/balance or generalized lower extremity
             weakness
         iii) disturbance with coordination
         iv) hyperreflexia
v) Hoffmann sign

vi) positive Babinski sign and / or clonus

**OR**

b) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with corresponding evidence of spinal cord or nerve root compression on an MRI or CT scan images - immediate surgical evaluation is indicated (Bono, 2011; Matz, 2009b; Tetreault, 2013).

**OR**

c) When **ALL of the following** criteria are met (Bono, 2011; Nikolaidis, 2010):

i) Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity: **AND**

ii) Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least 6 weeks of conservative treatment: **AND**

iii) Documented failure of at least 6 consecutive weeks of **any 2** of the following physician-directed conservative treatments:

   (1) Analgesics, steroids, and/or NSAIDs

   (2) Structured program of physical therapy

   (3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician

   (4) Epidural steroid injections and or selective nerve root block; **AND**

iv) Imaging studies confirm the presence of spinal cord or spinal nerve root compression (disc herniation or foraminal stenosis) at single level corresponding with the clinical findings (Bono, 2011). Imaging studies may include:

   (1) MRI (preferred study for assessing cervical spine soft tissue): **OR**

   (2) CT with or without myelography - indicated in patients in whom MRI is contraindicated; preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI): **AND**

v) Single level **symptomatic cervical** disease as evidence by (Anderson, 2007):

   (1) cervical spinal stenosis due to cervical spondylotic myelopathy (CSM): **or**

   (2) cervical spinal stenosis due to ossification of the posterior longitudinal ligament (OPLL): **or**

   (3) single level spinal cord or nerve root compression due to herniated disc.

**2) Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases** (Anderson, 2007; Tetreault, 2013; White, 1987; Zhu, 2013):

a) As outlined above for myelopathy or progressive neurological deficit scenarios.

b) Significant spinal cord or nerve root compression due to tumor, infection or trauma.

c) Fracture or instability on radiographic films measuring:
i) Sagittal plane angulation of greater than 11 degrees at a single interspace or greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction; OR
ii) Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

3) Not Recommended (Nikolaidis, 2010; Wang, 2011):
   a) In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
   b) In cases of neck pain alone, without neurological deficits, and no evidence of significant spinal nerve root or cord compression on MRI or CT. See V. Cervical Fusion for Treatment of Axial Neck Pain Criteria.

IV. Cervical Posterior Decompression with Fusion - Multiple Levels

1) Surgical indications for cervical spine stenosis/cervical spondylotic myelopathy (CSM) must meet the following criteria*:
   a) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with worsening spinal cord compression - immediate surgical evaluation is indicated (AAOS, 2013; Anderson, 2007; Cunningham, 2010; Holly, 2009; Matz, 2009d; Mummaneni, 2009; Tetreault, 2013; Yalamanchili, 2012; Zhu, 2013). Symptoms may include:
      i) upper extremity weakness
      ii) unsteady gait related to myelopathy/balance or generalized lower extremity weakness
      iii) disturbance with coordination
      iv) hyperreflexia
      v) Hoffmann sign
      vi) positive Babinski sign and/or clonus
   OR
   b) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with corresponding evidence of spinal cord or nerve root compression on an MRI or CT scan images - immediate surgical evaluation is indicated (Bono, 2011; Matz, 2009b; Tetreault, 2013).
   OR
   c) When ALL of the following criteria are met (Bono, 2011; Nikolaidis, 2010):
      i) Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity; AND
      ii) Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least 6 weeks of conservative treatment; AND
      iii) Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:
         (1) Analgesics, steroids, and/or NSAIDs
(2) Structured program of physical therapy  
(3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician  
(4) Epidural steroid injections and or facet injections /selective nerve root block;  

iv) Imaging studies indicate significant spinal cord or spinal nerve root compression at multiple levels corresponding with the clinical findings. Imaging studies may include (Bono, 2011):  
(1) MRI (preferred study for assessing cervical spine soft tissue): OR  
(2) CT with or without myelography - indicated in patients in whom MRI is contraindicated: preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI): AND  

v) Multilevel (>=2) symptomatic cervical disease as evidence by (Anderson, 2007; Bono, 2011):  
(1) cervical spinal stenosis due to cervical spondylotic myelopathy (CSM); or  
(2) cervical spinal stenosis due to ossification of the posterior longitudinal ligament (OPLL); or  
(3) evidence of significant spinal cord or nerve root compression from herniated discs at two or more levels.

2) *Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases* (Anderson, 2007; Tetreault, 2013; White, 1987; Zhu, 2013):  
  a) As outlined above for myelopathy or progressive neurological deficit scenarios.  
  b) Significant spinal cord or nerve root compression due to tumor, infection or trauma.  
  c) Fracture or instability on radiographic films measuring:  
     i) Sagittal plane angulation of greater than 11 degrees at a single interspace or greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction: OR  
     ii) Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.  

3) **Not Recommended** (Nikolaidis, 2010; Wang, 2011):  
   a) In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.  
   b) In cases of neck pain alone, without neurological deficits, and no evidence of significant spinal nerve root or cord compression on MRI or CT.  

V. **Cervical Fusion for Treatment of Axial Neck Pain:**  
In patients with non-radicular cervical pain for whom fusion is being considered, **ALL of the following criteria must be met** (Riew, 2010):
1) Improvement of the symptoms has failed or plateaued, and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 consecutive months of appropriate, active treatment, or at the end of longer duration of non-operative programs for debilitated patients with complex problems [NOTE: Mere passage of time with poorly guided treatment is not considered an active treatment program]: **AND**

2) All pain generators are adequately defined and treated: **AND**

3) All physical medicine and manual therapy interventions are completed: **AND**

4) X-ray, MRI, or CT demonstrating disc pathology or spinal instability: **AND**

5) Spine pathology limited to one or two levels unless other complicating factors are involved: **AND**

6) Psychosocial evaluation for confounding issues addressed.

**NOTE:** The effectiveness of three-level or greater cervical fusion for non-radicular pain has not been established (van Middelkoop, 2012).

**VI. Cervical Posterior Decompression**

1) Surgical indications for cervical nerve root decompression due to radiculopathy, disc herniation or foraminal stenosis. A posterior laminotomy and discectomy is occasionally used for patients with specific lateral disc herniations when the surgeon’s preference is that the individual would respond better with a posterior approach than an anterior one. **The following criteria must be met**:

a) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with worsening **spinal cord compression** - immediate surgical evaluation is indicated (AAOS, 2013; Bono, 2011; Heary, 2009; Mummaneni, 2009; Ryken, 2009; Tetreault, 2013; Wang, 2013; Yalamanchili, 2012; Zhu, 2013). Symptoms may include:
   i) upper extremity weakness
   ii) unsteady gait related to myelopathy/balance or generalized lower extremity weakness
   iii) disturbance with coordination
   iv) hyperreflexia
   v) Hoffmann sign
   vi) positive Babinski sign and / or clonus

OR

b) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with corresponding evidence of spinal cord or nerve root compression on an MRI or CT scan images - immediate surgical evaluation is indicated (Tetreault, 2013; Wang, 2013).

OR

c) When **ALL of the following criteria are met** (Bono, 2011):
   i) Cervical radiculopathy from ruptured disc, spondylosis, or deformity: **AND**
ii) Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least 6 weeks of appropriate conservative treatment; \textit{AND}

iii) Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:

\begin{itemize}
\item (1) Analgesics, steroids, and/or NSAIDs
\item (2) Structured program of physical therapy
\item (3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
\item (4) Epidural steroid injections and or facet injections /selective nerve root block; \textit{AND}
\end{itemize}

iv) Imaging studies confirm the presence of spinal cord or spinal nerve root compression at the level(s) corresponding with the clinical findings (Bono, 2011). Imaging studies may include any of the following:

\begin{itemize}
\item (1) MRI (preferred study for assessing cervical spine soft tissue); \textit{OR}
\item (2) CT with or without myelography—indicated in patients in whom MRI is contraindicated; preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI);
\end{itemize}

2) \textbf{Cervical decompression performed as first-line treatment without conservative care in the following clinical cases} (Ryken, 2009; Tetreault, 2013; Wang, 2013; Zhu, 2013):

\begin{itemize}
\item a) As outlined above for myelopathy or progressive neurological deficit scenarios.
\item b) Spinal cord or nerve root compression due to tumor, infection or trauma.
\end{itemize}

3) \textbf{Not Recommended} (Nikolaidis, 2010; Wang, 2011):

\begin{itemize}
\item a) In asymptomatic or mildly symptomatic cases.
\item b) In cases of neck pain alone, without neurological deficits and abnormal imaging findings. \textit{See E. Cervical Fusion for Treatment of Axial Neck Pain Criteria.}
\item c) In patients with kyphosis or at risk for development of postoperative kyphosis.
\end{itemize}

\section*{VII. Cervical Artificial Disc Replacement (Single or Two Level)}

This involves the insertion of a prosthetic device into the cervical intervertebral space with the goal of maintaining physiologic motion at the treated cervical segment. The use of artificial discs in motion-preserving technology is based on the surgeon’s preference and training. Only FDA-approved artificial discs are appropriate.

1) Indications for artificial cervical disc replacement are as follows (Bono, 2011; Cheng, 2009; Davis, 2015; Matz, 2009e):

\begin{itemize}
\item a) Skeletally mature patient; \textit{AND}
\item b) Patient has intractable radiculopathy caused by one or two level disease (either herniated disc or spondolytic osteophyte) located at C3-C7; \textit{AND}
\item c) Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least 6 weeks of appropriate conservative treatment; \textit{AND}
\end{itemize}
d) Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:
   1) Analgesics, steroids, and/or NSAIDs
   2) Structured program of physical therapy
   3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
   4) Epidural steroid injections and or facet injections /selective nerve root block; AND

e) Imaging studies confirm the presence of compression at the level(s) corresponding with the clinical findings (MRI or CT); AND

f) No prior neck surgery; AND

g) Use of an FDA-approved prosthetic intervertebral discs.

2) Cervical Artificial Disc Replacement is NOT indicated when any of the following clinical scenarios exists (Davis, 2015):
   a) Symptomatic multiple level disease affecting 3 or more levels
   b) Adjacent level disease: degenerative disease adjacent to a previous cervical fusion
   c) Infection (at site of implantation or systemic)
   d) Osteoporosis or osteopenia
   e) Instability
      i) Translation greater than 3mm difference between lateral flexion-extension views at the symptomatic levels;
      ii) 11 degrees of angular difference between lateral flexion-extension views at the symptomatic levels
   f) Sensitivity or allergy to implant materials
   g) Severe spondylosis defined as (Davis, 2015):
      i) > 50% disc height loss compared to minimally or non-degenerated levels; OR
      ii) Bridging osteophytes; OR
      iii) Absence of motion on lateral flexion-extension views at the symptomatic site
   h) Severe facet arthropathy
   i) Ankylosing spondylitis
   j) Rheumatoid arthritis
   k) Previous fracture with anatomical deformity
   l) Ossification of the posterior longitudinal ligament (OPLL)
   m) Active cervical spine malignancy

VIII. Cervical Fusion without Decompression
Cervical fusion without decompression will be reviewed on a case-by-case basis. Atraumatic instability due to Down Syndrome-related spinal deformity, rheumatoid arthritis, or basilar invagination are uncommon, but may require cervical fusion (Trumees, 2017).
IX. **Cervical Anterior Decompression (without fusion)**
All requests for anterior decompression without fusion will be reviewed on a case-by-case basis (Bono, 2011; Botelho, 2012; Gebremariam, 2012; Matz, 2009a; Matz, 2009e).

X. **ADDITIONAL INFORMATION:**
1) **Conservative Therapy:** (Musculoskeletal) includes primarily physical therapy and/or injections; and a combination of modalities, such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, diathermy, chiropractic treatments, or physician supervised home exercise program. Part of this combination may include the physician instructing patient to rest the area or stay off the injured part.

2) **Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan AND
   b) Follow up with member with documentation provided regarding completion of HEP, (after 4 – 6 week period) or inability to complete HEP due to physical reason; i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

3) A comprehensive assimilation of factors should lead to a specific diagnosis with positive identification of the pathologic condition(s).
   a) Early intervention may be required in acute incapacitating pain or in the presence of progressive neurological deficits.
   b) Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.
   c) Patients may present with localized pain or severe pain in combination with numbness, extremity weakness, loss of coordination, gait issues, or bowel and bladder complaints. Nonoperative treatment continues to play an important role in the care of patients with degenerative cervical spine disorders. If these symptoms progress to neurological deficits, from corresponding spinal cord or nerve root compression, than surgical intervention may be warranted.
   d) All patients being considered for surgical intervention should first undergo a comprehensive neuromusculoskeletal examination to identify those pain generators that may either respond to non-surgical techniques, or may be refractory to surgical intervention.
   e) If operative intervention is being considered, particularly those procedures that require a fusion, it is recommended that the person refrain from smoking for at least six weeks prior to surgery and during the time of healing.
   f) In situations requiring the possible need for operation, a second opinion may be necessary. Psychological evaluation is strongly encouraged when surgery is being performed for isolated axial pain to determine if the patient will likely benefit from the treatment.
   g) It is imperative for the clinician to rule out non-physiologic modifiers of pain presentation, or non-operative conditions mimicking radiculopathy, myelopathy or spinal instability (peripheral compressive neuropathy, chronic soft tissue injuries, and psychological conditions), prior to consideration of elective surgical intervention.
4) Degenerative cervical spine disorders, while often benign and episodic in nature, can become debilitating, resulting in axial pain and neurological damage to the spinal cord or roots. Compression on the nerve root and/or spinal cord may be caused by (1) a herniated disc with or without extrusion of disc fragments and/or (2) degenerative cervical spondylosis.

XI. Anterior Approaches – Additional Information:
1) Anterior surgical approaches to cervical spine decompression emerged in the 1950s in response to technical limitations experienced with posterior approaches, including restricted access to and exposure of midline bony spurs and disc fragments.

2) The first reports in the literature describe anterior cervical discectomy combined with a spinal fusion procedure (ACDF). Fusion was added to address concerns about potential for loss of spinal stability and disc space height, leading to late postsurgical complications such as kyphosis and radicular pain (Sonntag and Klara, 1996; Dowd and Wirth, 1999; Matz et al, 2009a; Matz et al 2009b; Denaro and Di Martino, 2011; Botelho et al, 2012; van Middelkoop et al, 2012).

3) Anterior cervical fusion (ACF) accounted for approximately 80% of cervical spine procedures performed in the United States between 2002 and 2009, while posterior cervical fusion (PCF) accounted for 8.5% of these procedures (Oglesby et al, 2013).

4) Anterior Cervical Discectomy and Fusion (ACDF) – removal of all or part of a herniated or ruptured disc or spondolytic bony spur to alleviate pressure on the nerve roots or on the spinal cord in patients with symptomatic radiculopathy. Discectomy is most often combined with fusion to stabilize the spine.

XII. Posterior Approaches
1) Laminectomy – removal of the bone between the spinal process and facet pedicle junction to expose the neural elements of the spine; this allows for the inspection of the spinal canal, identification and removal of pathological tissue, and decompression of the cord and roots.

2) Laminoplasty – the opening of the lamina to enlarge the spinal canal. There are several laminoplasty techniques; all aim to alleviate cord compression by reconstructing the spinal canal. Laminoplasty is commonly performed to decompress the spinal cord in patients with multilevel degenerative spinal stenosis and neutral or lordotic alignment.

3) Laminoforaminotomy (also known as posterior discectomy) – the creation of a small window in the lamina to facilitate removal of arthritic bone spurs and herniated disc material pressing on the nerve root as it exits through the foramen. The procedure widens the opening of the foramen so that the nerve exits without being compressed.
REFERENCES


OVERVIEW:

This guideline outlines the key surgical treatments and indications for common lumbar spinal disorders and is a consensus document based upon the best available evidence. Spine surgery is a complex area of medicine and this document breaks out the treatment modalities for lumbar spine disorders into surgical categories: lumbar discectomy/microdiscectomy, lumbar decompression, and lumbar fusion surgery. See the additional information section for procedures considered not medically necessary.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INTRODUCTION

I. **Lumbar Discectomy/Microdiscectomy** is a surgical procedure to remove part of the damaged spinal disc. The damaged spinal disc herniates into the spinal canal and compresses the nerve roots. Nerve root compression leads to symptoms like low back pain, radicular pain, numbness and tingling, muscular weakness, and paresthesia. Typical disc herniation pain is exacerbated with any movement that causes the disc to increase pressure on the nerve roots.

II. **Lumbar Decompression (Laminectomy, Laminotomy, Facetectomy, and Foraminotomy):** Laminectomy is a common decompression surgery. The American Association of Neurological Surgeons defines laminectomy as a surgery to remove the back part of vertebra, lamina, to create more space for the spinal cord and nerves. The most common indication for laminectomy is spinal stenosis. Spondylolisthesis and herniated disk are also frequent indications for laminectomy. Decompression surgery is usually performed as part of lumbar fusion surgery.

III. **Lumbar Fusion Surgery:** Lumbar spinal fusion (arthrodesis) is a surgical procedure used to treat spinal conditions of the lumbar, e.g., degenerative disc disease, spinal stenosis, injuries/fractures of the spine, spinal instability, and spondylolisthesis. Spinal fusion is a “welding” process that permanently fuses or joins together two or more adjacent bones in the spine, immobilizing the vertebrae and restricting motion at a painful joint. It is usually performed after other surgical procedures of the spine, such as discectomy or laminectomy. The goal of fusion is to increase spinal stability, reduce irritation of the affected nerve roots, compression on the spinal cord, disability, and pain and/or numbness. Clinical criteria for single level fusion versus multiple level fusions are outlined under the indications section.

INDICATIONS FOR LUMBAR SURGERY: (This section of the clinical guidelines provides the clinical criteria for each of the lumbar and pre-sacral spine surgery categories.)
I. Indications for Lumbar Discectomy/Microdiscectomy: Surgical indications for intervertebral disc herniation*:

a) When ALL of the following are present:
   i) Primary radicular symptoms noted upon clinical exam that significantly hinders daily activities (Chou 2009; Kreiner 2014; Peul 2007; Tosteson 2011); AND
   ii) Failure to improve with at least six (6) consecutive weeks of documented, physician directed appropriate conservative treatment to include at least 2 of the following (Kreiner 2013; Kreiner 2014; Peul 2007):
      1) Analgesics, steroids, and/or NSAIDs
      2) Structured program of physical therapy
      3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
      4) Epidural steroid injections and or selective nerve root block; AND
   iii) Imaging studies showing evidence of intervertebral disc herniation that correlate exactly with the patient’s symptoms / signs (Fardon 2001; Kreiner 2014).

OR

*Other indications: Microdiscectomy may be used as the first line of treatment (no conservative treatment required) in the following clinical scenarios (Kreiner 2014):

b) Progressive nerve compression resulting in an acute motor neurologic deficit sensory or motor due to herniated disc. The neurological deficits should be significant: 0-2/5 on the motor function scale for L5 or S1 roots; 0-3/5 for L3 or L4 roots. Lesser degrees of motor dysfunction may resolve with conservative treatment and are not considered an indication for early surgery;

OR

c) Cauda equina syndrome (loss of bowel or bladder control).

NOTE: Percutaneous lumbar discectomy, radiofrequency disc decompression, and related procedures are deemed investigational procedures and are not approved. Discectomy and microdiscectomy are the gold standards.

II. Indications for Lumbar Decompression: Laminectomy, Laminotomy, Facetectomy, and Foraminotomy. These procedures allow decompression by partial or total removal of various parts of vertebral bone and ligaments. Surgical Indications for spinal canal decompression due to lumbar spinal stenosis*:

a) When ALL of the following are present:
   i) Neurogenic claudication, and/or radicular leg pain that impairs daily activities (Atlas 2005; Chou 2009; Genevay 2010; Kreiner 2013; Peul 2007; Tosteson 2011; Tosteson 2008; Weinstein 2007); AND
   ii) Failure to improve with at least six (6) consecutive weeks of documented, physician directed appropriate conservative treatment to include at least two (2) of the following (Kreiner 2013; Peul 2007):
      1) Analgesics, steroids, and/or NSAIDs
      2) Structured program of physical therapy
      3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
      4) Epidural steroid injections and or selective nerve root block; AND
   iii) Imaging findings demonstrating moderate to severe stenosis consistent with clinical signs/symptoms (Genevay 2010; Kreiner 2013; Weinstein 2007).
OR

*Other Indications*: Lumbar decompression may be used as the first line of treatment (*no conservative treatment required*) in any of the following clinical scenarios (Kreiner 2013; Kreiner 2014):

b) Progressive nerve compression resulting in an acute neurologic (sensory or motor) deficit. The neurological deficits should be significant—0-2/5 on the motor function scale for L5 or S1 roots; 0-3/5 for L3 or L4 roots. Lesser degrees of motor dysfunction may resolve with conservative treatment and are not considered an indication for early surgery;

OR

c) Cauda equina syndrome (loss of bowel or bladder control);

OR

d) Spinal stenosis due to tumor, infection, or trauma

NOTE: Percutaneous decompressions, endoscopic decompression, and related procedures (laser, etc.) are deemed investigational procedures and are not approved. Open or microdecompressions via laminectomy or laminotomy are the gold standards (Kreiner 2014).

III. Indications for Lumbar Spine Fusion:

A. Single Level Fusion with or without decompression

Because of variable outcomes with fusion surgery, patients should be actively involved in the decision-making process and provided appropriate decision-support materials when considering this intervention.

a) When *All of the following* are present*:

a) Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for at least 6 months (Bogduk 2009; Brox 2003; Carreon 2008; Chou 2009; Fritzell 2001; Kreiner 2013; Mannion 2016; Matz 2014; NASS 2009; Resnick 2005; Tosteson 2011; Tosteson 2008; Weinstein 2007); AND

b) Failure to improve with at least six (6) consecutive weeks of documented, physician directed appropriate conservative therapy (six months for isolated LBP) to include at least two (2) of the following (Brox 2003; Chou 2009; Kreiner 2013; Matz 2014; NASS 2009; Resnick 2005):

   1) Analgesics, steroids, and/or NSAIDs
   2) Structured program of physical therapy
   3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
   4) Epidural steroid injections and or facet injections /selective nerve root block; AND

   c) Imaging studies corresponding to the clinical findings (Genevay 2010; Kreiner 2013; Matz 2014; NASS 2009; Resnick 2005; Weinstein 2007); AND

   d) At least one of the following clinical conditions:

   1) Spondylolisthesis [Neural Arch Defect -Spondyloytic spondylolisthesis, degenerative spondylolisthesis, and congenital unilateral neural arch hypoplasia] (Carreon 2008; Kwon 2005; Matz 2014; NASS 2009; Weinstein 2007); OR

   2) Evidence of segmental instability -Excessive motion, as in degenerative spondylolisthesis, segmental instability, and surgically induced segmental instability (Carreon 2008; Kwon 2005; Matz 2014; NASS 2009; Weinstein 2007); OR
3) Revision surgery for failed previous operation(s) for pseudoarthrosis at the same level at least 6-12 months from prior surgery** if significant functional gains are anticipated (Trumees 2017); OR

4) Revision surgery for failed previous operation(s) repeat disk herniations if significant functional gains are anticipated (Note: Many recurrent disc herniations can be treated with discectomy alone, so specific indications for the addition of fusion will be required) (Kreiner 2014); OR

5) Fusion for the treatment of spinal tumor, cancer, or infection (Trumees 2017); OR

6) *Chronic low back pain or degenerative disc disease* (disc degeneration without significant neurological compression presenting with low back pain) must have failed at least 6 months of appropriate active non-operative treatment (*completion of a comprehensive cognitive -behavioral rehabilitation program is mandatory*) and must be evaluated on a case-by-case basis (Bogduk 2009; Brox 2003; Chou 2009; Fardon 2001; Fritzell 2001; Mannion 2016).

**NOTE:** The results of several randomized trials suggests that in many degenerative cases uninstrumented posterolateral intertransverse fusion has similar results to larger instrumented (PLIF, TLIF, etc.) fusion techniques with fewer morbidities and less likelihood of revision surgery. Accordingly, specific findings suggesting more significant instability should be present when larger techniques are used (gapping of facets, gross motion on flexion / extension radiographs, wide disc spaces) (Carreon 2008; Deyo 2010).

**OR**

*Other Indications:* Lumbar spinal fusion may be used as the first line of treatment (*no conservative treatment required*) in the following clinical scenarios (Kreiner 2014):

b) Progressive nerve compression resulting in an acute neurologic deficit (motor); *AND*
   - One of the aforementioned clinical conditions, *except* chronic low back pain or degenerative disc disease. The neurological deficits must be significant: 0-2/5 on the motor function scale for L5 or S1 roots; or 0-3/5 for L3 or L4 roots. Lesser degrees of motor dysfunction may resolve with conservative treatment and are not considered an indication for early surgery.

c) Cauda equina syndrome (loss of bowel or bladder control); *AND*
   - One of the aforementioned clinical conditions, *except* chronic low back pain or degenerative disc disease.

**REPEAT LUMBAR SPINE FUSION OPERATIONS:** Repeat lumbar fusion operations will be reviewed on a case-by-case basis upon submission of medical records and imaging studies that demonstrate remediable pathology. The below must also be *documented and available for review of repeat* fusion requests (Bogduk 2009; Chou 2009; Mannion 2016):

1) Rationale as to why surgery is preferred over other non-invasive or less invasive treatment procedures.

2) Signed documentation that the patient has participated in the decision-making process and understands the high rate of failure/complications.

Instrumentation, bone formation or grafting materials, including biologics, should be used at the surgeon’s discretion; however, use should be limited to FDA approved indications regarding the specific devices or biologics.

**NOTE:** Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is not an approved surgical approach due to insufficient evidence. Artificial lumbar disc replacement or other lumbar implants are not an approved procedure due to insufficient evidence.
B. Multi-level Fusion with or without decompression (all multi-level fusion surgeries will be reviewed on a case-by-case basis).

Because of variable outcomes with fusion surgery, patients should be actively involved in the decision-making process and provided appropriate decision-support materials when considering this intervention.

a) When **ALL of the following** are present*:
   i) Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for **at least 6 months** (Bogduk 2009; Brox 2003; Chou 2009; Fritzell 2001; Mannion 2016; Tosteson 2011; Tosteson 2008; Weinstein 2007): **AND**

   ii) Failure to improve with at least six (6) consecutive weeks of documented, physician directed appropriate conservative therapy to include at least two (2) of the following (Brox 2003; Matz 2014; NASS 2009):
       1) Analgesics, steroids, and/or NSAIDs
       2) Structured program of physical therapy
       3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
       4) Epidural steroid injections and or facet injections /selective nerve root block: **AND**

   iii) Imaging studies corresponding to the clinical findings (Genevay 2010; Kreiner 2013; Matz 2014; NASS 2009; Resnick 2005; Weinstein 2007): **AND**

   iv) At least **one of the following** clinical conditions (Carreon 2008; Kwon 2005; Matz 2014; NASS 2009):
       1) Multiple level spondylolisthesis (Note: Fusions in cases with single level spondylolisthesis should be limited to the unstable level); **OR**
       2) Fusion for the treatment of spinal tumor, trauma, cancer, or infection affecting multiple levels; **OR**
       3) Intra-operative segmental instability

**OR**

*Other Indications*: Lumbar spinal fusion may be used as the first line of treatment (**no conservative treatment required**) in the following clinical scenarios (Kreiner 2014):

b) Progressive nerve compression resulting in an acute neurologic deficit (motor): **AND**
   - One of the aforementioned clinical conditions except chronic low back pain or degenerative disc disease. The neurological deficits must be significant: 0-2/5 on the motor function scale for L5 or S1 roots; or 0-3/5 for L3 or L4 roots. Lesser degrees of motor dysfunction may resolve with appropriate conservative treatment and are not considered an indication for early surgery.

**OR**

c) Cauda equina syndrome (loss of bowel or bladder control): **AND**
   - One of the aforementioned clinical conditions, except chronic low back pain or degenerative disc disease.

**NOTE**: Instrumentation, bone formation or grafting materials, including biologics, should be used at the surgeon’s discretion; however, use should be limited to FDA approved indications regarding the specific devices or biologics.
NOTE: This lumbar surgery guideline does not address spinal deformity surgeries or the clinical indications for spinal deformity surgery.

NOTE: Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is not an approved surgical approach due to insufficient evidence. Artificial lumbar disc replacement or other lumbar implants are not an approved procedure due to insufficient evidence.

IV. CONTRAINDICATIONS FOR SPINE SURGERY (Note: Cases will not be approved if the below contraindications exist):

1) **Medical contraindications** to surgery, e.g., severe osteoporosis; infection of soft tissue adjacent to the spine and may be at risk for spreading to the spine; severe cardiopulmonary disease; anemia; malnutrition and systemic infection (Puvanesarajah 2016).

2) **Psychosocial risk factors.** It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, sympathetically mediated pain syndromes, sacroiliac dysfunction, psychological conditions, etc.) prior to consideration of elective surgical intervention (Kreiner 2014). Patients with clinically significant depression or other psychiatric disorders being considered for elective spine surgery will be reviewed on a case-by-case basis and the surgery may be denied for risk of failure.

3) **Active Tobacco or Nicotine** use prior to fusion surgery. Patients must be free from smoking and/or nicotine use for at least six weeks prior to surgery and during the entire period of fusion healing (Andersen 2001; Glassman 2000; Patel 2013).

4) **Morbid Obesity.** Contraindication to surgery in cases where there is significant risk and concern for improper post-operative healing, post-operative complications related to morbid obesity, and/or an inability to participate in post-operative rehabilitation (Epstein 2017). These cases will be reviewed on a case-by-case basis and may be denied given the risk of failure.

V. ADDITIONAL INFORMATION

1) **Spinal surgeries should be performed only by those with extensive surgical training (neurosurgery, orthopaedic surgery)**

2) **Services Not Covered:** The following procedures are considered either still under investigation or are not recommended based upon the current evidence: Percutaneous lumbar discectomy; Laser discectomy; Percutaneous Radiofrequency Disc Decompression; Intradiscal electrothermal annuloplasty (IDEA) or more commonly called IDET (Intradiscal Electrothermal therapy); Nucleus Pulpous Replacement; Pre-Sacral Fusion, or Lumbar Artificial Disc Replacement.

   a) **PERCUTANEOUS DISCECTOMY** is an invasive operative procedure to accomplish partial removal of the disc through a needle which allows aspiration of a portion of the disc under imaging control. It’s only indication is in order to obtain diagnostic tissue, due to lack of evidence to support long-term improvement compared to gold standard discectomy. This includes radiofrequency disc decompression.

   b) **LASER DISCECTOMY** is a procedure which involves the delivery of laser energy into the center of the nucleus pulposus using a fluoroscopically guided laser fiber under local anesthesia. The energy denatures protein in the nucleus, causing a structural change which is intended to reduce intradiscal pressure. Its effectiveness has not been fully established.
c) **INTRADISCAL ELECTROTHERMAL ANNULOPLASTY (IDEA)** (more commonly called **IDET**, or Intradiscal Electrothermal therapy) is an outpatient non-operative procedure in which a wire is guided into the identified painful disc using fluoroscopy. The wire is then heated at the nuclear-annular junction within the disc. It has not been shown to be effective.

d) **NUCLEUS PULPOSUS REPLACEMENT** Involves the introduction of a prosthetic implant into the intervertebral disc, replacing the nucleus pulposus while preserving the annulus fibrosus. It has not been shown to be effective relative to other gold standard interventions.

e) **LUMBAR ARTIFICIAL DISC REPLACEMENT**: Involves the insertion of a prosthetic device into an intervertebral space from which a degenerated disc has been removed, sparing only the peripheral annulus. The prosthetic device is designed to distribute the mechanical load of the vertebrae in a physiologic manner and maintain range of motion. Studies do not demonstrate a long-term advantage of measured function or pain over comparison groups undergoing fusion. The longevity of this prosthetic device has not yet been determined.

3) **Conservative Therapy**: (Musculoskeletal) includes primarily physical therapy and/or injections; and a combination of modalities, such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, diathermy, chiropractic treatments, or physician supervised home exercise program. Part of this combination may include the physician instructing patient to rest the area or stay off the injured part.

4) **Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan AND
   b) Follow up with member with information provided regarding completion of HEP (after suitable 4–6 week period), or inability to complete HEP due to physical reason, i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

5) **Isolated Low Back Pain** - Pain isolated to the lumbar region of the spine and the surrounding paraspinal musculature. Also referred to ‘mechanical low back pain’ or ‘discogenic pain’. No associated neurogenic claudication or radiculopathy.

6) **Claims Billing & Coding**:
   a) NIA uses a combination of internally developed edits in addition to an enhanced set of industry standard editing. NIA’s Claims Edit Module is a group of system edits that run multiple times per day. Edits that are part of this module include industry standard edits that apply to spine surgery services and NIA custom edits developed specifically for spine surgery. The following describes each of the edits NIA applies:

7) **Outpatient Code Editor (OCE)**: This edit performs all functions that require specific reference to HCPCS codes, HCPCS modifiers, and ICD-9-CM diagnosis codes. The OCE only functions on a single claim and does not have any cross claim capabilities. NIA is consistent with CMS.

8) **National Correct Coding Initiative (NCCI) editing**: The edit prevents improper payment when incorrect code combinations are reported. The NCCI contains two tables of edits. The Column One/Column Two Correct Coding Edits table and the Mutually Exclusive Edits table include code pairs that should not be reported together for a number of reasons explained in the Coding Policy Manual. NIA is consistent with CMS.

   a) Incidental edits: This edit applies if a procedure being billed is a component of another procedure that occurred on the same date of service for the same provider and tax ID and claimant.
b) Mutually exclusive editing: This edit applies if a procedure being billed is mutually exclusive with a procedure that occurred on the same date of service for the same provider tax ID and claimant.

9) **Multiple Procedure Discounts (MPD):** This edit applies a reduction to the second and any other subsequent services by the same provider, in the same setting, for the same member. We typically apply a 50% reduction. NIA follows the CMS methodology that began in January 2011 which allows for application of MPD to codes within CMS’s two specific advanced imaging code families. However, NIA differs from CMS in that we apply MPD to all provider types unless health plan contracts prohibit this.

10) **Lumbar Fusion** - Fusions can be performed either anteriorly, laterally, or posteriorly, or via a combined approach; although simple posterolateral fusions are indicated in the great majority of cases requiring fusion. Aggressive surgical approaches to fusion may be an indication for denial of cases (when such techniques have not been demonstrated to be superior to less morbid techniques) or recommendation for alternative procedure. These are the surgical approaches:
   a) Intertransverse Fusion or Posterolateral Fusion
   b) Anterior Interbody Fusion (ALIF)
   c) Lateral or Transpsoas Interbody Fusion (XLIF)
   d) Posterior or Trans-foraminal Interbody Fusion (PLIF or TLIF)
   e) Anterior/posterior Fusion (360-degree)
   f) Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is still being investigated and is not recommended.

11) Use of bone grafts including autologous or allograft which might be combined with metal or biocompatible devices to produce a rigid, bony connection between two or more adjacent vertebrae are common. Bone formation or grafting materials including biologics should be used at the surgeon’s discretion; however, use of biologics should be limited to FDA approved indications in order to limit complications (especially BMP).

12) All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests and must be performed by surgeons with appropriate training (neurosurgery, orthopaedic surgery). A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). A failure of accurate correlation may be an indication for denial of cases. It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, sympathetically mediated pain syndromes, sacroiliac dysfunction, psychological conditions, etc.) prior to consideration of elective surgical intervention.

13) Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.
   a) All patients being considered for surgical intervention should first undergo a comprehensive neuro-musculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention.
   b) While sufficient time allowances for non-operative treatment are required to determine the natural cause and response to non-operative treatment of low back pain disorders, timely decision making for operative intervention is critical to avoid de-conditioning and increased disability (exclusive of "emergent" or urgent pathology such as cauda equina syndrome or associated rapidly progressive neurologic loss).

14) In general, if the program of non-operative treatment fails, operative treatment is indicated when:
a) Improvement of the symptoms has plateaued or failed to occur and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 weeks of active treatment, or at the end of longer duration of non-operative programs for debilitated patients with complex problems; and/or

b) Frequent recurrences of symptoms cause serious functional limitations even if a non-operative active treatment program provides satisfactory relief of symptoms, and restoration of function on each recurrence.

15) **Lumbar spinal stenosis and associated lumbar spondylolisthesis** - Spinal stenosis is narrowing of the spinal column or of the neural foramina where spinal nerves leave the spinal column, causing pressure on the spinal cord. The most common cause is degenerative changes in the lumbar spine. Neurogenic claudication is the most common symptom, referring to “leg symptoms encompassing the buttock, groin and anterior thigh, as well as radiation down the posterior part of the leg to the feet.” In addition to pain, leg symptoms can include fatigue, heaviness, weakness and/or paresthesia. Some patients may also suffer from accompanying back pain. Symptoms are worse when standing or walking and are relieved by sitting. Lumbar spinal stenosis is often a disabling condition, and it is the most common reason for lumbar spinal surgery in adults over 65 years.

16) **Degenerative lumbar spondylolisthesis** - is the displacement of a vertebra in the lower part of the spine; one lumbar vertebra slips forward on another with an intact neural arch and begins to press on nerves. The slippage occurs at the L4-L5 level most commonly. The most common cause, in adults, is degenerative disease although it may also result from bone diseases and fractures. Spondylolisthesis seldom occurs before the age of 50 years and it disproportionately affects women, especially black women. Degenerative spondylolisthesis is not always symptomatic. *The indications for fusion in this group are evolving and as more evidence emerges, changes to the accepted indications and acceptable techniques used may be made.*

17) **Lumbar degenerative disease without stenosis or spondylolisthesis** - Spondylosis is an umbrella term describing age-related degeneration of the spine. Lumbar degenerative disease without stenosis or spondylolisthesis is characterized by disabling low back pain and spondylosis at L4-5, L5-S1, or both levels.
REFERENCES


Mannion AF, Brox JI, Fairbank JC. Long-term results of all RCTs show that fusion is no better than non-operative care in improving pain and disability in chronic low back pain. Spine J, 2016;16: 588-90.


CPT Codes:
Cervical Thoracic Region: 62320, 62321, 64479 (+64480)
Lumbar Sacral Region: 62322, 62323, 64483 (+64484)

INTRODUCTION:

Therapeutic Spinal Epidural Injections or Select Nerve Root Blocks (Transforaminal) are types of interventional pain management procedures. The therapeutic use of epidural injections is for short-term pain relief associated with acute back pain or exacerbation of chronic back pain. With therapeutic injections a corticosteroid is injected close to the target area with the goal of pain reduction. Epidural injections should be used in combination with other active conservative treatment* modalities and not as stand alone treatment for long-term back pain relief. There are different approaches used when administering spinal epidural injections:

1. **Interlaminar** epidural injections, with steroids, access the epidural space between two vertebrae (Interlaminar) to treat cervical, lumbar or thoracic pain with radicular pain. These procedures should be performed using fluoroscopic guidance (AHRQ 2013). Interlaminar epidural injections are the most common type of epidural injection.

2. **Transforaminal** epidural injections (also called selective nerve root blocks) access the epidural space via the intervertebral foramen where the spinal nerves exit (cervical, lumbar or thoracic region). It is used both diagnostically and therapeutically. Some studies report lack of evidence and risks of transformaminal epidural injections. These procedures are always aided with fluoroscopic guidance (AHRQ 2013).

3. **Caudal** epidural injections, with steroids, are used to treat back and lower extremity pain, accessing the epidural space through the sacral hiatus, providing access to the lower nerve roots of the spine. These procedures should be performed using fluoroscopic guidance (AHRQ 2013). Failed back surgery syndrome is the most common reason for the caudal approach.

The rationale for the use of spinal epidural injections is that the sources of spinal pain, e.g., discs and joints, are accessible and amendable to neural blockade.

Medical necessity management for epidural injections includes an initial evaluation including history and physical examination and a psychosocial and functional assessment. The following must be determined: nature of the suspected organic problem; non-responsiveness to active conservative treatment*; level of pain and functional disability; conditions which may be contraindications to epidural injections; and responsiveness to prior interventions.

Interventional pain management specialists do not agree on how to diagnose and manage spinal pain; there is a lack of consensus with regards to the type and frequency of spinal interventional techniques for treatment of spinal pain. The American Society of Interventional Pain Physicians (ASIPP) guidelines and International Spine Intervention Society (SIS) guidelines provide an algorithmic approach which provides a step-by-step procedure for managing chronic spinal pain based upon evidence-based guidelines. It is
based on the structural basis of spinal pain and incorporates acceptable evidence of diagnostic and therapeutic interventional techniques available in managing chronic spinal pain.

The guidelines and algorithmic approach referred to above include the evaluation of evidence for diagnostic and therapeutic procedures in managing chronic spinal pain and recommendations for managing spinal pain. The Indications and Contraindications presented within this document are based on the guidelines and algorithmic approach. Prior to performing this procedure, shared decision-making between patient and physician must occur, and patient must understand the procedure and its potential risks and results (moderate short-term benefits, and lack of long-term benefits).

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

I. INDICATIONS FOR EPIDURAL INJECTIONS OR SELECTIVE NERVE BLOCKS (caudal, interlaminar, and transforaminal) (Injection of local anesthetics with corticosteroids)

1) Acute pain or exacerbation of chronic radicular pain with the following clinical timeframes:
   o Neck or back pain with acute radicular pain (AHRQ 2013; Summers 2013):
     i) after 2 weeks or more of acute radicular pain that has failed to respond or poorly responded to conservative (including medication) management unless the medical reason this conservative treatment cannot be done is clearly documented (AHRQ 2013; Manchikanti 2013; Summers 2013; ODG 2017); OR
     o Failed back surgery syndrome or epidural fibrosis causing radicular pain (AHRQ 2013; ODG 2017):
       i) typically not done immediately post-surgery. Documentation requires a medical reason that clearly indicates why an injection is needed.
       ii) patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months or details of engagement in other forms of active conservative non-operative treatment if the patient had any prior spinal injections prior to epidural injections unless the medical reason this conservative treatment cannot be done is clearly documented (AHRQ 2017; Manchikanti 2013; Summers 2013; ODG 2017); OR
     o Spinal stenosis (foraminal, central or disc disease) causing radicular pain (AHRQ 2017; ODG 2017):
       ▪ patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months or details of engagement in other forms of active conservative non-operative treatment if the patient had any prior spinal injections prior to epidural injections unless the medical reason this conservative treatment cannot be done is clearly documented; (AHRQ 2017; Manchikanti 2013; Summers 2013; ODG 2017); OR
   d) Diagnostic transforaminal injection to identify the pain generator for surgical planning (Manchikanti 2013); AND
   e) Pain causing functional disability or average pain levels of ≥ 6 on a scale of 0 to 10 (AHRQ 2013; Manchikanti 2011; NASS 2013; NASS 2012; Manchikanti 2013; Summers 2013).

II. FREQUENCY OF REPEAT THERAPEUTIC INJECTIONS:

1) Epidural injections may be repeated only as medically necessary. Each epidural injection requires an authorization and the following criteria must be met for repeat injections:
a) Documented proof that the prior injection had a positive response by significantly decreasing the patient’s pain (at least 30% reduction in pain after initial injections or significant documented functional improvement) (NASS 2013; ODG 2017). Or a second injection may be performed at a different spinal level or with a different epidural technique if there is documentation of a question about the pain generator or there is evidence of multilevel pathology (ODG 2017); **AND**

b) No more than 3 procedures in a 12-week period of time per region with at least 14 days between injections in the initial diagnostic phase. At least 50% or more cumulative pain relief obtained for a minimum of 6 weeks after initial injections (Manchikanti 2013); **AND**

c) The patient continues to have ongoing pain or documented functional improvement (pain causing functional disability or pain level ≥ 6 on a scale of 0 to 10 (AHRQ 2013; Manchikanti 2011; NASS 2013; Manchikanti 2013; Summers 2013); **AND**

d) The patient is actively engaged in other forms of active conservative non-operative treatment (unless pain prevents the patient from participating in conservative therapy*) (AHRQ 2013; Qassem 2017; Summers 2013); **AND**

e) In the first year of treatment, which may include an initial series of 3 injections in the initial diagnostic phase and additional injections in the treatment phase, a total of 6 epidural injections may be performed (Manchikanti 2013).

f) Repeat injections after the initial diagnostic phase should be done at intervals of at least 2 months provided that previous injections resulted in at least 50% relief or functional improvement for at least 2 months and are limited to a maximum total of 4 therapeutic procedures per region per 12 months (Manchikanti 2013; NASS 2013). If special circumstances are documented (e.g. elderly patient with severe spinal stenosis and not an operative candidate) then repeat injections are limited to a maximum of 6 procedures in 12 months (NASS 2013).

**NOTE:** Each epidural injection requires an authorization.

g) If the neural blockade is applied for different regions, injections may be administered at intervals of no sooner than 7 days for most types of procedures (Manchikanti 2013).

h) *Injecting multiple regions or performing multiple procedures during the same visit may be deemed medically unnecessary unless documentation is provided outlining an unusual situation (ODG 2017).*

i) No more than 2 levels of transforaminal blocks should be done in one day (ODG 2017).

**NOTE:** An injection of opioid or other substance for the purpose of completing a trial for an implantable infusion pump is approvable.

III. **CONTRAINDICATIONS FOR EPIDURAL INJECTIONS**

1) Bleeding diathesis and full anticoagulation (risk of epidural hematoma);
2) Severe spinal stenosis resulting in intraspinal obstruction;
3) Local infection at injection site;
4) Predominantly psychogenic pain;
5) Sepsis;
6) Hypovolemia;
7) Uncontrolled diabetes;
8) Uncontrolled glaucoma;
9) High concentrations of local anesthetics in patients with multiple sclerosis;
10) For diagnosis or treatment of facet mediated pain;
11) Known or suspected allergic reaction to steroid medications;
12) Spinal infection; OR
13) Acute fracture.
IV. ADDITIONAL INFORMATION:

1) **Conservative Therapy**: (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care (AHRQ 2013; Qassem 2017; Summers 2013).

2) **Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan and may include yoga, Tai chi, or supervised aerobic exercise (Qassem 2017; Sculpo 2001), AND
   b) Follow up with member with documentation provided regarding completion of HEP, (after suitable 4-6 week period) or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP) (AHRQ 2013; Qassem 2017; Summers 2013).

3) Terminology: Interlaminar Epidural; Selective Nerve Root Injection (transforaminal only); Transforaminal Injection: Injections of Spinal Canal

4) Hip-spine syndrome - Hip-spine syndrome is a condition that includes both debilitating hip osteoarthritis and low back pain. Abnormal spinal sagittal alignment and difficulty in maintaining proper balance, as well as a wobbling gait, may be caused by severe osteoarthritis of the hip joint. Epidural injections are used to determine a primary pain generator in this condition.

5) Spondylolisthesis and nerve root irritation - Degenerative lumbar spondylolisthesis is the displacement of a vertebra in the lower part of the spine: one lumbar vertebra slips forward on another with an intact neural arch and begins to press on nerves. The most common cause, in adults, is degenerative disease although it may also result from bone diseases and fractures. Degenerative spondylolisthesis is not always symptomatic. Epidural injections may be used to determine a previously undocumented nerve root irritation as a result of spondylolisthesis.

6) Lumbar spinal stenosis with radiculitis - Spinal stenosis is narrowing of the spinal column or of the neural foramina where spinal nerves leave the spinal column, causing pressure on the spinal cord. The most common cause is degenerative changes in the lumbar spine. Neurogenic claudication is the most common symptom, referring to “leg symptoms encompassing the buttock, groin and anterior thigh, as well as radiation down the posterior part of the leg to the feet.” In addition to pain, leg symptoms can include fatigue, heaviness, weakness and/or paresthesia. Some patients may also suffer from accompanying back pain. Symptoms are worse when standing or walking and are relieved by sitting. Lumbar spinal stenosis is often a disabling condition, and it is the most common reason for lumbar spinal surgery in adults over 65 years. The most common levels of stenosis are L3 through L5, but it may occur at multilevels in some patients. Radiculitis is the inflammation of a spinal nerve root that causes pain to radiate along the nerve paths. Epidural injections help to ascertain the level of the pain generator in this condition.

7) Postoperative epidural fibrosis - Epidural fibrosis is a common cause of failed back surgery syndrome. With the removal of a disc, the mechanical reason for pain may be removed, but an inflammatory condition may continue after the surgery and may cause pain. Epidural corticosteroids, with their anti-inflammatory properties, are used to treat postoperative fibrosis and may be used along with oral Gabapentin to reduce pain.
8) **Lumbar herniated disc** - Epidural steroid injections have been proven to be effective at reducing symptoms of lumbar herniated discs. Evidence shows that they can be successful in 42% to 56% of patients who do not improve after 6 weeks of conservative treatment. Observation and epidural steroid injection are effective nonsurgical treatments for this condition.

9) **Failed back surgery syndrome** - Failed back surgery syndrome (FBSS) is characterized by persistent or recurring low back pain, with or without sciatica, following lumbar surgery. The most common cause of FBSS is epidural fibrosis which be triggered by a surgical procedure such as discectomy. The inflammation resulting from the surgical procedure may start the process of fibrosis and cause pain. Epidural steroid injections are administered to reduce pain.
REFERENCES


ODG- Official Disability Evidence-Based Guideline, 22nd annual edition, 2017


CPT Codes:
Cervical Thoracic Region: 64490 (+ 64491, +64492)
Lumbar Sacral Region: 64493 (+64494, +64495)

INTRODUCTION

Facet joints (also called zygapophysial joints or z-joints), posterior to the vertebral bodies in the spinal column and connecting the vertebral bodies to each other, are located at the junction of the inferior articular process of a more cephalad vertebra and the superior articular process of a more caudal vertebra. These joints provide stability and enable movement, allowing the spine to bend, twist, and extend in different directions. They also restrict hyperextension and hyperflexion.

Facet joints are clinically important spinal pain generators in patients with chronic spinal pain. In patients with chronic low back pain, facet joints have been implicated as a cause of the pain in 15% to 45% of patients. Facet joints are considered as the cause of chronic spinal pain in 48% of patients with thoracic pain and 54% to 67% of patients with chronic neck pain. Facet joints may refer pain to adjacent structures, making the underlying diagnosis difficult as referred pain may assume a pseudoradicular pattern. Lumbar facet joints may refer pain to the back, buttocks, and lower extremities while cervical facet joints may refer pain to the head, neck and shoulders.

Imaging findings are of little value in determining the source and location of ‘facet joint syndrome’, a term originally used by Ghormley and referring to back pain caused by pathology at the facet joints. Imaging studies may detect changes in facet joint architecture, but correlation between radiologic findings and symptoms is unreliable. Although clinical signs are also unsuitable for diagnosing facet joint-mediated pain, they may be of value in selecting patients for controlled local anesthetic blocks of either the medial branches or the facet joint itself.

Medical necessity management for paravertebral facet injections includes an initial evaluation including history and physical examination and a psychosocial and functional assessment. The following must be determined: nature of the suspected organic problem; non-responsiveness to conservative treatment; level of pain and functional disability; conditions which may be contraindications to paravertebral facet injections; and responsiveness to prior interventions.

The most common source of chronic pain is the spine and about two-thirds of the U.S. population suffers from spinal pain sometime during their life span. Facet joint interventions are used in the treatment of pain in certain patients with a confirmed diagnosis of facet joint pain. Interventions include intraarticular injections and medial branch nerve blocks in the lumbar, cervical and thoracic spine. Prior to performing this procedure, shared decision-making between patient and physician must occur, and patient must understand the procedure and its potential risks and results. Facet joint injections or medial branch nerve blocks require guidance imaging.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.
I. **Indications for Facet Joint Injections or Medial Branch Nerve Blocks:**

1) To confirm disabling non-radicular low back (lumbosacral), mid back (thoracic) or neck (cervical) pain*, suggestive of facet joint origin as documented in the medical record based upon ALL of the following:

   a) history, consisting of mainly axial or non-radicular pain unless stenosis is caused by synovial cyst (Khan, 2006; Manchikanti, 2009; Manchikanti, 2013); **AND**

   b) Lack of evidence, either for discogenic or sacroiliac joint pain as the main pain generators (Manchikanti, 2009; Manchikanti, 2013); **AND**

   c) Lack of disc herniation or evidence of radiculitis as the main pain generators unless stenosis is caused by synovial cyst (Khan, 2006; Manchikanti, 2009; Manchikanti, 2013); **AND**

   d) Facet blocks should not be performed at same levels as previous surgical fusion 15; **AND**

   e) Pain causing functional disability or average pain levels of ≥ 6 on a scale of 0 to 10 (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013; Summers, 2013); **AND**

   f) Duration of pain of at least 3 months (Manchikanti, 2009; Manchikanti, 2013); **AND**

   g) Failure to respond to conservative non-operative therapy management* for a minimum of 6 weeks in the last 6 months prior to facet injections or details of active engagement in other forms of active conservative non-operative treatment if the patient had prior spinal injections unless the medical reason this treatment cannot be done is clearly documented (AHRQ, 2013; Manchikanti, 2013; ODG, 2017; Summers, 2014); **AND**

   h) All procedures must be performed using fluoroscopic or CT guidance (AHRQ, 2013). **NOTE:** Ultrasound guidance is not a covered benefit and procedure performed using ultrasound guidance are not reimbursable.

II. **FREQUENCY OF FACET BLOCK:**

1) There must be **a minimum of 14 days** between injections (Manchikanti, 2013).

2) There must be a positive response of ≥ 50% pain relief or improved ability to function or a change in technique, for example from an initial intraarticular facet block to a facet joint nerve block can be considered. Repeat therapeutic injections should be performed at a frequency of 2 months or longer provided that at least 50% relief is obtained for a minimum of 2 months after the previous injection (Manchikanti, 2013). The patient is actively engaged in other forms of active conservative non-operative treatment if the patient is receiving therapeutic facet joint injections unless pain prevents the patient from participating in conservative therapy*) (AHRQ, 2013; Qassem, 2017; Summers, 2013).

3) **In the diagnostic phase a maximum of 2 procedures may be performed. In the therapeutic phase a maximum of 4 procedures per region every 12 months except under unusual circumstances such as a recurrent injury.** (NOTE: Unilateral facet blocks performed at the same level on the right vs. left within 2 weeks of each other would be considered as one procedure) (Manchikanti, 2013).
4) If the procedures are applied for different regions, they may be performed at intervals 1-2 weeks for most types of procedures (Manchikanti, 2013).

5) **Radiofrequency** neurolysis procedures should be considered in patients with positive facet blocks (with at least 70% pain relief and/or improved ability to function, but with insufficient sustained relief (less than 2-3 months improvement) (AHRQ, 2013; Manchikanti, 2013; Summers, 2013; ODG, 2017).

6) The patient continues to have ongoing pain or documented functional disability (pain causing functional disability or pain level ≥ 6 on a scale of 0 to 10) (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013; Summers, 2013).

### III. CONTRAINDICATIONS FOR FACET JOINT INJECTIONS:

1) History of allergy to contrast administration, local anesthetics, steroids, or other drugs potentially utilized;

2) Hypovolemia;

3) Infection over puncture site;

4) Bleeding disorders or coagulopathy;

5) History of allergy to medications to be administered;

6) Inability to obtain percutaneous access to the target facet joint;

7) Progressive neurological disorder which may be masked by the procedure;

8) Pregnancy;

9) Spinal infection; OR

10) Acute fracture

### IV. ADDITIONAL INFORMATION:

1) **Conservative Therapy**: (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care (AHRQ, 2013; Qassem, 2017; Summers, 2013).

2) **Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan and may include yoga, Tai chi, or supervised aerobic exercise (Qassem, 2017; Sculpo, 2001), AND
   b) Follow up with member with documentation provided regarding completion of HEP, (after suitable 4-6 week period) or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

3) **Terminology**: Facet Injections; Facet Joint Blocks; Paravertebral Facet Injections; Paravertebral Facet Joint Injections; Paravertebral Facet Joint Nerve Injections; Zygaphophyseal injections; Lumbar Facet Blockade; Medial Branch blocks
REFERENCES


INTRODUCTION

Facet joints (also called zygapophysial joints or z-joints), posterior to the vertebral bodies in the spinal column and connecting the vertebral bodies to each other, are located at the junction of the inferior articular process of a more cephalad vertebra and the superior articular process of a more caudal vertebra. These joints provide stability and enable movement, allowing the spine to bend, twist, and extend in different directions. They also restrict hyperextension and hyperflexion.

Facet joints are clinically important spinal pain generators in patients with chronic spinal pain. Pain mediated by the facet joints may be caused by repetitive stress and/or cumulative low-level trauma resulting in osteoarthritis and inflammation. In patients with chronic low back pain, facet joints have been implicated as a cause of the pain in 15% to 45% of patients. They are considered as the cause of chronic spinal pain in 48% of patients with thoracic pain and 54% to 67% of patients with chronic neck pain. Facet joints may refer pain to adjacent structures, making the underlying diagnosis difficult as referred pain may assume a pseudoradicular pattern. Lumbar facet joints may refer pain to the back, buttocks, and proximal lower extremities while cervical facet joints may refer pain to the head, neck and shoulders.

Imaging findings are of little value in determining the source and location of ‘facet joint syndrome’, a term originally used by Ghormley and referring to back pain caused by pathology at the facet joints. Imaging studies may detect changes in facet joint architecture, but correlation between radiologic findings and symptoms is unreliable. Although clinical signs are also unsuitable for diagnosing facet joint-mediated pain, they may be of value in selecting patients for controlled local anesthetic blocks of either the medial branches or the facet joint itself. This is an established tool in diagnosing facet joint syndrome.

Facet joints are known to be a source of pain with definitive innervations. Interventions used in the treatment of patients with a confirmed diagnosis of facet joint pain include: medial branch nerve blocks in the lumbar, cervical and thoracic spine; and radiofrequency neurolysis (see additional terminology). The medial branch of the primary dorsal rami of the spinal nerves has been shown to be the primary innervations of facet joints. Substance P, a physiologically potent neuropeptide considered to play a role in the nociceptive transmission of nerve impulses, is found in the nerves within the facet joint.

Radiofrequency neurolysis is a minimally invasive treatment for cervical, thoracic and lumbar facet joint pain. It involves using energy in the radiofrequency range to cause necrosis of specific nerves (medial branches of the dorsal rami), preventing the neural transmission of pain. The objective of radiofrequency neurolysis is to both provide relief of pain and reduce the likelihood of recurrence.

Members of the American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Medicine (ASRA) have agreed that conventional or thermal radiofrequency ablation of the medial branch nerves to the facet joint should be performed for neck or low back pain. Radiofrequency neurolysis has been employed for over 30 years to treat facet joint pain. Prior to performing this procedure, shared decision-making between patient and physician must occur, and patient must understand the procedure and its potential risks and results.
Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

I. **INDICATIONS FOR THERAPEUTIC PARAVertebral FACET JOINT DENERVATION (RADIOFREQUENCY NEURolysis)** (local anesthetic block followed by the passage of radiofrequency current to generate heat and coagulate the target medial branch nerve)

1) Positive response to one or two controlled local anesthetic blocks of the facet joint nerves (medial branch blocks), with at least 70% pain relief and/or improved ability to function for a minimal duration at least equal to that of the local anesthetic, but with insufficient sustained relief (less than 2-3 months relief); AND a failure to respond to more active conservative non-operative management for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented (AHRQ 2013; Manchikanti, 2009; Manchikanti, 2013; Summers, 2013); OR

2) Positive response to prior radiofrequency neurolysis procedures with at least 50% pain relief and/or improved ability to function for at least 4 months, and the patient is actively engaged in other forms of appropriate active conservative non-operative treatment (unless pain prevents the patient from participating in conservative therapy*) (AHRQ, 2013; Manchikanti, 2013; Qassem, 2017; Sculpo, 2001; Summers, 2013); AND

3) The presence of ALL of the following:
   a) Lack of evidence that the primary source of pain being treated is from discogenic pain, sacroiliac joint pain, disc herniation or radiculitis (Manchikanti, 2009; Manchikanti, 2013);
   b) Pain causing functional disability or an average pain levels of ≥ 6 on a scale of 0 to 10 prior to each radiofrequency procedure including radiofrequency procedures done unilaterally on different days (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013; Summers, 2013);
   c) Duration of pain of at least 3 months (AHRQ, 2013; Manchikanti, 2013; Summers, 2013)

II. **FREQUENCY:**

1) Limit to 2 facet neurolysis procedures every 12 months, per facet joint (Manchikanti, 2013).

   *NOTE:* **Unilateral radiofrequency denervations performed at the same level on the right vs left within 2 weeks of each other would be considered as one procedure toward the total number of radiofrequency procedures allowed per 12 months. Every radiofrequency procedure requires pre-authorization.**

III. **CONTRAINDICATIONS FOR PARAVertebral FACET JOINT DENERVATION (RADIOFREQUENCY NEURolysis):**

1) History of allergy to local anesthetics or other drugs potentially utilized;
2) Lumbosacral radicular pain (dorsal root ganglion);
3) Conditions/diagnosis for which procedure is used are other than those listed in Indications;
4) Absence of positive diagnostic blocks; OR
5) For any nerve other than the medial branch nerve.

IV. **ADDITIONAL INFORMATION:**

1) **Conservative Therapy:** (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (including trigger point), and diathermy can be utilized. Active modalities may consist of
physical therapy, a physician supervised home exercise program**, and/or chiropractic care (AHRQ, 2013; Summers, 2013; Qassem, 2017).

2) **Home Exercise Program (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:

   a) Information provided on exercise prescription/plan and may include yoga, Tai Chi, or supervised aerobic exercise (Qassem, 2017; Sculpo, 2001): **AND**

   b) Follow up with member with documentation provided regarding completion of HEP, (after suitable 6 week period) or inability to complete HEP due to physical reason - i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

3) **Terminology:** Paravertebral Facet Joint Denervation, Radiofrequency Neurolysis, Destruction Paravertebral Facet Joint Nerve, Facet Joint Rhizotomy, Facet Neurolysis, Medial Branch Radiofrequency Neurolysis, Medial Branch Radiofrequency Neurotomy or Radiofrequency Denervation.
REFERENCES


TOC

22532 – Thoracic Spine Surgery

CPT Codes: 22532, 22534, 22556, 22585, 22610, 22614, 22830, 63003, 63016, 63046, 63048, 63055, 63057, 63064, 63066, 63077, 63078

OVERVIEW:

Thoracic Decompression with or without fusion:
Thoracic disc herniation with or without nerve root compression is usually treated conservatively (non-surgically). A back brace may be worn to provide support and limit back motion. Injection of local anesthetic and steroids around the spinal nerve (spinal nerve blocks) may be effective in relieving radicular pain. As symptoms subside, activity is gradually increased. This may include physical therapy and/or a home exercise program. Preventive and maintenance measures (e.g., exercise, proper body mechanics) should be continued indefinitely. Job modification may be necessary to avoid aggravating activities.

Simple laminectomy is rarely used in the treatment of thoracic disc herniation because of the high risk of neurologic deterioration and paralysis. Excision of the disc (discectomy) may be performed via several different surgical approaches—anteriolorly, laterally, or transpedicularly. Fusion should be performed only if surgery causes instability in the spinal column. Many newer techniques do not usually destabilize the thoracic spine.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS:
All requests for thoracic spine surgery will be reviewed on case-by-case basis. The following criteria must be met for consideration.

1. **INDICATIONS FOR DECOMPRESSION SURGERY ONLY INCLUDE:**
   - Positive Clinical Findings of Myelopathy with evidence of progressive neurologic deficits consistent with worsening **spinal cord compression**—immediate surgical evaluation is indicated. Symptoms may include any of the following:
     - lower extremity weakness
     - unsteady gait related to myelopathy/balance or generalized lower extremity weakness
     - disturbance with coordination
     - hyperreflexia
     - positive Babinski sign
     - clonus
   
   OR
   
   - Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) or lower extremity weakness (0-3/5 on the strength scale) or paralysis with corresponding evidence
of spinal cord or nerve root compression on an MRI or CT scan images — immediate surgical evaluation is indicated:

OR

• When **ALL of the following** criteria are met:
  • Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to **at least 12 weeks of conservative treatment** concerted conservative treatment to include completed and appropriate therapy (including stabilization exercises and epidural steroid injections):  **AND**
  • Imaging studies confirm the presence of spinal cord or spinal nerve root compression at the level corresponding with the clinical findings (MRI or CT).

2. **INDICATIONS FOR THORACIC DECOMPRESSION WITH FUSION SURGERY INCLUDE:**

   a) Deformity Cases—please refer to our **Deformity Spine Surgery (Adult) Guideline.**

   OR

   b) For Myelopathy or radiculopathy secondary to cord or root compression (see criteria described below) satisfying the indications for decompressive surgery requiring extensive decompression that results in destabilization of the thoracic spine.

   NOTE: There is no current evidence base to support fusion in the thoracic spine for degenerative disease without significant neurological compression or significant deformity as outlined above.

**CONTRAINDICATIONS FOR SPINE SURGERY**

- **Medical contraindications to surgery.** e.g., severe osteoporosis; infection of soft tissue adjacent to the spine, whether or not it has spread to the spine; severe cardiopulmonary disease; anemia; malnutrition and systemic infection.

- **Psychosocial risk factors.** It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, sympathetically mediated pain syndromes, sacroiliac dysfunction, psychological conditions, etc.) prior to consideration of elective surgical intervention.

- **Active nicotine use prior to fusion surgery.** The patient must refrain from nicotine use for at least six weeks prior to surgery and during the period of fusion healing.

- **Morbid Obesity.** Contraindication to surgery in cases where there is significant risk and concern for improper post-operative healing, post-operative complications related to morbid obesity, and/or an inability to participate in post-operative rehabilitation.

   NOTE: Cases of severe myelopathy and progressive neurological dysfunction may require surgery despite these general contraindications.
REFERENCES:


CPT Codes: 27096, G0260

INTRODUCTION

This guideline addresses the use of sacroiliac joint injections for the treatment of low back pain that originates in the region of the sacroiliac joint. An injection of anesthetic and/or steroid may be used for the diagnosis and treatment of sacroiliac joint (SIJ) pain syndrome disorders (such as degenerative joint disease, postsurgical injuries, or traumatic injuries), or for treatment of spondyloarthropathy (inflammatory disorders of the joints and ligaments of the spine).

Sacroiliac joint injections are typically used for the following conditions:

- **Sacroiliac joint pain syndrome** may be caused by various events, including pain secondary to postsurgical or traumatic injury, degeneration (wear and tear), or pregnancy. Physical examination (history and physical, provocative maneuvers) and diagnostic injection help to identify the source of pain as the SIJ.

- **Diagnostic SIJ injections** are used to determine if the SIJ pain originates with the SIJ. Diagnostic blocks can reveal (or fail to reveal) that the source of pain is originating from the SIJ, and then an appropriate treatment plan can be developed (Curatolo et al, 2010; Manchikanti et al, 2013a).

- **Therapeutic SIJ injections** may be used to treat SIJ pain once it has been determined that the SIJ is the origin of the pain. A therapeutic injection typically includes a corticosteroid and a local anesthetic that can be injected directly into the joint (intra-articular) or into the tissues surrounding the joint (periarticular).

- **Spondyloarthropathy** (also known as spondyloarthritis) is the name for a family of rheumatic diseases that cause arthritis. Sacroiliitis is a key indicator of spondyloarthritis and is diagnosed with imaging. Patients with spondyloarthropathy are generally managed by rheumatologists and account for only a small percentage of the cases that present in interventional pain management settings.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.
I. INDICATIONS FOR SACROILIAC JOINT INJECTIONS (SJI)

1) For the treatment of SIJ pain:
   All of the following must be met:
   a) Low back pain maximal below level of L5 which may radiate to the groin or lower extremity persisting at least 3 months (Manchikanti, 2013a; ODG, 2016); AND
   b) Positive exam findings to suggest the diagnosis which may include the pelvic distraction test, pelvic compression test, thigh thrust test, FABER (Patrick’s test) or Gaenslen’s test (Laslett, 2008; MacVicar, 2017; ODG, 2016); AND
   c) Active conservative treatment for a minimum of 6 weeks in the last 6 months (including physical therapy, home exercise, patient education, psychosocial support, and/or medication) has failed unless the medical reason this conservative treatment cannot be done is clearly documented (AHRQ, 2013; Manchikanti, 2013a; ODG, 2016; Summers, 2013); AND
   d) Pain causing functional limitations or average pain levels of ≥ 6 on a scale of 0 to 10 (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013a; Summers, 2013); AND
   e) Lack of evidence for disc-related pain or facet joint pain as the main pain generators (Manchikanti, 2009; Manchikanti, 2013a).

2) For the treatment of spondyloarthropathy (ACR 2012):
   All of the following must be met:
   a) The patient has experienced ≥ 3 months of low back pain; AND
   b) Age of onset < 45 years; AND
   c) Comprehensive pain management program including physical therapy, home exercise, patient education, psychosocial support, and/or oral medication is in place; AND
   d) Prior history of evidence of sacroiliitis on imaging (i.e., active inflammation on magnetic resonance imaging [MRI] or definite radiographic sacroiliitis grade > 2 bilaterally or grade 3–4 unilaterally); AND
   e) 1 or more spondyloarthropathy features:
      a. Inflammatory back pain with at least 4 of the following criteria present:
         (1) Age at onset < 45 years
         (2) Insidious onset
         (3) Improvement with exercise
         (4) No improvement with rest
         (5) Pain at night (with improvement upon getting up)
   f) Arthritis
   g) Enthesitis of the heel (irritability of muscles, tendons, or ligaments where they enter the bone)
   h) Uveitis (inflammation of the uvea, the middle layer of the eye)
i) Dactylitis (inflammation of a finger or toe)

j) Psoriasis

k) Crohn's/colitis

l) Good response to NSAIDs

m) Family history of spondyloarthropathy

n) Positive testing for HLA-B27

o) Elevated C-reactive protein (CRP)

II. FREQUENCY OF REPEAT THERAPEUTIC INJECTIONS

1) SIJ injections may be repeated up to 2 times in the initial treatment phase no sooner than 2 weeks apart provided that at least 50% relief is obtained (Manchikanti, 2013a); **AND**

2) SIJ injections may only be repeated after the initial treatment phase if symptoms recur and the patient has had at least a 50% improvement for a minimum of 6 weeks after each therapeutic injection (Manchikanti, 2013a); **AND**

3) The patient is actively engaged in other forms of active conservative non-operative treatment (unless pain prevents the patient from participating in conservative therapy (AHRQ, 2013; Qassem, 2017; Summers, 2013); **AND**

4) Repeat injections should not be done more frequently than every two months for a total of 4 injections in a 12 month period (Manchikanti, 2013a); **AND**

5) Pain causing functional limitations or average pain levels of ≥ 6 on a scale of 0 to 10 (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013a; Summers, 2013).

III. CONTRAINDICATIONS FOR SACROILIAC JOINT INJECTIONS

1) Active systemic infection

2) Skin infection at the site of needle puncture

3) Bleeding disorder or anticoagulation therapy

4) Uncontrolled high blood pressure

5) Uncontrolled diabetes

6) Unstable angina

7) Congestive heart failure

8) Allergies to contrast, anesthetics, or steroids (AAOS, 2009)

IV. ADDITIONAL INFORMATION

1) **Conservative Therapy:** (Musculoskeletal) includes a combination of modalities, such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, diathermy, chiropractic treatments, or physician supervised home exercise program. Part of
this combination may include the physician instructing patient to rest the area or stay off the injured part (AHRQ, 2013; Qassem, 2017; Summers, 2013).

2) **Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:

a) Information provided on exercise prescription/plan and may include yoga, Tai chi, or supervised aerobic exercise (Qassem, 2017; Sculpo, 2001); **AND**

b) Follow up with member with information provided regarding completion of HEP (after suitable 6 week period), or inability to complete HEP due to physical reason: i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

Low back pain is one of the most common of all spinal pain problems. According to the Centers for Disease Control and Prevention (CDC), the prevalence of low back pain in adults 18 years of age and older is 28.4% and may range as high as 32.1% in adults ≥ 75 years (CDC, 2012). Symptoms of low back pain may arise from multiple sites, including lumbar intervertebral discs, facet joints, sacroiliac joints, ligaments, fascia, muscles, and nerve root dura. The sacroiliac joint has been shown to be a source of pain in 10% to 27% of chronic low back pain (Hansen et al, 2007; Simopoulos et al, 2012; Manchikanti et al, 2013a).

The sacroiliac joint (SIJ) is located between the sacrum (located at the base of the spine) and the pelvis, and supports the weight of the upper body in the standing position. There are SIJs in both the right and left side of the lower back. Strong ligaments hold the joints in place. The SIJ is well innervated and has been shown to be capable of being a source of low back pain and referred pain in the lower extremity. Low back pain originating from the SIJ can result from inflammatory conditions such as sacroiliitis, spondyloarthropathy (ankylosing spondylitis; rheumatoid spondylitis), or from postsurgical or traumatic injury, degeneration (wear and tear), or pregnancy. SIJ pain most often occurs in the buttocks and lower back, and may radiate down through the buttocks and the leg. Physical examination and radiographic techniques may confirm a diagnosis related to spondyloarthropathy. Physical examination, including provocative maneuvers to elicit pain response, and controlled SIJ injections can help diagnose noninflammatory pain arising from the SIJ (Hansen et al, 2007; Medline Plus, 2012; Mayo Clinic, 2013).

In order to confirm correct placement of the injectable medication into the intra-articular space, fluoroscopic or computed tomography (CT) guidance is used. A periarticular injection into the soft tissue may be used if ligamentous or muscular attachments are suspected to be involved. The goal of the therapeutic injection is to reduce inflammation and/or pain and provide longer pain relief. Long-term relief is generally defined as 6 weeks or longer, but positive responders generally have a much longer duration of response; serial injections may be required in order to maintain therapeutic effectiveness (Hansen et al, 2007; AAOS, 2009; Laukkainen et al, 2002; Hawkins et al, 2009).

Spinal injections for the treatment of SIJ pain syndrome are typically performed as one part of a comprehensive treatment program, which will nearly always include an exercise program to improve or maintain spinal mobility. Potential candidates for SIJ injections include those with low back pain originating from the SIJ that is unresponsive to conservative treatments.

Treatment for SIJ pain depends upon the signs and symptoms, as well as the underlying cause for the pain. Medications, such as over-the-counter analgesics, a short course of narcotics, muscle relaxants or tumor necrosis factor (TNF) inhibitors, such as etanercept (Enbrel), adalimumab (Humira), or infliximab (Remicade), may be prescribed. Therapy sessions with a physical therapist involving range-of-motion, stretching, and strengthening exercises may be used to maintain joint
flexibility and strengthen the muscles. Other interventional procedures used to treat SIJ pain include corticosteroid injections to reduce inflammation and pain, radiofrequency denervation, electrical stimulation, or in rare cases, joint fusion (Mayo Clinic, 2013).

The indications for coverage for the treatment of spondyloarthropathy have been established through use of the reviewed clinical studies and through criteria developed by the Assessment of SpondyloArthritis International Society (ASAS) for the classification of axial spondyloarthritis (Sieper et al, 2009). They are in keeping with the benefit guidelines developed by the Centers for Medicare & Medicaid Services (CMS).

While evidence supports that SIJ injection is an effective method of determining the source of pain, evidence supporting the efficacy of SIJ in the treatment of SIJ pain syndrome is considerably limited. There are limited controlled or prospective clinical studies to support SIJ injection for therapeutic purposes. Despite the limited quality of the clinical studies supporting SIJ injection for the treatment of SIJ pain, the procedure is recommended by the American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Management (ASRAPM) Practice Guidelines. The indications for coverage have been established from the 2009 Comprehensive Evidence-Based Guidelines for Interventional Techniques in the Management of Chronic Spinal Pain, and updated with the 2013 An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations.
REFERENCES


CPT Codes:
27130, 27132, 27134, 27137, 27138, S2118

HIP ARTHROPLASTY
Total & Revision/Conversion Hip Replacement

Introduction
This guideline addresses elective, non-emergent hip arthroplasty (hip replacement) procedures, including total hip arthroplasty, resurfacing arthroplasty, and revision/conversion arthroplasty procedures.

Arthritis is the most common cause of chronic hip pain and disability. Degenerative, age-related osteoarthritis causes cartilage to wear away and eventually the bones within the joint rub against each other causing pain and stiffness. In a total hip replacement, the femoral head and acetabulum are removed and replaced with prosthetic components. In hip resurfacing arthroplasty, a metal cup is placed in the acetabulum and a metal cap is placed over the head of the femur with limited removal of the femoral head and neck.

In some cases, the hip prosthesis may wear out or loosen. If loosening is painful, a second surgery, such as a revision or conversion may be necessary. In this procedure some or all of the components of the original replacement prosthesis are removed and replaced with new ones.

Hemiarthroplasty or partial hip replacement involves the reconstruction of the femoral head but not the acetabulum. This procedure is indicated for select traumatic events, guidelines for which fall outside of the scope of this document.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual patient needs and based on an assessment of the local delivery system.

General Requirements
Elective hip arthroplasty may be considered if the following general criteria are met:
- Defined as a deviation from normal hip function, which may include painful weight bearing; painful or inadequate range of motion to accomplish age-appropriate activities of daily living (ADLs) and/or employment; and mechanical catching, locking.
- Patient is medically stable with no uncontrolled comorbidities (such as diabetes)
- Patient does not have an active local or systemic infection
- Patient does not have active, untreated drug dependency (including but not limited to narcotics, opioids, muscle relaxants) unless engaged in treatment program
- Patient has good oral hygiene and does not have major dental work scheduled or anticipated (ideally within one year of joint replacement), due to increased post-surgical infection risk.

Clinical notes should address
• Symptom onset, duration, and severity;
• Loss of function and/or limitations;
• Type and duration of non-operative management modalities.
Non-operative management must include at least two or more of the following unless otherwise specified in clinical indications below:
• Rest or activity modifications/limitations;
• Weight reduction for patient with elevated BMI;
• Protected weight-bearing with cane, walker or crutches;
• Physical therapy modalities;
• Physician-supervised exercise program (including home exercise program);
• Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, or analgesics;
• Intra-articular injection(s)

Clinical Indications:

Total Hip Arthroplasty (THA)

THA may be considered medically necessary when the following criteria are met:

a) Hip pathology is due to rheumatoid arthritis, femoral neck fracture in the setting of pre-existing arthritis, malignancy, failure of previous surgery, dysplasia, or avascular necrosis with collapse, confirmed by imaging.

OR

b) When ALL of the following criteria are met:

i) Pain due to advanced osteoarthritis (Kellgren-Lawrence grade 3 or 4 or Tönnis grade 2 or 3 [see grading appendix]) and documented loss of function that has been present for at least 6 months:

ii) Failure of at least 3 months of non-operative treatment, including at least two of the following:

   a. Rest or activity modifications/limitations
   b. Weight reduction for patient with elevated BMI
   c. Protected weight-bearing with cane, walker or crutches
   d. Physical therapy modalities
   e. Physician-supervised exercise program (including home exercise program)
   f. Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, or analgesics
   g. Intra-articular corticosteroid injection

iii) Physical exam demonstrates findings of hip pathology as evidenced by one or more of the following:

   (1) Painful, limited range of motion or antalgic gait
   (2) Contracture
   (3) Crepitus
   (4) Leg length difference;

iv) Imaging demonstrates advanced hip joint arthritis of at least Kellgren-Lawrence grade 3 or 4 or Tönnis grade 2 or 3 [see grading appendix];

v) No injection into the joint within 3 months of surgery.
Relative Contraindications:

- Metal allergy (dependent upon implant choice)
- Chronic renal insufficiency (due to metal ions circulating and potential renal toxicity)

Absolute Contraindications:

- Any injection into the joint within 3 months of surgery
- Local or remote active infection
- Female of child-bearing age (due to metal ions circulating in blood with potential risk to fetus)  
  (Note: this only applies to metal on metal replacements)

**Hip Resurfacing Arthroplasty:**

Hip resurfacing procedures will be reviewed on a case by case basis.

Hip resurfacing arthroplasty may be considered medically necessary when **ALL** of the following criteria are met:

a) Pain and documented loss of function are present for at least 6 months;

b) 3 months of non-operative treatment have failed to improve symptoms;

c) Physical exam has typical findings of hip pathology as evidenced by one or more of the following:
   i) Painful, limited range of motion or antalgic gait
   ii) Contracture
   iii) Crepitus
   iv) Leg length difference;

d) Imaging demonstrates advanced hip joint pathology of at least Kellgren-Lawrence grade 3-4, Tönnis grade 2 or 3, or avascular necrosis involving less than 50% of the femoral head;  
[see grading appendix]

e) Male patient is less than 65 years old or female patient is less than 55 years old;

f) BMI less than 40;

g) No injection into the joint within 3 months of surgery:

Absolute Contraindications:

- Any injection into the joint within 3 months of surgery
- Osteoporosis or osteopenia (DEXA scan bone mineral density evaluation)
- Other co-morbidity (including medications that contribute to decreased bone mineral density  
  (glucocorticoid steroids, heparin, aromatase inhibitors, thiazolidinediones, proton pump inhibitors,  
  loop diuretics, cyclosporine, anti-retrovirals, anti-psychotics, anti-seizures, certain breast cancer  
  drugs, certain prostate cancer drugs, depo-provera, aluminum-containing antacids) that may  
  contribute to active bone demineralization
- Cystic degeneration at the junction of the femoral head and neck on radiographs or MRI or CT
- Malignancy at the proximal femur
- Evidence of current, ongoing, or inadequately treated hip infection, or sepsis
- Female of child-bearing age (due to metal ions circulating in blood with potential risk to fetus)
- Chronic renal insufficiency (due to metal ions circulating and potential renal toxicity)
• Metal allergy

**Total Hip Arthroplasty Revision/Conversion Arthroplasty**

Hip Revision/Conversion Arthroplasty may be considered medically necessary when a previous hip reconstruction meets **ALL** of the following criteria in either of the following subsections:

a) Previous removal of infected hip prosthesis AND no evidence of current, ongoing, or inadequately treated hip infection (ruled out by synovial fluid aspiration/biopsy (cell count and culture)) AND off antibiotics:

OR

a) When all of the following criteria are met:

  i) Failed hip arthroplasty as defined by symptomatic and unstable joint upon physical exam (documented persistent, severe and disabling pain, loss of function);

  ii) Physical exam and radiographic evidence supports extensive disease or damage due to fracture, malignancy, osteolysis, other bone or soft-tissue reactive or destructive process, inappropriate positioning of components, recurrent instability, subluxation, dislocation, or other mechanical failure. (NOTE: MRI is used less often in these circumstances unless it is a metal-on-metal prosthesis and looking for soft-tissue lesions; x-ray, CT, nuclear studies are used more frequently);

  iii) No evidence of current, ongoing, or inadequately treated hip infection (ruled out by synovial fluid aspiration/biopsy (cell count and culture)) AND off antibiotics

*Note: Removal of infected hip prosthesis and subsequent insertion of antibiotic spacer is not considered an elective surgery.*

**Non-Covered Services:**

The following procedures are not considered a covered service and are not reimbursable based on lack of current scientific evidence for clinically important improvement, safety or efficacy; or based on scientific evidence of increased risk of serious complications:

• Procedures utilizing computer-navigated or patient-specific or gender-specific instrumentation.

**Grading Appendix**

**Kellgren-Lawrence Grading System:**

*MRI should not be the primary tool used to determine the presence or severity of arthritic changes in the joint.*

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No radiographic features of osteoarthritis</td>
</tr>
<tr>
<td>1</td>
<td>Possible joint space narrowing and osteophyte formation</td>
</tr>
<tr>
<td>2</td>
<td>Definite osteophyte formation with possible joint space narrowing</td>
</tr>
<tr>
<td>Grade</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
</tr>
<tr>
<td>0</td>
<td>No signs of osteoarthritis</td>
</tr>
<tr>
<td>1</td>
<td>Mild: Increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity</td>
</tr>
<tr>
<td>2</td>
<td>Moderate: Small cysts, moderate narrowing of the joint space, moderate loss of head sphericity</td>
</tr>
<tr>
<td>3</td>
<td>Severe: Large cysts, severe narrowing or obliteration of the joint space, severe deformity of the head</td>
</tr>
</tbody>
</table>


McIntosh AL, et al. Recent intraarticular steroid injection may increase infection rates in primary THA. *Clinical Orthopaedics and Related Research.* 2006;451: 50-54.


CPT Codes:
Femoroacetabular Impingement (FAI) Hip Surgery: 29914, 29915, 29916
Hip Surgery – Other: 29860, 29861, 29862, 29863

INTRODUCTION:

This guideline addresses the following elective, non-emergent, arthroscopic hip repair procedures:
- Diagnostic arthroscopy
- Femoroacetabular Impingement (FAI)
- Labral Repair Only
- CAM, Pincer, CAM & Pincer combined
- Synovectomy, Biopsy, or Removal of Loose or Foreign Body
- Chondroplasty or abrasion for Chondral injuries, chondromalacia

Arthroscopy introduces a fiber-optic camera into the hip joint through a small incision for diagnostic visualization purposes. This camera may also be used in the surrounding extra-articular areas, in a procedure called endoscopy. Other instruments may then be introduced to remove, repair, or reconstruct joint pathology.

Open, non-arthroplasty hip repair surgeries are performed as dictated by the type and severity of injury and/or disease.

Surgical indications are based on relevant clinical symptoms, physical exam, radiologic findings, and response to non-operative, conservative management when medically appropriate.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

General Requirements

- Elective arthroscopic surgery of the hip may be considered if the following general criteria are met:
  - There is clinical correlation of patient’s subjective complaints with objective exam findings and/or imaging (when applicable);
  - Patient has limited function (age-appropriate activities of daily living (ADLs), occupational, athletic);
  - Patient is medically stable with no uncontrolled comorbidities (such as diabetes);
  - Patient does not have an active local or systemic infection;
  - Patient does not have active, untreated drug dependency (including but not limited to narcotics, opioids, muscle relaxants) unless engaged in treatment program

- Clinical notes should address:
  - Symptom onset, duration, and severity;
  - Loss of function and/or limitations;
  - Type and duration of non-operative management modalities (where applicable).
• Non-operative management must include **TWO** or more of the following, unless otherwise specified:
  o Physical therapy or properly instructed home exercise program:
  o Rest or activity modification:
  o Ice/Heat:
  o Protected weight bearing:
  o Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics:
  o Brace/orthosis:
  o Weight optimization:
  o Corticosteroid injections

**Clinical Indications**

**Diagnostic Hip Arthroscopy**

All requests for diagnostic hip arthroscopy will be considered and decided on a case-by-case basis and are rarely deemed medically necessary.

Diagnostic hip arthroscopy may be medically necessary when **ALL** of the following criteria are met:
  a) At least 6 months of hip pain with documented loss of function;
  b) Failure of at least 12 weeks of non-operative treatment, including at least **two** of the following:
     i) Rest or activity modifications/limitations
     ii) Ice/heat
     iii) Protected weight bearing
     iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
     v) Brace/orthosis
     vi) Physical therapy modalities
     vii) Supervised home exercise
     viii) Weight optimization
     ix) Corticosteroid injection
     c) Indeterminate radiographs **AND** MRI findings;
     d) Radiographs demonstrate the following:
        i) AP Pelvis radiograph: neck shaft angle 120-135 degrees, joint space >2 mm (weight-bearing), alpha angle less than 50 degrees, lateral center edge angle between 25-40 degrees, Tonnis angle between 0-10 degrees
        ii) Dunn 45 radiograph: alpha angle less than 50 degrees
        iii) Femoral head extrusion index less than 25%
        iv) False profile radiograph (if obtained): anterior center edge angle between 25-40

As noted above, patient must have no evidence of any of the following: posterior wall sign, ischial spine sign, crossover sign, no protrusio acetabulae, fracture (femur, acetabulum), labral tear (on MRI or MR arthrogram), PVNS, synovial chondromatosis, intra-articular loose body, subchondral bone marrow edema, adductor tear, pubic edema, osteitis pubis, hamstring tear, abductor (gluteus medius, minimus) tear, ischiofemoral impingement (narrowed ischiofemoral and quadratus femoris spaces).
Femoroacetabular Impingement (FAI)

FAI is a condition characterized by a mechanical impingement between the femur (cam) and/or the acetabulum (pincer) that may result in labral injury (labral tear) or articular cartilage injury (chondral defect, arthritis). Up to 95% of labral tears are observed in the presence of FAI and “isolated” labral tears are very uncommon (as are labral tears caused by trauma).

There is no evidence to support hip arthroscopy for FAI and/or labral tear in an asymptomatic patient and there is a very high prevalence of abnormal radiographs found in asymptomatic patients: 33% of asymptomatic hips have a cam lesion, 66% of asymptomatic hips have a pincer lesion, and 68% of asymptomatic hips have a labral tear.

Even though hip dysplasia as well as symptomatic FAI and labral tears are believed to be precursors to hip arthritis, arthroscopy is never indicated for the treatment of osteoarthritis of the hip and rarely (if ever) indicated for dysplasia.

Labral Repair

Arthroscopic labral repair may be medically necessary when ALL of the following criteria are met:

a) Hip or groin pain in positions of flexion and rotation that may be associated with mechanical symptoms of locking, popping, or catching;
b) Positive provocative test on physical exam with pain at the hip joint with flexion, adduction, and internal rotation;
c) Acetabular labral tear on MRI, with or without intra-articular contrast;
d) Failure of at least 6 weeks of non-operative treatment, including at least two of the following:
   i) Physical therapy or properly instructed home exercise program
   ii) Rest or activity modification
   iii) Ice/Heat
   iv) Protected weight bearing
   v) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics
   vi) Weight optimization
   vii) Corticosteroid injection
e) No evidence of hip joint arthritis, defined as a Tönnis Grade 2 or 3 (joint space less than 2 millimeters) on weight-bearing AP radiograph [see Grading Appendix];
f) Patient is less than 50 years of age.

NOTE: Arthroscopy of the hip for labral repair is considered not medically necessary in the presence of significant hip joint arthritis (Tönnis grade 2 or greater) [see grading appendix], dysplasia [see grading appendix] or other structural abnormality that would require skeletal correction.

CAM, Pincer, Combined CAM & Pincer Repair

Technically not a repair, this procedure involves bony decompression, shaving, osteoplasty, femoroplasty, acetabuloplasty, and/or osteochondroplasty. Greater than 95% of labral repairs should be performed with at least a femoral osteoplasty or an acetabuloplasty.

Arthroscopic CAM, Pincer or combined CAM and Pincer repair may be medically necessary when ALL of the following criteria are met:

a) Positional hip pain:
b) Failure of at least 6 weeks of non-operative treatment, including at least two of the following:
   i) Physical therapy or properly instructed home exercise program
   ii) Rest or activity modification
   iii) Ice/Heat
   iv) Protected weight bearing
   v) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics
   vi) Weight optimization
   vii) Corticosteroid injection

c) Positive impingement sign on physical exam (hip or groin pain with flexion, adduction and internal rotation (FADIR):

d) ANY of the following radiograph, CT and/or MRI findings of FAI:
   i) Nonspherical femoral head or prominent head-neck junction (pistol-grip deformity) with alpha angle >55 degrees indicating CAM impingement [see radiographic measurement appendix];
   ii) Overhang of the anterolateral rim of the acetabulum, posterior wall sign, prominent ischial spine sign, acetabular protrusion, or retroversion with a center edge (CE) angle >35° and/or cross-over sign indicating pincer deformity [see radiographic measurement appendix];
   iii) Combination of CAM and pincer criteria;

e) No evidence of hip joint arthritis, defined as a Tönnis Grade 2 or 3 (joint space less than 2 millimeters) on weight-bearing AP radiograph [see Grading Appendix];

f) Skeletally mature patient;

g) Under age < 50* years old;

h) BMI < 40*;

i) Radiographic images show no evidence of ANY indicators for hip dysplasia [see grading appendix].

* Patients age > 50 years (with no evidence of OA) or patients with BMI >40 will be reviewed on a case by case basis.

NOTE: Arthroscopy of the hip for FAI is considered not medically necessary or contraindicated in the presence of significant hip joint arthritis (Tönnis grade 2 or greater) [see grading appendix], in the skeletally immature patient (open proximal femoral physis).

Arthroscopy for Synovectomy, Biopsy, or Removal of Loose or Foreign Body

Arthroscopic synovectomy, biopsy, removal of loose or foreign body, or a combination of these procedures may be medically necessary when the following criteria are met:

   a) Radiographic evidence of acute post-traumatic intra-articular foreign body or displaced fracture fragment;

   OR

b) When ALL of the following criteria are met:
   i) Hip pain associated with grinding, catching, locking, or popping;
   ii) Physical exam findings confirm painful hip with limited range of hip motion;
   iii) Failure of at least 12 weeks of non-operative treatment, including at least two of the following:
      a. Physical therapy or properly instructed home exercise program
      b. Rest or activity modification
      c. Ice/Heat
      d. Protected weight bearing
      e. Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics
f. Weight optimization
g. Corticosteroid injection

iv) Radiographs, CT, and/or MRI demonstrate synovial proliferation, calcifications, nodularity, inflammation, pannus, loose body.

**Shaving or debridement of articular cartilage (chondroplasty), and/or abrasion arthroplasty**

*There are no clinical indications for performing an independent debridement procedure within the hip. Debridement should always be combined or secondary to another procedure, and is primary performed within FAI procedures.*

**Extra-articular (Endoscopic) Hip Surgery**

*Arthroscopy for extra-articular hip pathology is recognized as a less invasive adjunctive tool to correct or minimize symptoms of structural pathology, but is not supported in current high level evidence-based literature.*

*Extra-articular hip applications may be used to minimize symptoms of internal snapping hip (internal coxa saltans, iliopsoas tendinitis, snapping iliopsoas), iliopsoas tendon at iliopectineal eminence or anterior inferior iliac spine, external snapping hip (external coxa saltans, snapping iliotibial band, iliotibial band at greater trochanter). May also include proximal hamstring endoscopy for partial tear of proximal hamstring with or without bursitis or proximal hamstring, sciatic neurolysis, ischiofemoral decompression (for ischiofemoral impingement), or anterior inferior iliac spine (subspine) decompression for subspine impingement.*

3 types of anterior inferior iliac spine:
- Type 1: small, tip does not extend to sourcil;
- Type 2: medium, tip extends down to sourcil;
- Type 3: large, tip extends down below sourcil.

*Symptomatic patients with type 3 should be considered for surgical decompression. Most patients presenting with type 2 should be considered for surgical decompression. Patients presenting with type 1 should never require surgical decompression.*

**Requests for the use of arthroscopy to treat extra-articular hip pathology (endoscopy) will be decided on a case-by-case basis and when criteria in either of the following subsections are met:**

a) Activity related painful snapping sensation around the hip joint caused by the iliotibial tract over the greater trochanter or bursa (external snapping hip) and/or the iliopsoas tendon over medial bony prominence or bursa (internal snapping hip) unresponsive to non-operative care;  

**OR**

a) Activity related pain and tenderness at the greater or lesser trochanter due to bursal inflammation, tendinosis and/or tendinitis, or tear of the tendon (gluteus medius or minimus) unresponsive to non-operative care;

b) Failure of at least 6 months of non-operative treatment, including at least two of the following:
   i) Physical therapy or properly instructed home exercise program
   ii) Rest or activity modification
   iii) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics
iv) Corticosteroid injection

Physical exam findings align with patient symptoms and at least one of the following documented:

i) Limp or painful ambulation

ii) Tenderness and/or crepitus to palpation

iii) Visible, audible, or palpable snapping at the greater trochanter or pelvic brim

iv) Pain and/or weakness with active or resisted motion of the hip

v) Pain relief with diagnostic local anesthetic injection

Grading Appendix

**Kellgren-Lawrence Grading System:**
*MRI should not be the primary tool used to determine the presence or severity of arthritic changes in the joint.*

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No radiographic features of osteoarthritis</td>
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<tr>
<td>1</td>
<td>Possible joint space narrowing and osteophyte formation</td>
</tr>
<tr>
<td>2</td>
<td>Definite osteophyte formation with possible joint space narrowing</td>
</tr>
<tr>
<td>3</td>
<td>Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour (<em>some sclerosis and cyst formation and deformity of femoral head and acetabulum</em>)</td>
</tr>
<tr>
<td>4</td>
<td>Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour (<em>increased deformity of the femoral head and acetabulum</em>)</td>
</tr>
</tbody>
</table>

**Tönnis Classification of Osteoarthritis by Radiographic Changes**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No signs of osteoarthritis</td>
</tr>
<tr>
<td>1</td>
<td>Mild: Increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity</td>
</tr>
<tr>
<td>2</td>
<td>Moderate: Small cysts, moderate narrowing of the joint space, moderate loss of head sphericity</td>
</tr>
<tr>
<td>3</td>
<td>Severe: Large cysts, severe narrowing or obliteration of the joint space, severe deformity of the head</td>
</tr>
</tbody>
</table>

**Hip Dysplasia:**

Defined as any of the following criteria:

a) Lateral center edge angle <20 degrees

b) Anterior center edge angle <20 degrees

c) Tönnis angle >15 degrees
c) Femoral head extrusion index >25%

**Radiographic Measurement Appendix**


**Alpha Angle:**
- Alpha angle was measured on the AP pelvis and Dunn 45° radiographs. First, a Mose circle was placed around the circumference of the femoral head. A line was drawn from the center of the femoral head down the center of the femoral neck. A line was then drawn connecting the center of the femoral head to the point of the Mose circle where the head goes out of round. The angle bisecting these two lines was the alpha angle.
  - An alpha angle of 55° (Dunn 45°) or greater or an alpha angle of 50° (AP pelvis) was defined as cam morphology.

**Femoral head extrusion:**
- Femoral head extrusion index was measured as the proportion (%) of laterally uncovered femoral head versus the femoral head (horizontal distance).
  - A femoral head extrusion index greater than 25% defined dysplasia.

**Global acetabular retroversion:**
- Global acetabular retroversion was defined by the presence of a prominent ischial spine sign or posterior wall sign.
  - Prominent ischial spine sign: Visible ischial spine medial to the iliopectineal line on AP pelvis radiograph.
  - Posterior wall sign: Center of the femoral head lateral to the posterior wall of the acetabulum.

**Lateral center edge angle:**
- Lateral center edge angle was measured after multiple lines were drawn on the AP pelvis radiograph. First, a Mose circle was placed around the circumference of the femoral head. Next, a line was drawn connecting the ischial tuberosities. A perpendicular line was then drawn up through the center of the femoral head from the ischial tuberosity line. Then, a line was drawn from the center of the femoral head to the most lateral aspect of the sourcil. The angle bisecting the latter two lines was the lateral center edge angle.
  - A lateral center edge angle less than 20° defined dysplasia, 20 to 25° borderline dysplasia, 26 to 39° normal, and greater than 40° lateral over coverage pincer impingement.
  - Lateral overcoverage was defined as a lateral center edge angle greater than 40°.
References


CPT Codes:
Revision Knee Arthroplasty: 27486, 27487, 27488, 27438
Total Knee Arthroplasty (TKA): 27447
Partial-Uncompartmental Knee Arthroplasty (UKA): 27446

INTRODUCTION:

This guideline addresses elective, non-emergent knee arthroplasty (knee replacement) procedures, including total knee arthroplasty (TKA), unicompartmental/unicondylar knee arthroplasty (UKA) or hemiarthroplasty (partial knee replacement), and revision arthroplasty procedures.

Arthroplasty describes the surgical replacement and reconstruction of a joint with implanted devices when the joint has been damaged by an arthritic or traumatic process. A normal knee functions as a hinge joint between the femur and the tibia. The surfaces where these bones meet can become worn out over time, due to arthritis or other conditions, which can cause pain and swelling.

TKA replaces and reconstructs all articular joint surfaces. In some cases, only one surface within the knee develops arthritis and associated pain and functional loss. In these cases, a partial knee replacement may be necessary to remove and reconstruct only the damaged region of the knee.

In some cases, the knee prosthesis may wear out or loosen. If loosening is painful, a revision surgery may be necessary. In this procedure some or all of the components of the original replacement prosthesis are removed and replaced with new ones.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

General Requirements

Elective knee arthroplasty may be considered if the following general criteria are met:

- Knee pain with documented loss of function, which may include painful weight bearing, painful or inadequate range of motion to accomplish age-appropriate activities of daily living (ADLs) and/or employment, and painful mechanical catching, locking, or popping
- Patient is medically stable with no uncontrolled comorbidities (such as diabetes)
- Patient does not have an active local or systemic infection
- Patient does not have active, untreated drug dependency (including but not limited to narcotics, opioids, muscle relaxants) unless engaged in treatment program
- Patient has good oral hygiene and does not have major dental work scheduled or anticipated (ideally within one year of joint replacement), due to increased post-surgical infection risk.

Clinical notes should address

- Symptom onset, duration, and severity;
- Loss of function and/or limitations;
- Type and duration of non-operative management modalities.
Non-operative management must include at least **TWO** or more of the following unless otherwise specified in clinical indications below:

- Rest or activity modifications/limitations;
- Weight reduction for patient with elevated BMI;
- Protected weight-bearing with cane, walker or crutches;
- Brace/orthosis;
- Physical therapy modalities;
- Physician-supervised exercise program (including home exercise program);
- Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, or analgesics;
- Intra-articular injection(s)

**Clinical Indications:**

**Total Knee Arthroplasty (TKA)**

TKA may be considered medically necessary when the following criteria are met:

a) Extensive disease or damage due to rheumatoid arthritis, fracture, or avascular necrosis confirmed by imaging (radiographs, MRI or other advanced imaging) and persistent pain and documented loss of function. **NOTE:** There is no medical necessity to perform TKA in patients with severe disease and no symptoms.

OR

b) When **ALL** of the following criteria are met:

i) Pain due to advanced osteoarthritis (Kellgren-Lawrence (K-L) grade 3 or grade 4 degeneration [see grading appendix]) that is persistent and severe and/or patient has documented loss of function that has been present for at least 6 months resulting in a diminished quality of life;

ii) Failure of at least 3 months of non-operative treatment, including at least **two** of the following:

   a. Rest or activity modifications/limitations
   b. Weight reduction for patient with elevated BMI
   c. Protected weight-bearing with cane, walker or crutches
   d. Brace/orthosis
   e. Physical therapy modalities
   f. Physician-supervised exercise program (including home exercise program)
   g. Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, or analgesics
   h. Injections: corticosteroid/viscosupplementation/PRP (platelet rich plasma);

iii) Physical exam findings demonstrate one or more of the following: tenderness, swelling/effusion, limited range of motion (decreased from uninvolved side or as compared to a normal joint), flexion contracture, palpable or audible crepitus, instability and/or angular deformity:

iv) Radiographic findings show evidence of advanced arthritic changes, documented by standing, weight-bearing radiographs described as Kellgren-Lawrence (K-L) grade 3 or grade 4 degeneration. (MRI should not be the primary radiographic test used to determine the presence or severity of arthritic changes in the joint):

v) No injection into the joint within 3 months of surgery.
All requests for simultaneous bilateral total knee replacements will be reviewed on a case by case basis and records should clearly indicate why simultaneous TKA is preferable to staged procedures.

All requests for TKA in patients with chronic, painless effusion and extensive radiographic arthritis will be evaluated on a case-by-case basis.

**Absolute contraindication:**
- Active infection (local or remote)
- Any injection into the joint within 3 months of surgery

**Relative contraindication:**
- Prior infection at site (unless aspiration with cultures and serology [CBC with differential, ESR, CRP] demonstrates no infection). If prior infection at site, tissue biopsies should be sent intra-operatively to exclude latent/dormant infection.
- Extreme morbid obesity (BMI > 40)
- Extensor mechanism deficiency
- Neuropathic joint
- Severe peripheral vascular disease
- Compromised soft tissue envelope
- Uncontrolled comorbidities

**Unicompartmental Knee Arthroplasty (UKA)/Partial Knee Replacement (PKA)**

Unicompartmental knee arthroplasty (UKA) is also called partial replacement, hemiarthroplasty, unicompartmental knee, or bicondylar knee arthroplasty. This procedure involves reconstruction of either the medial or lateral weight bearing compartment of the knee and/or patellofemoral joint. **Medial UKA is performed more frequently than lateral procedures.**

Medial or Lateral UKA/PKA may be medically necessary when **ALL** of the following criteria are met:
- At least 6 months of pain localized to the medial or lateral compartment;
- Failure of at least 3 months of non-operative treatment, including at least **two** of the following:
  1. Rest or activity modifications/limitations
  2. Weight reduction for patient with elevated BMI
  3. Protected weight-bearing with cane, walker or crutches
  4. Brace/orthosis
  5. Physical therapy modalities
  6. Physician-supervised exercise program (including home exercise program)
  7. Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, or analgesics
  8. Injections: corticosteroid/viscosupplementation/PRP (platelet rich plasma);
- Total arc of motion (goniometer) > 90 degrees;
- Normal ACL or stable reconstructed ACL per physical exam test;
- Age > 50 years;
- Standing, weight-bearing radiographs demonstrate **only** unicompartmental disease (with or without patellofemoral involvement), described as Kellgren-Lawrence grade 3 or grade 4 degeneration. **NOTE:** MRI should not be the primary radiographic test used to determine the presence or severity of arthritic changes in the joint;
• Contracture < 5-10 degrees upon physical exam (goniometer);
• Angular deformity < 10 degrees, passively correctable to neutral upon physical exam (goniometer);
• BMI < 40;
• No injection into the joint within 3 months of surgery.

All requests for UKA in patients with chronic, painless effusion and extensive radiographic arthritis will be evaluated on a case-by-case basis.

Contraindications for Medial or Lateral UKA/PKA:
• Any injection into the joint within 3 months of surgery
• Local or systemic active infection
• Inflammatory arthritis
• Angular deformity or contracture greater than indicated range
• Significant arthritic involvement of other knee compartments
• ACL instability
• Poor bone quality or significant osteoporosis or osteopenia
• Meniscectomy of the opposite compartment
• Stiffness greater than indicated range of motion

Patellofemoral UKA/PKA may be medically necessary when ALL of the criteria are met within one of the following two subsections:

a) Failure of prior patellofemoral unloading procedures (Maquet, Fulkerson);
b) Failure of at least 3 months of non-operative treatment, including at least two of the following:
   i) Rest or activity modifications/limitations
   ii) Weight reduction for patient with elevated BMI
   iii) Protected weight-bearing with cane, walker or crutches
   iv) Brace/orthosis
   v) Physical therapy modalities
   vi) Physician-supervised exercise program (including home exercise program)
   vii) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, or analgesics
   viii) Injections: corticosteroid/viscosupplementation/PRP (platelet rich plasma);
c) Standing, AP or PA weight-bearing radiographs (must include at least a lateral view and Merchant view) demonstrate only unicompartmental disease of the patellofemoral joint, described as Kellgren-Lawrence grade 3 or grade 4 degeneration, with no evidence of medial or lateral arthritis.

OR

a) At least 6 months of isolated patellar/anterior knee pain;
b) Patellar/anterior knee pain that is exacerbated by stairs, inclines, transfers or prolonged sitting;
c) Reproducible patellofemoral pain upon physical exam;
d) No ligamentous instability upon physical exam;
e) Failure of at least 3 months of non-operative treatment, including at least two of the following:
   i) Rest or activity modifications/limitations
   ii) Weight reduction for patient with elevated BMI
   iii) Protected weight-bearing with cane, walker or crutches
   iv) Brace/orthosis
   v) Physical therapy modalities
   vi) Physician-supervised exercise program (including home exercise program)
   vii) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, or analgesics
viii) Injections: corticosteroid/viscosupplementation/PRP (platelet rich plasma);
f) Standing, AP or PA weight-bearing radiographs (must include at least a lateral view and Merchant view) demonstrate only unicompartmental disease of the patellofemoral joint, described as Kellgren-Lawrence grade 3 or grade 4 degeneration, with no evidence of medial or lateral arthritis.
NOTE: MRI should not be the primary radiographic test used to determine the presence or severity of arthritic changes in the joint.

Contraindications for Patellofemoral UKA/PKA:
- Any injection into the joint within 3 months of surgery
- Local or systemic active infection
- Inflammatory arthritis
- Angular deformity or contracture greater than indicated range
- Significant arthritic involvement of the medial or lateral knee compartment(s)
- Ligament instability
- Poor bone quality or significant osteoporosis or osteopenia
- Stiffness greater than indicated range of motion

Revision Arthroplasty

Revision describes surgical reconstruction due to failure or complication of a previous arthroplasty.

Revision TKA may be considered medically necessary when the following criteria are met:
  a) Previous removal of infected knee prosthesis AND no evidence of current, ongoing, or inadequately treated knee infection (ruled out by synovial fluid aspiration/biopsy (cell count and culture)) AND off antibiotics;
     OR
  b) When ALL of the following criteria are met:
     i) Symptomatic UKA/PKA or TKA as evidence by persistent, severe disabling pain and loss of function;
     ii) Any of the following findings upon physical exam: tenderness to palpation objectively attributable to the implant, swelling or effusion, pain on weight-bearing or motion, instability on stress-testing, abnormal or limited motion (compared to usual function), palpable or audible crepitus or “clunking” associated with reproducible pain;
     iii) Aseptic loosening, instability, osteolysis, progressive bone loss, or mechanical failure confirmed on radiographic or advanced imaging (bone scan, CT scan, or MRI);
     iv) No injection into the joint within 3 months of surgery;

Note: Removal of infected knee prosthesis and subsequent insertion of antibiotic spacer is not considered an elective surgery and is not considered a revision knee arthroplasty.

Absolute contraindication:
- Active infection (local or remote)
- Any injection into the joint within 3 months of surgery
Relative contraindication:
- Deficiency of the extensor mechanism
- Neuropathic joint
- Unstable or poorly controlled comorbidities
- Severe peripheral vascular disease
- Compromised soft-tissue envelope (revision may be performed in conjunction with plastic surgical consultation for soft tissue coverage via pedicle flaps or other acceptable procedure)

Non-Covered Services:
The following procedures are not considered a covered service and are not reimbursable based on lack of current scientific evidence for clinically important improvement, safety or efficacy; or based on scientific evidence of increased risk of serious complications:
- a) Procedures utilizing computer-navigated or patient-specific or gender-specific instrumentation
- b) Bicompartmental arthroplasty (investigational at this time)
- c) Robot-assisted TKA (Makoplasty)

Grading Appendix

Kellgren-Lawrence Grading System:
*MRI should not be the primary tool used to determine the presence or severity of arthritic changes in the joint.*

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<td>3</td>
<td>Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour (<em>some sclerosis and cyst formation</em>)</td>
</tr>
<tr>
<td>4</td>
<td>Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour</td>
</tr>
</tbody>
</table>

Outerbridge Arthroscopic Grading System

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal cartilage</td>
</tr>
<tr>
<td>I</td>
<td>Softening and swelling/blistering</td>
</tr>
<tr>
<td>II</td>
<td>Partial thickness defect, fissures &lt; 1.5cm diameter/wide</td>
</tr>
<tr>
<td>III</td>
<td>Fissures/defects down to subchondral bone with intact calcified cartilage layer, diameter &gt; 1.5cm</td>
</tr>
</tbody>
</table>
IV Exposed subchondral bone

Other Notes:
Manipulation following total knee arthroplasty: SEE KNEE ARTHROSCOPY & OTHER OPEN PROCEDURES Guideline for specific Manipulation indications.
References


CPT Codes:
Knee Manipulation Under Anesthesia (MUA): 27570, 29884
Knee Ligament Reconstruction/Repair: 27405, 27407, 27409, 27427, 27428, 27429, 29888, 29889
Knee Meniscectomy/Meniscal Repair/Meniscal Transplant: 27332, 27333, 27403, 29868, 29880, 29881, 29882, 29883
Knee Surgery – Other: 27412, 27415, 27416, 27418, 27420, 27422, 27424, 27425, 29866, 29867, 29870, 29873, 29874, 29875, 29876, 29877, 29879, G0289

KNEE ARTHROSCOPY
Knee Arthroscopy & Open, Non-Arthroplasty

Introduction
This guideline addresses the following elective, non-emergent, arthroscopic knee repair procedures:

- Diagnostic knee arthroscopy
- Debridement with or without chondroplasty
- Meniscectomy/meniscal repair/meniscal transplant
- Ligament reconstruction/repair
- Articular cartilage restoration/repair (marrow stimulating and restorative techniques)
- Synovectomy (major [2+ compartments], minor [1 compartment])
- Loose body removal
- Lateral release/patellar realignment
- Manipulation under anesthesia (MUA)
- Lysis of adhesions for arthrofibrosis of the knee

Arthroscopy introduces a fiber-optic camera into the knee joint through a small incision for diagnostic visualization purposes. Other instruments may then be introduced to remove, repair, or reconstruct intra- and extra-articular joint pathology. Surgical indications are based on relevant subjective clinical symptoms, objective physical exam and radiologic findings, and response to previous non-operative treatments when medically appropriate.

Open, non-arthroplasty knee surgeries are performed instead of an arthroscopy as dictated by the type and severity of injury and/or disease.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

General Requirements
- Elective arthroscopic surgery of the knee may be considered if the following general criteria are met:
There is clinical correlation of patient's subjective complaints with objective exam findings and/or imaging (when applicable);

Knee pain with documented loss of function: Deviation from normal knee function which may include painful weight bearing, unstable articulation, and/or inadequate range of motion (>10 degrees flexion contracture or <110 degrees flexion or both) to accomplish age-appropriate activities of daily living (ADLs), occupational, athletic);

Patient is medically stable with no uncontrolled comorbidities (such as diabetes);

Patient does not have an active local or systemic infection;

Patient does not have active, untreated drug dependency (including but not limited to narcotics, opioids, muscle relaxants) unless engaged in treatment program

Clinical notes should address:

- Symptom onset, duration, and severity;
- Loss of function and/or limitations;
- Type and duration of non-operative management modalities (where applicable).

Non-operative management must include at least two more of the following, unless otherwise specified:

- Rest or activity modifications/limitations;
- Ice/heat;
- Protected weight bearing;
- Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
- Brace/orthosis;
- Physical therapy modalities;
- Supervised home exercise;
- Weight optimization;
- Injections: corticosteroid, viscosupplementation, platelet rich plasma (PRP)

Clinical Indications

Diagnostic Knee Arthroscopy

Diagnostic knee arthroscopy may be medically necessary when ALL of the following criteria are met:

a) At least 3 months of knee pain with documented loss of function;

b) Failure of at least 12 weeks of non-operative treatment, including at least two of the following:

   - Rest or activity modifications/limitations
   - Ice/heat
   - Protected weight bearing
   - Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
   - Brace/orthosis
   - Physical therapy modalities
   - Supervised home exercise
   - Weight optimization
   - Corticosteroid injection

c) Clinical documentation of painful weight bearing, joint line tenderness, effusion and/or limited motion compared to presymptomatic joint range;

d) Indeterminate radiographs AND MRI findings.
Debridement with or without Chondroplasty

Debridement for **non-patellofemoral (femoral condyle and tibial plateau) articular cartilage** may be medically necessary when **ALL** of the following criteria are met:

a) Knee pain with documented loss of function;

b) Failure of at least 12 weeks of non-operative treatment, including at least two of the following:
   i) Rest or activity modifications/limitations
   ii) Ice/heat
   iii) Protected weight bearing
   iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
   v) Brace/orthosis
   vi) Physical therapy modalities
   vii) Supervised home exercise
   viii) Weight optimization
   ix) Corticosteroid injection

c) MRI results showing evidence of unstable chondral flap; AND

d) Recurrent (more than 2) or persistent effusion(s):

Debridement chondroplasty for **patellofemoral chondrosis** when **ALL** of the following criteria are met:

a) Anterior knee pain with documented loss of function;

b) Other extra-articular or intra-articular sources of pain or dysfunction have been excluded (referred pain, radicular pain, tendinitis, bursitis, neuroma);

c) Physical exam localizes tenderness to the patellofemoral joint with pain aggravated by activities that load the joint (single leg squat, ascending >descending stairs, and being in seated position for extended periods of time with knee flexed);

d) Failure of at least 12 weeks of non-operative treatment, including at least two of the following:
   i) Rest or activity modifications/limitations
   ii) Ice/heat
   iii) Protected weight bearing
   iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
   v) Brace/orthosis
   vi) Physical therapy modalities
   vii) Supervised home exercise
   viii) Weight optimization
   ix) Corticosteroid injection

e) No evidence of moderate to severe osteoarthritis (Kellgren-Lawrence Grade 3-4 based on standing or weight-bearing radiographs and patellofemoral views [see grading appendix])

Debridement for **arthrofibrosis** may be medically necessary when **ALL** of the following criteria are met:

a) Arthrofibrosis as evidence by physical exam findings of painful stiffness and loss of motion due to proliferation of scar tissue in and around the joint. NOTE: Imaging is not necessary, but historically has been used to determine the diagnosis:
b) Failure of at least 6 weeks of supervised or self-directed physical therapy;

Arthroscopic debridement with or without chondroplasty for the treatment of osteoarthritis of the knee is considered NOT MEDICALLY NECESSARY.

**Meniscectomy/Meniscal Repair/Meniscal Transplant**

**Meniscectomy/Meniscal Repair**

Meniscectomy and/or meniscal repair may be medically necessary when **ALL** of the following criteria in any of the following subsections are met:

a) Symptomatic meniscal tear confirmed by MRI results that show a peripheral longitudinal tear in the vascular zone, associated with pain localized to the corresponding compartment upon physical exam;

**OR**

a) Pediatric or adolescent patient has pain and mechanical symptoms upon physical exam;

b) MRI results show unstable tear;

**OR**

a) When at least 2 of the following 5 criteria are met:
   i) History of “catching” or “locking” as reported by the patient;
   ii) Knee joint line pain with forced hyperextension upon physical exam;
   iii) Knee joint line pain with maximum flexion upon physical exam;
   iv) Knee pain, crepitus, or an audible or palpable click with the McMurray’s test or Apley grind test;
   v) Joint line tenderness to palpation upon physical exam;

b) Failure of at least 6 weeks of non-operative treatment, including at least two of the following:
   i) Rest or activity modifications/limitations
   ii) Ice/heat
   iii) Protected weight bearing
   iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
   v) Brace/orthosis
   vi) Physical therapy modalities
   vii) Supervised home exercise
   viii) Weight optimization
   ix) Corticosteroid injection

c) One of the following radiographic findings:
   i) Weight-bearing X-ray(s) that demonstrate no moderate or severe osteoarthritic changes (Kellgren-Lawrence Grade 3-4 [see grading appendix]);
   ii) MRI results confirm meniscal tear in patients < 40 years of age;
iii) MRI results confirm displaced tear (any age):

OR

a) Meniscus tear encountered during other medically necessary arthroscopic procedure

Absolute Contraindications: Meniscectomy/Meniscal Repair

- Arthroscopic meniscectomy or meniscal repair is never medically necessary in the presence of Kellgren-Lawrence Grade 4 osteoarthritis [see grading appendix].

Relative Contraindications: Meniscectomy/Meniscal Repair

- Meniscectomy or repair is considered NOT MEDICALLY NECESSARY in the presence of Kellgren-Lawrence Grade 3 osteoarthritis [see grading appendix] unless acute onset with effusion, locking (note: locking only. This does not include catching, popping, cracking), and MRI evidence of bucket-handle or displaced meniscal fragment that correlates with the correct compartment (i.e. medial tenderness and locking for a medial tear).
- If grade 3 changes are present, only a meniscectomy may be indicated, not repair. If evidence of meniscal extrusion on coronal MRI with/without subchondral edema, arthroscopy is relatively contraindicated, even if tear is present.
- BMI > 35

Meniscal Transplant

Meniscal Transplants may be medically necessary when ALL of the following criteria are met:

a) Patient is less than 40 years old;

b) Patient has no evidence of arthritic changes;

c) Symptomatic meniscal deficiency confirmed by MRI results that show a meniscal deficient compartment, OR previous arthroscopy photographs or video showing subtotal or total meniscectomy;

e) Failure of at least 6 weeks of non-operative treatment, including at least two of the following:
   i) Rest or activity modifications/limitations
   ii) Ice/heat
   iii) Protected weight bearing
   iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
   v) Brace/orthosis
   vi) Physical therapy modalities
   vii) Supervised home exercise
   viii) Weight optimization
   ix) Corticosteroid injection

Absolute Contraindications: Meniscal Transplant

- Uncorrected (staged or simultaneous) ligamentous insufficiency (ACL, PCL, MCL, LCL, PMC, PLC)
• Uncorrected (staged or simultaneous) malalignment greater than 5 degrees varus or 5 degrees valgus
• Uncorrected (staged or simultaneous) full-thickness articular cartilage isolated defects (International Cartilage Research Society Grade 3 or 4; Outerbridge Grade IV [see grading appendix])
• Kellgren-Lawrence Grade 3 or 4 osteoarthritis [see grading appendix]

Ligament Reconstruction/Repair

Anterior Cruciate Ligament (ACL) Reconstruction with Allograft or Autograft:

ACL reconstruction or repair may be medically necessary when **ALL** of the following criteria in any of the following subsections are met:

a) Knee instability (as defined subjectively as "giving way", "giving out", "buckling", two-fist sign) with clinical findings of instability: Lachman’s 1A, 1B, 2A, 2B, 3A, 3B, Anterior Drawer, Pivot Shift test, or instrumented (KT-1000 or KT-2000) laxity of greater than 3 mm side-side difference;

b) MRI results confirm complete ACL tear;

c) Patient has no evidence of severe arthritis (Kellgren-Lawrence** Grade 3 or 4 [see grading appendix]);

**OR**

a) At least ONE of the following criteria are met:

i) MRI results confirm ACL tear associated with other ligamentous instability or repairable meniscus;

ii) MRI results confirm partial or complete ACL tear AND patient has persistent symptoms despite at least 12 weeks of non-operative treatment;

iii) Acute ACL tear confirmed by MRI in high demand occupation or competitive athlete (as quantified by Marx activity score for athletics (any score greater than 4) and Tegner activity score for athletics and/or occupation (score greater than 2)) [see grading appendix];

b) Patient has no evidence of severe arthritis (Kellgren-Lawrence** Grade 3 or 4 [see grading appendix]);

Tears in patients less than age 13 will be reviewed on a case by case basis.

Posterior Cruciate Ligament (PCL) Reconstruction:

PCL reconstruction or repair may be medically necessary when the following criteria are met:

a) Knee instability (as defined subjectively as "giving way", "giving out", "buckling", two-fist sign) with clinical findings of positive Posterior Drawer, posterior Sag, or quadriceps active, or Dial test at 90 degrees knee flexion, reverse pivot shift test;

b) MRI results confirm complete PCL tear:
c) Failure of at least 12 weeks of non-operative treatment, including bracing and physical therapy emphasizing quadriceps strengthening;

d) Absence of medial and patellofemoral K-L grade 3-4 changes in chronic tears [see grading appendix]:

The following clinical scenarios will be considered and decided on a case-by-case basis:

- Pediatric and adolescent tears in patients with open physes or open growth plates;
- Symptomatic partial tears with persistent instability despite non-operative treatment;
- Incidental Kellgren-Lawrence grade 2-3 osteoarthritis [see grading appendix] in acute/subacute tears with unstable joint;
- Acute PCL repair or reconstruction when surgery is also required for the ACL, MCL or LCL.
- Tears in patients less than age 13

Collateral Ligament Repair or Reconstruction:
Collateral ligament repair or reconstruction should rarely occur independent of additional ligament repair or reconstruction surgery (ACL, MCL, LCL).

All non-traumatic collateral ligament repair/reconstruction requests will be reviewed on a case by case basis.

Articular Cartilage Restoration/Repair
Skeletally Immature Indications:
Articular Cartilage Restoration/Repair may be medically necessary when ALL of the following criteria in any of the following subsections are met:

- Skeletally immature patient;
- Patient is symptomatic (pain, swelling, mechanical symptoms of popping, locking, catching, or limited range of motion);
- Radiographic findings (any radiograph and MRI) of a displaced lesion;

OR

- Skeletally immature patient;
- Patient is symptomatic (pain, swelling, mechanical symptoms of popping, locking, catching, or limited range of motion);
- Failure of at least 12 weeks of non-operative treatment, including at least two of the following:
  i) Rest or activity modifications/limitations  
  ii) Ice/heat  
  iii) Protected weight bearing  
  iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol  
  v) Brace/orthosis
vi) Physical therapy modalities
vii) Supervised home exercise
viii) Weight optimization
ix) Corticosteroid injection
d) Radiographic findings (any radiograph and MRI) results finding of a stable osteochondral lesion

OR

a) When ALL of the following criteria are met:
   i) Skeletally immature;
   ii) Asymptomatic;
   iii) Failure of at least 12 weeks of non-operative treatment, including at least two of the following, to improve lesion stability or size:
      a. Rest or activity modifications/limitations
      b. Ice/heat
      c. Protected weight bearing
      d. Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
      e. Brace/orthosis
      f. Physical therapy modalities
      g. Supervised home exercise
      h. Weight optimization
      i. Corticosteroid injection
   iv) Radiographic findings (any radiograph and MRI) results finding of an unstable osteochondral lesion

Exclusion (applies to all criteria above):
Exclude patients with evidence of meniscal deficiency and/or malalignment IF these are not being addressed (meniscal transplant and/or lateral release/patellar realignment procedure) at the same time as the cartilage restoration procedure.

Skeletally Mature Indications, Listed By Surgical Approach:

Reparative Marrow Stimulation:
Reparative marrow stimulation techniques such as microfracture & drilling (note: abrasion arthroplasty is including in coding but is not indicated) may be medically necessary when ALL of the following criteria are met:
   a) Skeletally mature adult:
   b) MRI confirms a full-thickness weight-bearing lesion that is < 2.5 sq.cm:
c) Patient is symptomatic (pain, swelling, mechanical symptoms of popping, locking, catching, or limited range of motion);

d) Patient is less than 50 years of age;

e) BMI < 35 (optimal outcomes if patient BMI <30);

f) Physical exam findings and/or (imaging) results confirm knee has stable ligaments;

g) No evidence of prior meniscectomy in same compartment (medial femoral condyle full thickness lesion and prior medial meniscectomy) unless concurrent meniscal transplant performed.

**Restorative Marrow Techniques:**

Restorative techniques (abrasion arthroplasty, osteochondral autograft transfer or transplantation (OATS), mosaicoctoplasty, autologous chondrocyte implantation (ACI), osteochondral allograft implantation, minced articular cartilage allograft transplantation [DeNovo NT]) may be medically necessary when **ALL** of the following criteria are met:

a) Skeletally mature adult;

b) MRI results confirm a full thickness chondral or osteochondral lesion of the femoral condyles or trochlea > 2.5 cm;

c) Patient is less than 50 years of age;

d) Patient has been symptomatic (pain, swelling, mechanical symptoms of popping, locking, catching, or limited range of motion) for at least 6 months;

e) Failure of at least 6 months of non-operative treatment, including at least two of the following:

   i) Rest or activity modifications/limitations
   ii) Ice/heat
   iii) Protected weight bearing
   iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
   v) Brace/orthosis
   vi) Physical therapy modalities
   vii) Supervised home exercise
   viii) Weight optimization
   ix) Corticosteroid injection

f) MRI and/or physical findings confirm knee has normal alignment as defined as +/- 3 degrees from neutral on full-length mechanical axis long-leg x-ray (unless concurrent or staged tibial or femoral osteotomy performed) and stability (unless concurrent ligamentous repair or reconstruction performed);

g) BMI < 35 (optimal outcomes if patient BMI <30);

h) MRI shows no evidence of osteoarthritis (greater than Kellgren-Lawrence Grade 2 [see grading appendix]);

i) No prior meniscectomy in same compartment (unless concurrent or staged meniscal transplant performed)

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**Patellofemoral Chondrosis**
Surgical intervention for the treatment of patellofemoral chondrosis (osteochondral autograft transfer or transplantation (OATS), microfracture, autologous chondrocyte implantation (ACI), osteochondral allograft implantation, minced articular cartilage allograft transplantation [DeNovo NT], debridement chondroplasty, tibial tubercle osteotomy) may be medically necessary when ALL of the following criteria are met:

a) Anterior knee pain and loss of function;

b) Other extra-articular or intra-articular sources of pain or dysfunction have been excluded (referred pain, radicular pain, tendinitis, bursitis, neuroma);

c) Physical exam localizes tenderness to the patellofemoral joint with pain aggravated by activities that load the joint (single leg squat, descending > ascending stairs or stair climbing, and being in seated position for extended periods of time with knee flexed);

d) Radiologic imaging shows patellofemoral Chondrosis, grade I, II or IV by the Outerbridge Classification or grade 3 or 4 by International Cartilage Research Society classification [see grading appendix]

e) Failure of at least 6 months of non-operative treatment, including at least two of the following:
   i) Rest or activity modifications/limitations
   ii) Ice/heat
   iii) Protected weight bearing
   iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
   v) Brace/orthosis
   vi) Physical therapy modalities
   vii) Supervised home exercise
   viii) Weight optimization
   ix) Corticosteroid injection

f) No evidence of osteoarthritis (Kellgren-Lawrence Grade 3-4 based on standing or weight-bearing radiographs) in the medial/lateral compartments [see grading appendix].

**Synovectomy (major [2+ compartments], minor [1 compartment])**

Synovectomy may be medically necessary when ALL of the following criteria in any of the following subsections are met:

a) Proliferative rheumatoid synovium (in patients with established rheumatoid arthritis according to the American College of Rheumatology Guidelines [see grading appendix]):

b) Not responsive to disease modifying drug (DMARD) therapy for at least 6 months and failure of at least 6 weeks of non-operative treatment;

c) At least one instance of aspiration of joint effusion and corticosteroid injection (if no evidence of infection):

    **OR**

a) Hemarthrosis from injury, coagulopathy or bleeding disorder confirmed by physical exam, joint aspiration, and/or MRI:

    **OR**

a) Proliferative pigmented villonodular synovitis, synovial chondromatosis, sarcoid synovitis, or similar proliferative synovial disease, traumatic hypertrophic synovitis confirmed by history, MRI or biopsy;
b) Failure of at least 6 weeks of non-operative treatment, including at least two of the following:
   i) Rest or activity modifications/limitations
   ii) Ice/heat
   iii) Protected weight bearing
   iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol
   v) Brace/orthosis
   vi) Physical therapy modalities
   vii) Supervised home exercise
   viii) Weight optimization
   ix) Corticosteroid injection
c) At least one instance of aspiration of joint effusion and injection of corticosteroid (if no evidence of infection):
   
   OR
   
   a) Detection of painful plica confirmed by physical exam and MRI findings;
   b) Failure of at least 12 weeks of non-operative treatment (see above for criteria);
   c) At least one instance of aspiration of joint effusion OR single injection of corticosteroid (effusion may not be present with symptomatic plica);

Loose Body Removal
Loose body removal may be medically necessary when the following criteria are met:
   a) Documentation of mechanical symptoms the cause limitation or loss of function
   b) X-ray or MRI documentation of a loose body

Lateral Release/Patellar Realignment:
This guideline describes indications for surgical procedures to address patellofemoral pain disorders and abnormal alignment of the extensor mechanism of the knee by arthroscopic and/or open surgical techniques.

Lateral Patellar Compression Syndrome
Surgical intervention for the treatment of lateral patellar compression syndrome is indicated when ALL the following criteria are met:
   a) Evidence of lateral patellar tilt from radiologic images (patellofemoral view: Merchant (45 degrees flexion; and/or skyline (60-90 degrees flexion); and/or sunrise (60-90 degrees flexion);
   b) Associated lateral patella facet Kellgren-Lawrence changes grade 1, 2, or 3 [see grading appendix];
   c) Reproducible isolated lateral patellofemoral pain with patellar tile test;
   d) Failure of at least 6 months of non-operative treatment, including appropriate hamstring/IT band stretching and patellar mobilization techniques, and at least one of the following:
      i) Rest or activity modifications/limitations
      ii) Ice/heat
iii) Protected weight bearing  
iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol  
v) Brace/orthosis  
vi) Physical therapy modalities  
vii) Supervised home exercise  
viii) Weight optimization  
ix) Corticosteroid injection  
e) No evidence of patellar dislocation without documented patellar tilt:  
f) No evidence of medial patellofemoral changes (Kellgren-Lawrence Grade 2 osteoarthritis or higher [see grading appendix]);

**Patellar Malalignment and/or Patellar Instability**

Surgical intervention for the treatment of patellar malalignment and/or patellar instability is indicated when **ALL** of the following criteria in any of the following subsections are met:

a) Acute traumatic patellar dislocation is associated with an osteochondral fracture, loose body, vastus medialis obliquus/medial patellofemoral ligament muscle avulsion, or other intra-articular injury that requires urgent operative management;  

OR  
b) Repeat (greater than 2) patellar dislocations or subluxations have occurred despite 6 months of non-operative treatment with radiologic confirmation of MPFL (medial patellofemoral ligament) deficiency;  

OR  
a) Physical exam has patellofemoral tenderness and abnormal articulation of the patella in the femoral trochlear groove (patellar apprehension with positive J sign);  
b) Radiologic and advanced images (CT or MRI) rule out fracture or loose body, and show abnormal articulation, trochlear dysplasia, or other abnormality related to malalignment;  
c) Failure of at least 6 months of non-operative treatment, including at least 3 months of physical therapy, and one of the following:  
i) Rest or activity modifications/limitations  
ii) Ice/heat  
iii) Protected weight bearing  
iv) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics, tramadol  
v) Brace/orthosis  
vi) Supervised home exercise  
vii) Weight optimization  
viii) Corticosteroid injection  

**Manipulation under Anesthesia (MUA)**

Manipulation under anesthesia (MUA) may be indicated when **ALL** of the following criteria are met:  
a) Physical exam findings demonstrate inadequate range of motion of the knee defined as less than 110 degrees of flexion;  
b) Failure to improve range of motion of the knee despite 6 weeks (12 visits) of documented physical therapy;
c) Patient is less than 12 weeks after ligamentous or joint reconstruction

**Lysis of Adhesions for Arthrofibrosis of the knee**

Surgical indications are based on relevant clinical symptoms, physical exam, radiologic findings, time from primary surgery, and response to conservative management when medically appropriate. Improved range of motion may be accomplished through arthroscopically-assisted or open lysis of adhesions with general anesthesia, regional anesthesia, or sedation.

Lysis of Adhesions for Arthrofibrosis of the knee may be indicated when **ALL** of the following criteria in any of the following subsections are met:

a) Physical exam findings demonstrate inadequate range of motion of the knee, defined as less than 110 degrees of flexion;

b) Failure to improve range of motion of the knee despite 6 weeks (12 visits) of documented physical therapy;

c) Patient is more than 12 weeks after ligamentous or joint reconstruction, or resolved infection:

**OR**

a) Patient is more than 12 weeks after trauma, or resolved infection;

b) Patient has native knee;

c) Manipulation under anesthesia is also performed.

**Grading Appendix**

- Kellgren-Lawrence Grading System
- Outerbridge Arthroscopic Grading System
- Marx Scale
- Tegner Activity Score
- The International Cartilage Research Society (ICRS)
- American College of Rheumatology Guidelines

**Kellgren-Lawrence Grading System:**

*MRI should not be the primary tool used to determine the presence or severity of arthritic changes in the joint.*

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No radiographic features of osteoarthritis</td>
</tr>
<tr>
<td>1</td>
<td>Possible joint space narrowing and osteophyte formation</td>
</tr>
<tr>
<td>2</td>
<td>Definite osteophyte formation with possible joint space narrowing</td>
</tr>
</tbody>
</table>
3. Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour

4. Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour

**Outerbridge Arthroscopic Grading System**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal cartilage</td>
</tr>
<tr>
<td>I</td>
<td>Softening and swelling/blistering</td>
</tr>
<tr>
<td>II</td>
<td>Partial thickness defect, fissures &lt; 1.5cm diameter/wide</td>
</tr>
<tr>
<td>III</td>
<td>Fissures /defects down to subchondral bone with intact calcified cartilage layer, diameter &gt; 1.5cm</td>
</tr>
<tr>
<td>IV</td>
<td>Exposed subchondral bone</td>
</tr>
</tbody>
</table>

**Marx Scale**

Indicate how often you performed each activity in your healthiest and most active state, in the past year.

<table>
<thead>
<tr>
<th>Activity/Movement</th>
<th>Less than one time in a month</th>
<th>One time in a month</th>
<th>One time in a week</th>
<th>2 or 3 times in a week</th>
<th>4 or more times in a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Running: running while playing a sport or jogging</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Cutting: changing directions while running</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Deceleration: coming to a quick stop while running</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Pivoting: turning your body with your foot planted while playing sport: For example: skiing, skating, kicking, throwing, hitting a ball (golf, tennis, squash), etc.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
**Tegner Scores**

Indicate in the spaces below the HIGHEST level of activity that you participated in BEFORE YOUR INJURY and the highest level you are able to participate in CURRENTLY

<table>
<thead>
<tr>
<th>Level</th>
<th>Activity Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 10</td>
<td>Competitive sports - soccer, football, rugby (national elite)</td>
</tr>
<tr>
<td>Level 9</td>
<td>Competitive sports - soccer, football, rugby (lower divisions), ice hockey, wrestling, gymnastics, basketball</td>
</tr>
<tr>
<td>Level 8</td>
<td>Competitive sports - racquetball or bandy, squash or badminton, track and field athletics (jumping, etc.), down-hill skiing</td>
</tr>
</tbody>
</table>
| Level 7  | Competitive sports - tennis, running, motorcars speedway, handball  
Recreational sports - soccer, football, rugby, bandy, ice hockey, basketball, squash, racquetball, running |
| Level 6  | Recreational sports - tennis and badminton, handball, racquetball, down-hill skiing, jogging at least 5 times per week |
| Level 5  | Work - heavy labor (construction, etc.)  
Competitive sports - cycling, cross-country skiing; Recreational sports - jogging on uneven ground at least twice weekly |
| Level 4  | Work - moderately heavy labor (e.g. truck driving, etc.) |
| Level 3  | Work - light labor (nursing, etc.) |
| Level 2  | Work - light labor  
Walking on uneven ground possible, but impossible to back pack or hike |
| Level 1  | Work - sedentary (secretarial, etc.) |
| Level 0  | Sick leave or disability pension because of knee problems |

**The International Cartilage Research Society (ICRS)**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal cartilage</td>
</tr>
</tbody>
</table>
| 1     | Nearly normal cartilage   
*Superficial lesions. Soft indentation and/or superficial fissures and cracks.*
2 Abnormal cartilage

Lesions extending down to <50% of cartilage depth.

3 Severely abnormal cartilage

Cartilage defects extending down >50% of cartilage depth as well as down to calcified layer and down to but not through the subchondral bone. Blisters are included in this Grade.

4 Severely abnormal cartilage (through the subchondral bone)

Penetration of subchondral bone that may or may not be across the full diameter of defect

American College of Rheumatology Guidelines

<table>
<thead>
<tr>
<th>2010 ACR/EULAR: Classification Criteria for RA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>JOINT DISTRIBUTION (0-5)</strong></td>
</tr>
<tr>
<td>1 large joint</td>
</tr>
<tr>
<td>2-10 large joints</td>
</tr>
<tr>
<td>1-3 small joints (large joints not counted)</td>
</tr>
<tr>
<td>4-10 small joints (large joints not counted)</td>
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<tr>
<td>&gt;10 joints (at least one small joint)</td>
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<tr>
<td><strong>SEROLOGY (0-3)</strong></td>
</tr>
<tr>
<td>Negative RF AND negative ACPA</td>
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<tr>
<td>Low positive RF OR low positive ACPA</td>
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<tr>
<td>High positive RF OR high positive ACPA</td>
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<tr>
<td><strong>SYMPTOM DURATION (0-1)</strong></td>
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<tr>
<td>&lt;6 weeks</td>
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<tr>
<td>≥6 weeks</td>
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<tr>
<td><strong>ACUTE PHASE REACTANTS (0-1)</strong></td>
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<tr>
<td>Normal CRP AND normal ESR</td>
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<tr>
<td>Abnormal CRP OR abnormal ESR</td>
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≥6 = definite RA
References


CPT Codes:
Revision Shoulder Arthroplasty: 23473, 23474
Total/Reverse Shoulder Arthroplasty or Resurfacing: 23472
Partial Shoulder Arthroplasty/Hemiarthroplasty: 23470

SHOULDER ARTHROPLASTY
Total, Partial & Revision Shoulder Replacement

Introduction
This guideline addresses elective, non-emergent shoulder arthroplasty (shoulder replacement) procedures, including total shoulder arthroplasty, reverse shoulder arthroplasty, resurfacing arthroplasty, partial shoulder replacement or hemiarthroplasty, and revision arthroplasty procedures.

Arthroplasty describes the surgical replacement and reconstruction of a joint with implanted devices when the joint has been damaged by an arthritic or traumatic process.

In both a total shoulder replacement and a reverse shoulder replacement, the damaged joint surfaces (humeral head and glenoid) are removed and replaced with prosthetic components, with the goal of reducing pain and improving joint function. In a reverse shoulder procedure, the ball and socket feature of the joint is reversed, allowing for added rotator cuff support.

In the event the shoulder joint cannot support a glenoid prosthesis, a hemiarthroplasty, or partial joint replacement may be performed to replace the humeral head with a prosthesis.

In some cases, the shoulder prosthesis may wear out or loosen. If loosening is painful, a second surgery, such as a revision may be necessary. In this procedure some or all of the components of the original replacement prosthesis are removed and replaced with new ones.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual patient needs and based on an assessment of the local delivery system

General Requirements
- Elective surgery of the shoulder may be considered if the following general criteria are met:
  - There is clinical correlation of patient's subjective complaints with objective exam findings and/or imaging (when applicable);
  - Patient has limited function (age-appropriate activities of daily living (ADLs), occupational, athletic);
  - Patient is medically stable with no uncontrolled comorbidities (such as diabetes);
  - Patient does not have an active local or systemic infection;
  - Patient does not have active, untreated drug dependency (including but not limited to narcotics, opioids, muscle relaxants) unless engaged in treatment program
Patient has good oral hygiene and does not have major dental work scheduled or anticipated (ideally within one year of joint replacement), due to increased post-surgical infection risk.

- Clinical notes should address:
  - Symptom onset, duration, and severity;
  - Loss of function and/or limitations;
  - Type and duration of non-operative management modalities.

- Non-operative management, when required, will be specified within the clinical indications below and may include one or more of the following:
  - Physical therapy or properly instructed home exercise program
  - Rest or activity modification
  - Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics;
  - Corticosteroid injections

Clinical Indications:

**Total Shoulder Arthroplasty (TSA)**

The replacement of the glenohumeral joint is called a shoulder arthroplasty. It can be either a total shoulder arthroplasty (TSA), where both the glenoid and humerus are replaced, a partial arthroplasty of the humerus only (hemiarthroplasty, HA), or a partial resurfacing of the humerus (humeral head resurfacing, HHR, HR). In general, these arthroplasty procedures are reserved for end stage arthritis of the shoulder joint, including functional loss of motion, pain and disability. The choice of arthroplasty is dependent upon surgeon philosophy, experience and skill. Successful outcome, regardless of procedure, is more likely with high volume (> 20 per year) shoulder specialists. Revision shoulder arthroplasty is most commonly required because of technical problems encountered at the time of surgery, such as insertion of the wrong size components, improper technique, and poor surgical exposure.

Total Shoulder Arthroplasty may be necessary when ALL of the following criteria are met:

a) Evidence of painful osteoarthritis or inflammatory, non-infectious arthritis (e.g. rheumatoid) with functional limitations (such as activities of daily living or employment or simple recreation):

b) Complete or near-complete loss of joint space on axillary and AP x-rays (internal rotation and/or external rotation) (note: MRI should not be the primary imaging study to determine the extent of disease);

c) Failure of at least 12 weeks of non-operative treatment that includes at least ONE of the following:
   - Physical therapy or properly instructed home exercise program
   - Rest or activity modification
   - Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics;
   - Corticosteroid injections

d) Adequate bone stock (sufficient bone available to place a glenoid component. Requires either a good axillary x-ray, CT, or MRI) to support chosen device;

e) Functional and intact rotator cuff and deltoid;

f) No injection into the joint within 3 months of surgery.
NOTES

- In general, the more severe the disease, the more loss of motion and glenoid erosion will exist and the more likely a TSA will be required, regardless of age. However, if surgery is delayed too long, it can be exceedingly difficult to insert the glenoid component for a TSA due to posterior glenoid erosion, and even more difficult for a hemiarthroplasty. For optimal TSA success, only one replacement should be attempted during a patient’s lifetime.

- Additional research is necessary to support an accurate age range for each type of shoulder arthroplasty. At this time, patient age is a relative indication for surgery and ultimately relies on surgeon’s judgment and patient presentation. TSA can be done at any age, but in general, to minimize complications (future need of a TSA revision) and improve quality of life:
  - Age <55: Hemiarthroplasty may be the best surgical option due to the likelihood that these patients will need the joint converted to a total shoulder arthroplasty. Revising a total shoulder arthroplasty is much more complex and in some cases cannot be successfully performed.
  - Age 55-65: Depending on patient anatomy and desired activity level, TSA or resurfacing (HHR) may be indicated. Based on surgeon experience, some may choose a stemmed hemiarthroplasty (HA) as it is technically less demanding.
  - Age > 65: TSA is typically the best surgical option for patients over the age of 65.

Contraindications

- Neurological disease resulting in chronic pain syndrome (CRPS or its variants) or loss of deltoid or rotator cuff function.

- Active infection or any infection within 6 months of surgery:
  - History of prior shoulder joint infection without proof that indolent infection has been eliminated (patient has been off antibiotics for a minimum of 6 weeks) via laboratory work (serologies, including CBC with differential, ESR (erythrocyte sedimentation rate), CRP (C-reactive protein), with or without blood cultures, and synovial fluid aspiration (cultures, gram stain, cell count, differential, crystals)). Cultures must be for aerobic and anaerobic bacteria (AFB, fungal). Cultures must be held for minimum 30 days (especially to rule out propionobacterium acnes).
  - Nuclear scans, advanced imaging and often aspiration or soft tissue/bone biopsy (note: recent studies suggest only intra-operative tissue cultures are reliable indicators of joint contamination/infection and IF occult infection is a concern (after prior procedures), biopsies should be taken, delayed placement of the arthroplasty should be strongly considered after antibiotic spacer placement, and appropriate antibiotic management commenced once confirmed.

- Poor dental hygiene (e.g. tooth extraction should be performed prior to arthroplasty). Major dental work within 2 year after a joint replacement MAY lead to seeding of the implant and possible revision surgery. If possible, all dental work must be completed prior to shoulder arthroplasty as these procedures increase risk for infection. Following surgery, patients should receive antibiotics for routine dental check-ups for a minimum of two years.

- Any injection into the joint within 3 months of surgery.
Hemiarthroplasty

Hemiarthroplasty may be necessary when **ALL** of the following criteria are met:

a) Patient meets all of the criteria for a Total Shoulder Arthroplasty, as detailed above, **OR** patient with avascular necrosis or osteonecrosis of the humeral head without advanced glenoid disease;

b) No injection into the joint within 3 months of surgery;

Contraindications

- Any injection into the joint within 3 months of surgery.

Reverse Total Shoulder Arthroplasty (RTSA)

*This shoulder surgery involves placing the ball on the glenoid side (glenosphere and baseplate) of the joint and the socket on the humeral side.*

The original purpose of a RTSA was to allow basic function of a pseudoparalytic shoulder from a non-repairable chronic rotator cuff tear with arthropathy (or arthritis) in an inactive person over age 65. Because it is associated with a high complication rate (10-50% in primary procedures and as high as 70% in revisions), it should be used with careful consideration. Salvage after failed RTSA is difficult with poor outcomes.

It works by moving the center of joint rotation medial and downward and increasing deltoid tension to facilitate active abduction and elevation of the arm.

RTSA may be indicated for the **treatment of arthritis** when **ALL** of the following criteria are met:

a) Non-repairable massive (> 2 tendons) rotator cuff tear AND intact deltoid AND inability to actively elevate the arm above the level of the shoulder (90 degrees) (i.e. nonfunctional cuff tear arthropathy);

b) Age > 65 (note: requests for RTSA in patients less than 65 will be reviewed on a case-by-case basis);

c) Failure of at least 12 weeks of non-operative treatment that includes **ALL** of the following:
   
i) Formal physical therapy for deltoid retraining
   
ii) At least one corticosteroid injection

d) Patient must be compliant with instructions and understand long-term activity is limited to basic activities of daily living;

e) No injection into the joint within 3 months of surgery;

NOTE: If patient meets above criteria but **can raise the arm above shoulder level**, a stemmed or resurfacing extended articular surface resurfacing device (EAS) (CTA head) may be an appropriate option (i.e. FUNCTIONAL cuff tear arthropathy). This is also an option in those < 60 years old. These cases should be determined on a case by case basis.
Contraindications:
- Any injection into the joint within 3 months of surgery.

RTSA may be indicated for the treatment of fractures or failed Total Shoulder Arthroplasty when ALL of the following criteria are met:
  a) Acute 3-4 part fractures of proximal humerus with or without concomitant tuberosity as evidence by radiographic findings;
  b) Age >65 (note: requests for RTSA in patients less than 65 will be reviewed on a case-by-case basis)

Revision Arthroplasty
There are five primary indications for revision shoulder arthroplasty: (1) conversion of a hemiarthroplasty to a total shoulder arthroplasty, (2) conversion of a hemiarthroplasty to a reverse shoulder arthroplasty, (3) revision of a total shoulder arthroplasty to another total shoulder arthroplasty, (4) revision of a total shoulder arthroplasty to a reverse shoulder arthroplasty, (5) revision of a total shoulder arthroplasty to a reverse shoulder arthroplasty.

Note: Historically this procedure was coded as the removal of hardware and total shoulder arthroplasty. CPT introduced shoulder revision procedure codes in January 2013.

(1) Conversion of a hemiarthroplasty to a total shoulder arthroplasty may be necessary when ALL of the following criteria are met:
  a) Evidence of a prior hemiarthroplasty
  b) Persistent pain and functional loss
  c) Negative infection evaluation (including CRP, ESR, CBC, with or without negative aspiration)
  d) Clinical and radiographic evidence of intact rotator cuff (or repairable rotator cuff tear), including one of the following two options:
     i) Radiographic evidence of failed humeral component, including aseptic loosening or periprosthetic fracture. Documentation should include radiolucencies around cemented or uncemented components.
     ii) Clinical and radiographic evidence of glenoid articular cartilage disease (including progressive arthritis).

(2) Conversion of a hemiarthroplasty to a reverse shoulder arthroplasty may be necessary when ALL of the following criteria are met:
  a) Evidence of a prior hemiarthroplasty
  b) Persistent pain and functional loss
  c) Negative infection evaluation (including CRP, ESR, CBC, with or without negative aspiration)
  d) Clinical and radiographic evidence of irreparable rotator cuff tear
  e) Intact deltoid and intact axillary nerve
  f) Age >65
g) Evidence of pseudoparalysis (inability to elevate arm)

Note: Cases in patients age less than 65 or with limited/no pseudoparalysis will be reviewed on a case by case basis.

(3) Revision of a **total shoulder arthroplasty to another total shoulder arthroplasty** may be necessary when ALL of the following criteria are met:
   a) Evidence of prior total shoulder arthroplasty
   b) Persistent pain and functional loss
   c) Negative infection evaluation (including CRP, ESR, CBC, with or without negative aspiration)
   d) Clinical and radiographic evidence of intact rotator cuff (or repairable rotator cuff tear)
   e) Radiographic evidence of failed humeral and/or glenoid component, including aseptic loosening or periprosthetic fracture. Documentation should include radiolucencies around cemented or uncemented components.

(4) Revision of a **total shoulder arthroplasty to a reverse shoulder arthroplasty** may be necessary when ALL of the following criteria are met:
   a) Evidence of prior total shoulder arthroplasty
   b) Persistent pain and functional loss
   c) Negative infection evaluation (including CRP, ESR, CBC, with or without negative aspiration)
   d) Clinical and radiographic evidence of irreparable rotator cuff tear
   e) Intact deltoid and intact axillary nerve
   f) Age >65
   g) Evidence of pseudoparalysis (inability to elevate arm)

Note: Cases in patients age less than 65 or with limited/no pseudoparalysis will be reviewed on a case by case basis.

(5) Revision of a **reverse shoulder arthroplasty to another reverse shoulder arthroplasty** arthroplasty may be necessary when ALL of the following criteria are met:
   a) All cases should be reviewed case-by-case basis and include the following:
   b) Evidence of prior reverse shoulder arthroplasty
   c) Persistent pain and functional loss
   d) Negative infection evaluation (including CRP, ESR, CBC, with or without negative aspiration)
e) Radiographic evidence of failed humeral and/or glenoid component, including aseptic loosening or periprosthetic fracture. Documentation should include radiolucencies around cemented or uncemented components

f) Intact deltoid and intact axillary nerve

g) Surgeon must be cognizant of acromial stress fracture, scapular notching, and instability risks.

Contraindications

- Insufficient glenoid and/or humeral bone to support a revision component
- Active or recent history of infection
- Neurogenic pain syndrome
- Acromial fracture OR overly thin acromion from prior subacromial decompression
- Severe osteoporosis as evidenced by radiographic osteopenia, osteomalacia or severe osteoporosis on Dxa scan
- Non-functioning deltoid or axillary nerve injury / palsy.
References


CPT CODES:
Shoulder Rotator Cuff Repair: 23410, 23412, 23420, 29827,
Shoulder Labral Repair: 23450, 23455, 23460, 23462, 23465, 23466, 29806, 29807, S2300,
Frozen Shoulder Repair/Adhesive Capsulitis: 29825,
Shoulder Surgery Other: 23120, 23125, 23130, 23405, 23130, 23415, 23430, 23700, 29805, 29819, 29820, 29821, 29822, 29823, 29824, +29826, 29828

Introduction
This guideline addresses the following elective, non-emergent, arthroscopic shoulder repair procedures:
- Rotator Cuff Repair
- Labral Repairs
- Lysis of Adhesions (Capsulotomy)
- Distal Clavicle Excision (DCE)
- Long Head Biceps (LHB) Tenotomy or Tenodesis
- Synovectomy
- Subacromial Decompression (SAD)

Arthroscopy introduces a fiber-optic camera into the shoulder joint through a small incision for diagnostic visualization purposes. Other instruments may then be introduced to remove, repair, or reconstruct joint pathology.

Surgical indications are based on relevant subjective clinical symptoms, objective physical exam & radiologic findings, and response to previous non-operative treatments when medically appropriate.

Open, non-arthroplasty shoulder repair surgeries are performed as dictated by the type and severity of injury and/or disease.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

General Requirements
- Elective surgery of the shoulder may be considered if the following general criteria are met:
  - There is clinical correlation of patient’s subjective complaints with objective exam findings and/or imaging (when applicable);
  - Patient has limited function (age-appropriate activities of daily living (ADLs), occupational, athletic);
  - Patient is medically stable with no uncontrolled comorbidities (such as diabetes);
  - Patient does not have an active local or systemic infection;
  - Patient does not have active, untreated drug dependency (including but not limited to narcotics, opioids, muscle relaxants) unless engaged in treatment program
  - A smoking cessation program is highly recommended and should be instituted pre-operatively for all actively smoking patients
• Clinical notes should address:
  o Symptom onset, duration, and severity;
  o Loss of function and/or limitations;
  o Type and duration of non-operative management modalities (where applicable).

• Non-operative management, when required, will be specified within the clinical indications below and may include one or more of the following:
  o Physical therapy or properly instructed home exercise program
  o Rest or activity modification
  o Minimum of 4 weeks of oral NSAIDs (if not medically contraindicated)
  o Single injection of corticosteroid and local anesthetic into subacromial or intra-articular space, or bicipital groove

Clinical Indications

Rotator Cuff Repair (RCR)

*Surgical treatment of rotator cuff tear (RCT) should only be performed when there is a clinical correlation of patient symptoms, clinical exam findings, imaging, and failed non-operative management (where required). Note: Traditional open rotator cuff repair (RCR) with deltoid take-down should be rare given increased morbidity when compared to arthroscopic or mini-open surgery.*

Partial-Thickness Rotator Cuff Tear

Surgical repair of a partially torn rotator cuff may be necessary when **ALL** of the following criteria are met:

a) Reproducible rotator cuff pain patterns (lateral arm, deltoid pain not radiating past the elbow, night pain, or pain with overhead motions);

b) Positive impingement signs and/or tests on exam (reproducible pain when arm is positioned overhead (above plane of shoulder) with relief of pain when arm is repositioned below the plane of the shoulder);

c) Functional loss (age-appropriate activities of daily living (ADLs), occupational, athletic);

d) MRI that demonstrates a partial thickness tear (articular-sided, concealed, or bursal-sided);

e) Failure of at least 12 weeks of non-operative treatment, including at least **3** of the following criteria:
   
i) Physical therapy or properly instructed home exercise program
   ii) Rest or activity modification
   iii) Minimum of 4 weeks of oral NSAIDs (if not medically contraindicated)
   iv) Single injection of corticosteroid and local anesthetic into subacromial or intra-articular space.

Small (<1cm), Full-Thickness Rotator Cuff Tear

Surgical repair of a small full-thickness rotator cuff tear may be necessary when **ALL** of the following criteria are met:
a) Reproducible rotator cuff pain patterns (lateral arm, deltoid pain not radiating past the elbow, night pain, or pain with overhead motions);
b) Positive impingement signs and/or tests on exam (reproducible pain when arm is positioned overhead (above plane of shoulder) with relief of pain when arm is repositioned below the plane of the shoulder);
c) Functional loss (age-appropriate activities of daily living (ADLs), occupational, athletic);
f) Rotator cuff weakness on physical exam;
g) MRI that demonstrates a small, full thickness tear (<1cm);
h) Failure of at least 6 weeks of non-operative treatment*, including physical therapy or a properly instructed home exercise program (that includes exercises for scapular dyskinesis when present) AND at least one of the following:
   i) Rest or activity modification
   ii) Minimum of 4 weeks of oral NSAIDs (if not medically contraindicated)
   iii) Single injection of corticosteroid and local anesthetic into subacromial or intra-articular space

*Note: The requirement for conservative, non-operative treatment is waived in a patient less than age 55 with an acute traumatic tear (patient must be less than two months following injury)

Medium (1-3cm) or Large (3-5cm), Full-Thickness Rotator Cuff Tear

Surgical repair of a medium or large full-thickness rotator cuff tear may be necessary when the following criteria are met:

a) Significant progression of a full-thickness tear on serial imaging performed at least 3 months apart (at least 50% increase in tear size)
   OR when ALL of the following criteria are met:
   a) Reproducible rotator cuff pain patterns (lateral arm, deltoid pain not radiating past the elbow, night pain, or pain with overhead motions);
   b) Positive impingement signs and/or tests on exam (reproducible pain when arm is positioned overhead (above plane of shoulder) with relief of pain when arm is repositioned below the plane of the shoulder) OR Rotator cuff weakness on physical exam;
   c) Functional loss (age-appropriate activities of daily living (ADLs), occupational, athletic);
   d) MRI results support a Medium (1-3cm) or Large (3-5cm), full-thickness tear (tear must be a complete single tendon or greater).

Massive (>5 cm and least 2 tendons involved), Full-Thickness Rotator Cuff Tear

Surgical repair of a massive torn rotator cuff may be necessary when ALL of the following criteria are met:

a) MRI demonstrates Goutallier stage 0 (normal muscle), 1 (some fatty streaks), or 2 (less than 50% fatty degeneration or infiltration);
   b) Warner classification of atrophy "none" or "mild";
c) No x-ray evidence of chronic subacromial articulation of humeral head (e.g. acromiohumeral distance less than 7 millimeters, acetabularization or femoralization, no remodeling of greater tuberosity, lack of sclerotic lateral acromion, lack of extensive CA (coracoacromial) ligament calcification:

d) MRI showing massive (>5cm), full-thickness tear.

Revision Rotator Cuff Repair

Surgical revision within 1 year of a previously repaired small, medium, large or massive torn rotator cuff will be reviewed on a case-by-case basis, and must include a MRI (with or without arthrogram) or CT arthrogram that demonstrate failure of healing (Sugaya type 4-5) or recurrent tear > 3 months after index surgery.

Sugaya classification

- Type I Sufficient thickness, homogeneous tendon (low signal on T2 images)
- Type II Sufficient thickness, partial high-intensity from within the tendon
- Type III Insufficient thickness without discontinuity
- Type IV Minor discontinuity on more than one slice, suggesting a small tear
- Type V Major discontinuity suggesting a moderate or large tear

All RCR revision cases greater than 1 year following an initial repair must again meet indications as specified by tear size listed above.

Contraindications (applies to all Rotator Cuff Repair):

- Active infection (local or remote)
- Treatment of asymptomatic, full thickness rotator cuff tear
- Active systemic bacteremia
- Deltoid or rotator cuff paralysis
- Kellgren-Lawrence Grade 4 osteoarthritis [see grading appendix].

Labral Repairs

There is a tendency to misinterpret normal degenerative labral changes and variations as “tears” which may lead to over-utilization of surgery if decisions are made upon imaging reports alone. In addition, the anterior-superior labrum (from 12 to 3 o’clock for a right shoulder) has many normal variations that can be misinterpreted as a tear, including sublabral hole/foramen, Buford complex, and a labral overhang with an intact biceps anchor. In general, true labral tears lead to pain, catching, popping, functional limitations (including age-appropriate activities of daily living (ADLs), occupational and athletic), micro-instability, and gross instability. Labral repairs are most-frequently associated with a specific traumatic event.

Superior Labral Anterior-Posterior (SLAP) Tear

Surgical indications should be focused on clinical symptoms and failure to respond to non-operative treatments, rather than imaging (due to a higher percentage of tears being missed on images AND significant over-diagnosing of tears based on imaging-alone).

Repair (not debridement of a SLAP lesion) may be necessary when ALL of the following criteria are met:
a) History compatible with tear (acute onset in thrower or overhead athlete, fall, traction injury, shear injury (MVA), lifting injury);
b) Pain localized to the glenohumeral joint (often only associated with certain reaching or lifting activities and at night) or painful catching/popping/locking sensations;
c) Inability to perform desired tasks without pain (age-appropriate ADLs, sports, occupation);
d) Age < 40*;
e) MRI demonstrating superior labral tear;
f) Type 2 or 4 SLAP tear (not type 1 or 3);
   I Labral and biceps fraying, anchor intact
   II Labral fraying with detached biceps tendon anchor
   III Bucket handle tear, intact biceps tendon anchor (biceps separates from bucket handle tear)
   IV Bucket handle tear with detached biceps tendon anchor (remains attached to bucket handle tear)
g) Failure of at least 12 weeks of non-operative treatment, including activity modification/avoidance of painful activities AND at least one of the following:
   i) Minimum of 4 weeks of oral NSAIDs (if not medically contraindicated)
   ii) Physical therapy or a properly instructed home exercise program
   iii) Intra-articular injection

*NOTE: All requests for SLAP repair in patient age >40 will be reviewed on a case-by-case basis. 

Contraindications:
- ANY evidence of degenerative disease upon imaging
- Smoker and age >40
- Diabetics with poor control HgBA1c > 7
- MRI findings not attributable to normal common variants (for example, labral overhang)

NOTE: In cases where a true SLAP tear exists, but the patient has one or more contraindications, or findings at the time of surgery indicate that a repair is not feasible, a SLAP debridement (limited, extensive debridement), biceps tenotomy or tenodesis may be an alternative. 
See Tenotomy and Tenodesis Indications.

Anterior-Inferior Labral-Tear (Bankart lesion):
A Bankart tear of the glenoid labrum is located at the 3-6 o’clock position of a right shoulder. It is typically caused by a traumatic instability event (dislocation or subluxation). It can involve the labrum, the capsular ligaments (IGHL [inferior glenohumeral ligamentous complex]) and/or the bone (bony Bankart fracture). If symptomatic, bankart tears typically require surgical repair as patients less than 30 have a high recurrence rate of instability.

Bankart repair of an acute labral tear may be necessary when ALL of the following criteria are met:
   a) History of an acute event of instability (subluxation or dislocation) or acute onset of pain following activity;
   b) Acute labral tear on MRI or CT imaging;
c) Age < 30;

  d) Range of motion is not limited by stiffness upon physical exam;

  e) Clinical exam findings demonstrate positive apprehension test, positive relocation test, positive labral grind test, or objective laxity with pain.

Bankart repair of a recurrent (two or more dislocations) labral tear may be necessary when ALL of the following criteria are met:

  a) Recurrent instability (subluxation or dislocation);
  b) Evidence of a labral tear with or without bony Bankart fracture of the glenoid upon imaging;
  c) Range of motion is not limited by stiffness upon physical exam;
  d) Clinical exam findings demonstrate positive apprehension test, positive relocation test, positive labral grind test, or objective laxity with pain.

Contraindications:
- Pain only (no documented recurrent instability events) in patients over 40
- X-ray, MRI or CT documentation of degenerative arthritis of the glenohumeral joint
- Radiographic findings of a Hill Sachs humeral head defect (if surgery only includes Bankart repair)
- Cases demonstrating X-ray, MRI or CT documentation of greater than 20% glenoid bone loss require review on a case by case basis. These cases indicate that a Latarjet reconstruction or bone graft [autograft or allograft] repair may be required.

**Posterior Labral Tear:**

*Similar to Bankart tears, posterior labral tears are often associated with a paralabral cyst that grows large enough to compress the suprascapular nerve (isolated to infraspinatus). Posterior labral tears are frequently associated with contact sports or a patient history of a traumatic fall/posterior loading of the joint. They are often observed in athletes performing repetitive posterior loading of the joint (offensive linemen in football, weight-lifting: push-ups and bench press). These tears are more likely to result in pain and weakness rather than recurrent dislocations/instability. Posterior labral changes are often misinterpreted on MRI as a “tear” in age >40 years old, when changes due to early glenohumeral degeneration begin to appear.*

Surgical repair of a posterior labral tear may be necessary when ALL of the following criteria are met:

  a) Symptoms of pain OR painful catching/popping OR instability;
  b) MRI findings of posterior labral tear;
  c) Exam findings demonstrate positive load-shift test, jerk test, glenohumeral grind test, or objective laxity with pain or profound weakness;
  d) Failure of at least 12 weeks of non-operative treatment (unless presenting as a traumatic tear in a competitive athlete at any level) that includes any two of the following:
      i) Physical therapy or a properly instructed home exercise program
      ii) Rest or activity modification
iii) Minimum of 4 weeks of oral NSAIDs (if not medically contraindicated)

e) Age < 40:

f) No radiographic evidence of degenerative disease (e.g. posterior glenoid cartilage loss, subchondral glenoid cysts, mucoid degeneration of labrum, narrowing of joint space with posterior humeral head subluxation on axillary x-ray or axial MRI images).

**Combined Labral Tears (e.g. Anterior/Posterior, SLAP/Anterior, SLAP/Posterior, SLAP/Ant./Post.)**

Combined tears that require repair are almost always associated with significant recurrent instability. Often tears begin within one area and overtime the failure to repair the original injury causes the tear to extend.

Surgical repair of an acute combination tear may be necessary when **ALL** of the following criteria are met:

a) History of an acute event of instability (subluxation or dislocation);

b) Acute labral tear on MRI/CT imaging with/without bony Bankart fracture not > 25% of glenoid width upon imaging;

c) Age < 30;

d) Range of motion not limited by stiffness upon physical exam;

e) Clinical exam findings demonstrate positive apprehension test and positive relocation test, OR positive labral grind test OR objective laxity with pain;

f) Minimal to no evidence of degenerative changes on imaging.

Surgical repair of recurrent combination tear may be necessary when **ALL** of the following criteria are met:

a) Recurrent instability (subluxation or dislocation) with at least 2 instability events;

b) Labral tear on MRI or CT, with/without bony Bankart fracture not > 25% of glenoid width upon imaging;

c) Range of motion not limited by stiffness upon physical exam;

d) Clinical exam findings demonstrate positive apprehension test and positive relocation test, or positive labral grind test, or objective laxity with pain;

e) Minimal to no evidence of degenerative changes on imaging.

**NOTE:** Thermal capsulorrhaphy was previously used to augment unstable shoulders, with and without labral tears. It is no longer considered an accepted procedure for unstable shoulders.

**Open or Arthroscopic Capsulorrhaphy for Multidirectional Instability of the Shoulder (MDI)**

Surgical repair for MDI may be necessary when **ALL** of the following criteria are met:

a) Patient has pain and limited function (age-appropriate ADLs, occupation, or sports);

b) Patient has recurrent instability due to hyperlaxity or mobility and no traumatic dislocation;
c) Physical exam supports repeatable increased glenohumeral joint translation (greater than 1cm of movement during the sulcus test):

d) Imaging (x-ray and MRI) rules out fracture and/or other soft-tissue injury:

e) Failure of at least 6 months of formal physical therapy and activity modification

Adhesive Capsulitis (Lysis of Adhesions: Capsulotomy/Capsular Release)

Adhesive capsulitis is a thickening and tightening of the soft tissue capsule that surrounds the glenohumeral joint. Adhesive capsulitis usually begins with the gradual onset of pain and limitation of shoulder motion, with a progression to interference of activities of daily living. Primary adhesive capsulitis is the subject of much debate as the specific causes of this condition are not fully understood. Patients with uncontrolled diabetes have a significantly higher risk of developing adhesive capsulitis than the general population. Secondary (acquired) adhesive capsulitis develops from a known cause, such as stiffness following a shoulder injury, surgery, or a prolonged period of immobilization. Adhesive capsulitis may last from one to three years, despite active treatment, and is more common in women.

Surgery for adhesive capsulitis may be necessary when ALL of the following criteria are met:

a) Patient has pain, loss of motion, and limited function (age-appropriate ADLs, occupation, or sports);

b) Physical exam demonstrates loss of motion (use contralateral shoulder for comparison);

c) Comorbidities (such as diabetes, lung disease) and other causes of loss of shoulder motion have been ruled out. (Imaging (x-ray and/or MRI) may be used to identify other underlying problems);

d) Failure of at least 12 weeks of non-operative treatment that includes physical therapy or a properly instructed home exercise program and documentation of any of the following:
   i) Minimum of 4 weeks of oral or topical NSAIDs (if not medically contraindicated)
   ii) Rest or activity modification
   iii) Heat/Ice
   iv) Corticosteroid injection

Distal Clavicle Excision (DCE)

The AC joint (acromioclavicular joint) can develop degenerative disease in those over 30 years of age, those with a history of a prior grade I or II AC sprain/separation, those with a history of heavy lifting (labor occupation or strength training), or those with evidence of remote trauma. It can occur in isolated form in younger patients (distal clavicle osteolysis) but is more commonly observed concomitantly with rotator cuff disease in those over age 40 years of age.

Distal Clavicle Excision may be necessary when ALL of the following criteria are met:

a) Positive clinical exam findings as evidenced by pain upon palpation over AC joint and pain with cross-body adduction test;

b) Positive findings on X-Ray or MRI:
i) Radiographic (x-ray) demonstrates narrowed joint space, distal clavicle or medial acromial sclerosis, and/or osteophytes or cystic degeneration of distal clavicle or medial acromion correlating with the clinical findings, patient symptoms and diagnosis; OR
ii) MRI findings with edema in the distal clavicle and/or inflammatory change within the joint space correlating with the clinical findings, patient symptoms and diagnosis;
c) Failure of at least 12 weeks of non-operative treatment that includes at least two of the following:
   i) Oral or topical NSAIDS (4 week minimum for oral NSAIDS unless contraindicated)
   ii) Rest/activity modification
   iii) AC joint corticosteroid injection (if DCE is to be performed as a standalone procedure, AC injection must be performed*)
   iv) Physical therapy or a properly instructed home exercise program

*Note: If DCE is to be performed in isolation of other shoulder procedures, an AC joint injection is required for diagnostic purposes and documentation should support pain relief from injection. If no response to injection, this is a strong negative predictor to surgical outcome for isolated DCE.

**Long Head Biceps (LHB) Tenotomy/Tenodesis**

*Pain in the area of the long head of the biceps tendon is common, especially in overhead sports and in the presence of rotator cuff tears (especially subscapularis). It can be an isolated source of pain in chronic tenosynovitis, SLAP tears, or small tears of the biceps sling, resulting in dynamic or static subluxation or dislocation of the tendon. LHB problems are frequently missed on MRI (especially using contrast which can mask the pathology). The choice of tenodesis versus tenotomy is controversial. Typically, tenodesis is better for more active, muscular individuals performing higher demand activity (labor, sports). Tenotomy is generally a better option for older, less active patients with poor muscle definition, as it generally leaves the patient with a "popeye" deformity and the possibility of biceps cramping or anterior shoulder pain with activity. The choice of tenotomy vs. tenodesis is generally left up to the surgeon/patient.*

**NOTE:** The indications for tenodesis and tenotomy are the same with the exception that tenodesis is typically better for more active, muscular individuals that are performing higher-demand activities for work or sport. Tenotomy is often preferred in patients that smoke (this is a relative indication of tenotomy over tenodesis) due to healing problems in tenodesis.

Tenotomy or Tenodesis may be necessary when **ALL** of the following criteria are met:

a) Any of the following:
   i) Age > 50 with SLAP tear
   ii) Smoker with SLAP labral tear (regardless of age, more significant with increasing age)
   iii) Failed SLAP repair
   iv) SLAP tear in diabetic or patient with loss of motion or predisposition to stiff shoulder
   v) LHB hypertrophy/tearing/subluxation in association with RCR
   vi) Diagnosis of chronic LHB groove pain from tenosynovitis:
   **AND**

b) Failure of at least 12 weeks of non-operative treatment to include **TWO** of the following:
   i) Oral or topical NSAIDS (4 week minimum for oral NSAIDS unless contraindicated)
   ii) Rest/activity modification
iii) Bicipital groove or IA joint corticosteroid injection
iv) Physical therapy or a properly instructed home exercise program

**Synovectomy**

*Synovitis is common in many shoulder conditions and typically resolves when the primary pathology is treated. Most commonly, this includes loose bodies, inflammatory arthritis or degenerative arthritis, labral tears and adhesive capsulitis. Primary synovial diseases include pigmented villonodular synovitis, synovial chondromatosis, rheumatoid arthritis, other inflammatory arthritides, traumatic synovial hypertrophy or metaplasia.*

Synovectomy as an isolated procedure is usually reserved for primary synovial disease or in cases where secondary hypertrophic synovitis is documented during arthroscopy (these include adhesive capsulitis, osteoarthritis, chronic rotator cuff tear). These should be evident on arthroscopic photographs taken at surgery but may be missed on preoperative images.

**Subacromial Decompression (SAD)**

*There are 3 types of acromion anatomy according to Bigliani classification: type 1, flat (20%), type 2, curved (40%) and type 3, hooked, (40%). Acromioplasty involves removing bone from the undersurface of the acromion to change a type 3 (hooked) acromion to a type 1 (flat) acromion. Although debated for decades, current evidence concludes that there is no role for isolated acromioplasty (subacromial decompression), which prompted conversion of CPT code 29826 (acromioplasty, subacromial decompression) from an index, primary, "stand-alone" code to an "add-on" code only.*

Subacromial decompression may be necessary in conjunction with other shoulder procedures (listed below) if there is radiographic (x-ray) evidence of mechanical outlet impingement as evidenced by a Bigliani type 3 morphology. Subacromial decompression should not be performed in isolation.

- a) Rotator cuff repair
- b) Labral repair
- c) Capsulorrhaphy
- d) Loose body removal
- e) Synovectomy
- f) Debridement
- g) Distal clavicle excision
- h) Lysis of adhesions
- i) Biceps tenodesis/tenotomy

**Contraindications:**

- Type 1 or Type 2 or a thinned acromion. Subacromial bursectomy may be a reasonable option.
- If patient has received an injection in the subacromial space and there is failure to adequately respond—significant relief (>50%) for minimum of 1 week—to injection in the subacromial space (pain should respond temporarily if impingement).
- Prior subacromial decompression with either a Type 1 or a thinned acromion or no evidence of overhang on x-ray (unnecessary revision can thin the acromion and lead to deltoid avulsion and/or acromial fracture)
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Open SAD procedures should rarely be performed given the increased morbidity due to
deltoid disruption.

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Page 608 of 927


References


RADIATION ONCOLOGY GUIDELINES

2D – 3D Conformal Radiation Therapy (CRT), External Beam Radiation Therapy For Other Cancers

This guideline for 2D – 3D CRT applies to other cancers not listed below for programs that manage all cancer sites.

Refer to applicable site-specific guidelines for the management of primary malignancies. Applicable site-specific guidelines may include all or some of the sites below, depending on the specific program.

- Anal Cancer
- Bone Metastases
- Breast Cancer
- Cervical Cancer
- CNS Cancer
- Colon Cancer
- Rectal Cancer
- Endometrial Cancer
- Gastric Cancers
- Head and Neck Cancer
- Lung - Non Small Cell
- Lung - Small Cell Lung Cancer
- Lymphoma - Hodgkin’s Lymphoma
- Lymphoma - Non Hodgkin’s Lymphoma
- Pancreas Cancer
- Prostate Cancers

For metastasis to the brain, regardless of primary site, refer to the NIA clinical guideline for Central Nervous System (CNS). For metastasis to bone, refer to the NIA clinical guideline for Bone Metastases. For all other metastases, refer to the NIA clinical guideline for metastatic disease.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR 2D – 3D CRT

OTHER CANCER SITES NOT LISTED ABOVE
- Conventional 2D and 3D-CRT treatment delivery is appropriate for all primary malignancies not listed above.
- The number of fractions for definitive treatment is approvable up to 30 fractions. Fractions beyond 30 may be approvable upon physician review when clinical rationale is presented.
INTRODUCTION:

This guideline outlines methods suitable for delivering anal carcinoma radiation therapy. Techniques such as CT simulation, conformal approach and intensely modulated radiation therapy (IMRT) have shown promising results in ongoing clinical trials. IMRT use requires expertise in defining appropriate target volume over conventional conformal beam irradiation. As in most cancers, a multidisciplinary approach is preferred for treating patients with anal carcinoma.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY:

2D, 3D-CRT and IMRT are all appropriate techniques for treatment of anal cancer. Electron beam or photon beam are the most commonly used techniques for delivering boost radiotherapy.

- Dosage Guidelines: 45 Gy – 59.4 Gy in 28 to 33 fractions

  Unless otherwise indicated standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for anal cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.

Stereotactic Body Radiation Therapy (SBRT)
Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of anal cancer. A peer review is required with a radiation oncologist.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.

REFERENCES


INTRODUCTION:

Bone metastases are a common manifestation of malignancy that can cause severe and debilitating effects including pain, spinal cord compression, hypercalcemia, and pathologic fracture. Radiation therapy has a proven track record in the palliation of bone metastases. Following a course of palliative treatment, approximately one-third of patients will have complete relief of pain and two-thirds of patients will have significant reduction in their pain. The optimal delivery of radiation therapy has been the focus of multiple trials looking at the best dose fractionation. Common dose fractionation schedules have shown good rates of palliation, including 8 Gy in 1 fraction, 20 Gy in 4 fractions, 24 Gy in 6 fractions, or 30 Gy in 10 fractions. All provide excellent pain control with minimal side effects. The benefit of the single fraction is that it is the most convenient for patients, whereas the advantage of a longer course of treatment has the advantage of a lower incidence of re-treatment to the same site. Dose fractionation is typically determined based on location of the metastasis, patient’s clinical status, previous irradiation treatment, etc. Therefore, multiple factors must be reviewed prior to prescribing palliative radiotherapy.

MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY:

- Conventional 2D planning techniques is appropriate for the treatment of bone metastases.
- 3D-CRT may be indicated in select cases such as situations of re-treatment, overlapping volumes or adjacent critical structures that are likely to cause complications. Requests for 3D-CRT must be accompanied by supporting clinical rationale.

Favorable Risk: (Good performance status = ECOG less than 3)
- EBRT – Up to 10 fractions for multiple bone metastases
- EBRT – Up to 14 fractions for spinal cord compression symptoms or single lesion or instances that require a longer fractionated course to minimize patient discomfort (e.g. nausea).

Unfavorable Risk: (Poor performance status = ECOG 3 or greater or progressive metastatic disease)
- EBRT – Up to 5 fractions

Requests and supporting rationale for additional fractions can be discussed with a physician reviewer.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Intensity modulated radiation therapy (IMRT)

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for bone metastasis. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.
Requests for IMRT require physician review of the clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery. Supporting documentation will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Stereotactic Body Radiation Therapy (SBRT)**

Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of bone metastasis. A peer review is required with a radiation oncologist.

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for bone metastasis. Overall, studies of proton beam therapy have not shown clinical outcomes to be superior to conventional radiation therapy in bone metastases.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

*For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.*
REFERENCES


(Low Dose Radiation (LDR), High Dose Radiation (HDR), Selective Internal Radiation Therapy (SIRT, Electronic Brachytherapy)

CPT Codes:
LDR: 77761, 77762, 77763, 77778, 77789
HDR: 77767, 77768, 77770, 77771, 77772
Electronic Brachytherapy: 0394T, 0395T

INTRODUCTION:

This guideline applies to other cancers not listed below for programs that manage all cancer sites. LDR (low dose rate brachytherapy) and HDR (high dose rate brachytherapy) must be requested separately and are not interchangeable.

Refer to applicable site-specific guidelines for the management of primary malignancies. Applicable site-specific guidelines may include all or some of the sites below, depending on the specific program.

- Anal Cancer
- Bone Metastases
- Breast Cancer
- Cervical Cancer
- CNS Cancer
- Colon Cancer
- Rectal Cancer
- Endometrial Cancer
- Gastric Cancers
- Head and Neck Cancer
- Lung - Non Small Cell
- Lung - Small Cell Lung Cancer
- Lymphoma - Hodgkin’s Lymphoma
- Lymphoma - Non Hodgkin’s Lymphoma
- Pancreas Cancer
- Prostate Cancers

For metastasis to the brain, regardless of primary site, refer to the NIA clinical guideline for Central Nervous System (CNS). For metastasis to bone, refer to the NIA clinical guideline for Bone Metastases. For all other metastases, refer to the NIA clinical guideline for Metastatic Disease.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

- Brachytherapy for sites beyond those listed above may be approvable with submission of supportive documentation.
- Intracavitary balloon catheter brain brachytherapy for malignant gliomas or metastasis to the brain is considered investigational.
- Selective Internal Radiation Therapy (SIRT), also known as radioembolization with microsphere brachytherapy device (RMBD) and transarterial radioembolization, uses microscopic radioactive spheres to deliver radiation to the tumor site. Treatment is delivered through catheter injection of radioactive Yttrium-90 (90Y) microspheres into the hepatic artery. Indications for SIRT include:
• unresectable metastatic liver tumors – see “Metastatic Disease Guideline”
• unresectable metastatic liver tumors from primary colorectal cancer see “Metastatic Disease Guideline”
• unresectable primary hepatocellular carcinoma
• unresectable neuroendocrine tumors

• The use of electronic brachytherapy for basal cell and squamous cell cancers of the skin (of non-melanomatous skin cancers) and benign skin conditions are considered investigational and experimental at this time.
REFERENCES


INTRODUCTION:

Breast cancer is the second most commonly diagnosed cancer among women, after skin cancer, and it accounts for nearly 25% of cancer diagnoses in U.S. women. After a breast cancer diagnosis is made, it is followed by a staging evaluation to determine extent of disease (local, regional, or metastatic) and prognostic findings. Importance is placed on tumor size, lymph node involvement (sentinel node), the histopathological interpretation, margins of resection, and hormonal and growth-factor receptor status. Treatment for breast cancer may consist of one of several mastectomy options or breast-conserving surgery and radiation therapy.

Radiation therapy is used to treat the breast and lymph node bearing areas after partial mastectomy or lumpectomy. Since breast cancers are relatively responsive to moderate doses of radiation therapy following tumor excision, treatment for cure may be achieved by external beam techniques or by partial breast irradiation techniques.

The methods suitable for delivering breast radiation therapy have been established through clinical trials providing strong evidence in support of radiation therapy as an effective breast cancer treatment. The traditional approach utilizes tangential radiation fields to the breast and chest wall; based on the clinical and pathological factors, this may be followed by boost to the site of excision (tumor bed). The axilla and supra-clavicular regions also may be included in a separate field based on analysis of prognostic risk factors. Improvements in technology, the observation that local tumor recurrence is most frequently observed near the site of excision, and the desire to limit the extent of radiation have led to restriction of the radiation to the tumor bed (partial breast irradiation) for selected cases.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS:

This guideline outlines several methods suitable for the employment of radiation therapy in conjunction with breast cancer treatment. These include the use of three-dimensional conformal radiation therapy (3D-CRT), intensity-modulated radiation therapy (IMRT), image guided radiation therapy (IGRT) and internal radiation (brachytherapy). IMRT is not indicated as a standard treatment option for breast cancer but may be indicated for selected cases of breast cancer with close proximity to critical structures. Most external beam treatments are delivered using a high energy linear accelerator. Brachytherapy is generally delivered using temporary HDR sources such as 192-Iridium (192-Ir) or Cesium-137 (137-Cs).

**Whole Breast Radiation**

Three-dimensional conformal radiation therapy (3D-CRT) is the appropriate technique for treatment of the whole breast following breast conserving surgery (lumpectomy, breast conservation surgery). Electron beam or photon beam are the most commonly used techniques for delivering boost radiotherapy.

**Dosage Guidelines**

- 45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions
- Hypofractioned radiation therapy is considered medically necessary with 40-45 Gy at 2.66 Gy per fraction in 15 to 16 fractions.

**Partial Breast Irradiation**

Accelerated partial breast irradiation (APBI) may be considered as the sole form of radiation therapy, in lieu of whole breast radiation following lumpectomy for selected cases. Patients with a small tumor, clear surgical margins after lumpectomy, and no lymph nodes containing cancer are typically eligible for APBI. APBI is considered appropriate for patients who meet all of the following criteria:

- Age 50 or older
- No use of adjuvant chemotherapy
- Lymph nodes negative
- Negative surgical margins
- Tumor size less than or equal to 3 cm (including ductal carcinoma in situ)
- Clinically or microscopically unifocal
- Absence of BRCA in 1/2 mutation, if applicable

**Dosage Guidelines**

- Appropriate fractionation schemes for APBI are 34 Gy in 10 fractions delivered twice per day with brachytherapy or 38.5 Gy in 10 fractions twice per day with external beam photon therapy

**Chest Wall Radiation**

Three-dimensional conformal radiation therapy (3D-CRT) is the appropriate technique for treatment of the chest wall following mastectomy. Electron beam or photon beam are the most commonly used techniques for delivering boost radiotherapy.

**Dosage Guidelines**

- 45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions

**Other Considerations**

- Re-irradiation following local or regional recurrence after prior mastectomy and prior breast or chest wall radiation may be appropriate.

- For inflammatory breast cancer, whole breast or chest wall radiation, consider nodal radiation with or without chest wall boost.

**Dosage Guidelines**

45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions. *Standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.*

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:**

**Intensity modulated radiation therapy (IMRT)**
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for breast cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans. 3D-CRT techniques such as step-and-shoot or field-in-field should be considered for the comparison.

- Confirm the IMRT requested will be inversely planned (forward plans or 'field-in-field' plans are not considered IMRT).

- Provide tissue constraints for both the target and affected critical structures.

**Brachytherapy**
Interstitial brachytherapy boost treatment requires a peer review and documentation that improvement in dose delivery to the boost target cannot be delivered with external beam therapy. Other emerging techniques such as intraoperative radiotherapy (IORT) and Non invasive Image Guided Breast Brachytherapy (NIIGBB) techniques are being investigated and are not considered a medically necessary treatment option for the treatment of breast cancer.

**Proton Beam Radiation Therapy**
Proton beam is not an approved treatment option for breast cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation or IMRT. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

**THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:**

*For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.*
REFERENCES


INTRODUCTION:

The role of radiation therapy in the treatment of cervical cancer has been long established through clinical trial, providing strong evidence of support as an effective cervical cancer treatment. The traditional approach utilizes external beam irradiation therapy to the pelvis ± periaortic lymph nodes, as well as some form of brachytherapy boost, based on clinical and pathologic factors. There have been improvements in radiation therapy technology, reducing dose to normal surrounding tissue (bladder, rectum, and small bowel), but the majority of the experience to date is based on a point A dosing system.

This guideline outlines several methods suitable for the employment of radiation therapy in conjunction with cervical cancer treatment. These include the use of three-dimensional conformal radiation therapy (3D-CRT), intensity-modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT), and internal radiation (brachytherapy). Although intensity modulated radiation therapy (IMRT) is becoming more widely available, the routine use in treating cervical cancer remains to be validated. IMRT may be useful when high doses are required to treat gross disease in regional lymph nodes. However IMRT should not be used as routine alternatives to brachytherapy for treatment of central disease in patients with an intact cervix. Although there have been significant advances in imaging, planning and treatment delivery, this must be tailored to a thorough understanding to the stage of disease, pathways for dissemination and recurrence risk. Most external beam treatments are delivered using a high-energy linear accelerator. Brachytherapy is generally delivered as either low dose permanent implant or high dose rate implant. Principles of radiation therapy for these guidelines closely follow what is recommended both by the American Brachytherapy Society (Cervical Cancer Brachytherapy Task Group), as well as in National Comprehensive Cancer Network Practice Guidelines for Cervical Cancer.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS:

Definitive/Preoperative Radiation Therapy

- Stage IA – IA2 – Brachytherapy (LDR or HDR) +/- 2D/3D-CRT (40-50 Gy; 28 fx max)
- Stage IB1 – Pelvic 2D/3D-CRT (40-50 Gy; 28 fx max) + brachytherapy boost
- Stage IB2-IIA – Pelvic radiation therapy 2D/3D-CRT (40-50 Gy; 28 fx max) + brachytherapy boost and concomitant chemotherapy +/- adjuvant hysterectomy.
- Stage IIB-IVA – Pelvic and/or paraortic 2D/3D-CRT + brachytherapy + concurrent chemotherapy.
- Stage IVB – 2D/3D-CRT +/- brachytherapy for palliation only (symptom control)

Grossly involved unresected nodes may be evaluated for boosting with an additional 10-15 Gy

Postoperative (Adjuvant) Radiation Therapy

- Patients found to have deep cervical stromal invasion, lymphovascular invasion and/or bulky primary tumors.
  - Pelvic 2D/3D-CRT (45-50.Gy; 28 fx max) +/- concurrent chemotherapy
- Patients with positive nodes, positive margins and/or parametrial invasion –
Pelvic 2D/3D-CRT (45-50 Gy; 28 fx max) + concurrent chemotherapy

Pelvic 2D/3D-CRT (45-50 Gy; 28 fx max) +/- vaginal brachytherapy boost (LDR or HDR) can be considered in women with a positive margin.

**Local /Regional Recurrence**
- No previous RT or outside previous RT fields
  - 2D/3D-CRT + chemotherapy +/- brachytherapy
- Previous RT
  - Intraoperative Radiation Therapy (IORT) for centralized disease
  - Possible Brachytherapy (LDR or HDR) for centralized disease < 2cm Tumor directed 2D/3D-CRT +/- chemotherapy if noncentral disease

*Grossly involved unresected nodes may be evaluated for boosting with an additional 10-15 Gy.*

*Unless otherwise indicated standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.*

**TREATMENT OPTIONS REQUIRING ADDITIONAL CLINICAL REVIEW:**

**Intensity modulated radiation therapy (IMRT)**

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for cervical cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for circumstances in which radiation therapy is indicated and

- Non-IMRT techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance. The non-IMRT delivery is anticipated to contribute to potential late toxicity
- Tumor volume dose heterogeneity from non-IMRT techniques is such that unacceptable hot or cold spots are created

Requests for IMRT treatment delivery to the cervix will be reviewed for medical necessity prior to authorization based on the above criteria. Clinical rationale and documentation for performing IMRT rather than non-IMRT techniques must be provided for review. This includes a statement of medical necessity from the requesting provider and a dosimetric comparison plan addressing the approval criteria above.

The plan will:
- Demonstrate how non-IMRT treatment planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Stereotactic Body Radiation Therapy (SBRT)**

Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of cervical cancer.

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for cervical cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.
THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.
REFERENCES


INTRODUCTION:

Metastatic tumors for the Central Nervous System (CNS) start in other organs, e.g., lung, breast or colon, and spread to the brain and spinal cord. In adults, these are more common than primary CNS/brain tumors. Both primary and metastatic brain tumors can readily spread through the brain or spinal cord, destroying and compressing normal brain tissue. Metastatic brain tumors occur at some point in 20 to 40% of persons with cancer and are the most common type of brain tumor. Prognosis is dependent on several factors including the type of tumor, location, response to treatment, an individual's age, and overall health status.

Surgery, radiation therapy and chemotherapy are the primary modalities used to treat CNS tumors, either alone or in combination. There are many different approaches in delivering radiation therapy to CNS tumors, including fractionated radiation therapy, stereotactic fractionated radiotherapy, stereotactic radiosurgery, brachytherapy, and proton beam irradiation. Fractionated conformal beam irradiation is the most common approach.

Radiation therapy may be delivered following surgical resection, debulking or biopsy procedures. It may also be used to treat recurrences in patients whose initial treatment was surgery alone. The value of radiation therapy lies in its ability to cure some patients, and to prolong disease-free survival for others. Combined modality approaches that include chemotherapy may also contribute to prolonged disease-free survival in pediatric patients with medulloblastoma, germ cell tumors and gliomas.

The dose and fractionation of radiation depends not only on the tumor type, but also in the curative/palliative setting.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.
INDICATIONS FOR RADIATION THERAPY FOR PATIENTS WITH METASTATIC CENTRAL NERVOUS SYSTEM TUMORS

Metastatic Brain Tumors

- **Favorable Risk** (stable systemic disease or new diagnosis, pathologically confirmed diagnosis, no resection)
  - Whole Brain Radiation Therapy (WBRT) 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)
  - WBRT 2D/3D-CRT + 3D/IMRT boost
  - Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) alone for lesions ≤4cm, controlled systemic disease, Eastern Cooperative Oncology Group (ECOG) rating of less than 3, 4 or less metastasis prior to procedure (maximum 5 fractions)

- **Unfavorable Risk** (poor systemic control, no role for chemotherapy, pathologically confirmed diagnosis, no resection)
  - WBRT 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)

Post Metastasis Resection

- WBRT 20-40 Gy (20 fractions maximum)
- WBRT + external beam boost
- Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) post metastasis resection (up to 5 fractions)

Metastatic Spine Tumors

- 2D/3D-CRT – 8-30 Gy (maximum 10 fractions)
- Dose/fraction dependent on tumor type and performance status
- Stereotactic radiotherapy/IMRT may be appropriate for re-treatment.

INDICATIONS FOR PROTON BEAM THERAPY:

**Treatment of the following in children less than 21 years of age:**

- Metastatic central nervous system tumors when sparing of surrounding normal tissues cannot be achieved with photon therapy

**Treatment at any age:**

- Spinal tumors (primary or metastatic) where spinal cord has previously been treated with radiation or where the spinal cord tolerance may be exceeded with conventional treatment
- Tumors as the base of skull (chordoma, chondrasarcomas)

Requests for Proton Beam Radiation Therapy beyond the indications listed above require physician review by a radiation oncologist as outlined below to determine medical necessity.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

**Intensity Modulated Radiation Therapy (IMRT)**
Intensity Modulated Radiation Therapy (IMRT) may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)**

- For metastatic brain tumors with unfavorable risk (poor systemic control, no role for chemotherapy, pathologically confirmed diagnosis, no resection), the following requests require review with a physician reviewer:
  - WBRT 2D/3D-CRT + SRS/SBRT boost (15-24 Gy, maximum 1 fractions)
  - WBRT 2D/3D-CRT + fractionated SRS/SBRT boost (up to 5 fractions and limited to symptomatic metastasis not responding to WBRT)

Requests for SRS/SBRT, beyond the indications listed above, require review by a radiation oncologist of documentation supporting medical necessity. For patients with 4 or more lesions, SRS may be appropriate in patients with good performance status and low overall tumor volume.”

**Proton Beam Radiation Therapy**

- Proton Beam Radiation Therapy for central nervous system lesions adjacent to the brain stem, spinal cord, or optic nerve requires physician review by a radiation oncologist. A treatment plan with a comparison to conventional IMRT/SRS may be required.
- Requests for Proton Beam Radiation Therapy beyond the indications listed above require physician review by a radiation oncologist.
REFERENCES


INTRODUCTION:

There are many different types of brain tumors. Because brain tumors are located at the control center for thought, emotion, and movement, their effects on an individual's physical and cognitive abilities can be devastating. Prognosis or expected outcome is dependent on several factors including the type of tumor, location, response to treatment, an individual's age, and overall health status. The most common CNS tumors are astrocytomas and glioblastomas, followed by meningiomas and a variety of other less common tumors. Metastatic brain tumors start in other organs, e.g., lung, breast, or colon and spread to the brain. In adults, these are more common than primary brain tumors. Both primary and metastatic brain tumors can readily spread through the brain or spinal cord, destroying and compressing normal brain tissue.

Surgery, radiation therapy and chemotherapy are the primary modalities used to treat CNS tumors, either alone or in combination. The first step in brain tumor treatment is usually surgical resection, with two primary goals: (1) removing as much of the tumor as possible while preserving neurological function and (2) establishing a histologic diagnosis. If the tumor cannot be completely removed, subtotal resection, (debulking) can increase the effectiveness of other treatments. Deep-seated tumors of the brain stem, e.g., pontine gliomas, are generally diagnosed and treated based on clinical and imaging evidence.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY FOR PRIMARY CNS NEOPLASMS:

Gliomas

- Low Grade Tumors – Grade I or II
  - Post-operative/biopsy – 3D-CRT/IMRT (max 33 fx)
- Recurrence – Low Grade
  - 3D-CRT/IMRT – (max 33 fx)
  - Consider reirradiation on select cases. Dose on individual basis
- High Grade Tumors – Grade III or IV
  - Post-operative/biopsy – 3D-CRT/IMRT (max 33 fx)
- Recurrence – High Grade
  - 3D-CRT/IMRT – (max 33 fx)
  - Consider reirradiation on select cases. Dose on individual basis.

Ependymoma – High (Anaplastic) or Low Grade

- Brain and/or spine 3D-CRT/IMRT(max 33 fx)

Meningiomas

- Low Grade and High Grade
  - 3D-CRT/IMRT (max 33 fx)
  - SRS/SBRT (max 5 fx)
CNS Lymphoma

- Complete response to chemotherapy – 3D-CRT (max 20 fx)
- Less than complete response to chemotherapy
- Whole Brain – 3D-CRT (max 20 fx) with or without Limited field boost – 3D-CRT/IMRT (max 25 fx)

Medulloblastoma/Supratentorial PNET (adult)

Craniospinal radiation with brain primary site boost – 3D-CRT/IMRT (max 31 fx total)

Primary Spinal Cord

- 3D-CRT/IMRT (max 28 fx)
  - Tumor below conus medullaris 3D-CRT/IMRT (max 33 fx)
  - SRS/SBRT – (max 5 fx)

INDICATIONS FOR RADIATION THERAPY FOR PATIENTS WITH METASTATIC CENTRAL NERVOUS SYSTEM TUMORS

Metastatic Brain Tumors

- Favorable Risk (stable systemic disease or new diagnosis, pathologically confirmed diagnosis, no resection)
  - Whole Brain Radiation Therapy (WBRT) 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)
  - WBRT 2D/3D-CRT + 3D/IMRT boost
  - Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) alone for lesions ≤4cm, controlled systemic disease, Eastern Cooperative Oncology Group (ECOG) rating of less than 3, 4 or less metastasis prior to procedure (maximum 5 fractions)

- Unfavorable Risk (poor systemic control, no role for chemotherapy, pathologically confirmed diagnosis, no resection)
  - WBRT 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)

Post Metastasis Resection

- WBRT 20-40 Gy (20 fractions maximum)
- WBRT + external beam boost
- Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) post metastasis resection (up to 5 fractions)

Metastatic Spine Tumors

- 2D/3D-CRT – 8-30 Gy (maximum 10 fractions)
- Dose/fraction dependent on tumor type and performance status
- Stereotactic radiotherapy/IMRT may be appropriate for re-treatment.

INDICATIONS FOR PROTON BEAM THERAPY:

Treatment of the following in children less than 21 years of age:
• Primary, metastatic or benign solid tumors when sparing of surrounding normal tissues cannot be achieved with photon therapy

**Treatment at any age:**

• Spinal tumors (primary or metastatic) where spinal cord has previously been treated with radiation or where the spinal cord tolerance may be exceeded with conventional treatment
• Tumors as the base of skull (chordoma, chondrosarcomas)

Requests for Proton Beam Radiation Therapy beyond the indications listed above require physician review by a radiation oncologist as outlined below to determine medical necessity.

**TREATMENT OPTIONS REQUIRING ADDITIONAL CLINICAL REVIEW:**

**Intensity modulated radiation therapy (IMRT)**

If IMRT is not indicated as a standard treatment option, a peer review will be indicated. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

• Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans.

• Provide tissue constraints for both the target and affected critical structures.

**Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)**

If SRS or SBRT is not indicated as a medically necessary treatment option, a peer review will be required. For patients with 4 lesions or more SRS may be appropriate in patients with good performance status and low overall tumor volume.”

**Proton Beam Radiation Therapy**

• Requests for Proton Beam Radiation Therapy require a peer review with a radiation oncologist. A treatment plan with a comparison to conventional IMRT/SRS may be required. See Proton Beam Guideline.
REFERENCES


INTRODUCTION:

Colorectal cancer, also called colon cancer or large bowel cancer includes cancerous growths in the colon, rectum and appendix. Cancer of the colon is generally treated with both surgery and chemotherapy. Surgery may be used in the treatment of all stages of rectal cancer. Preoperative radiation therapy and chemotherapy (neoadjuvant therapy) are given to shrink the tumor before surgery, resulting in improved probability for successful resection. Postoperative radiation therapy and chemotherapy (adjuvant therapy) may decrease local recurrence and improve overall survival. It may also be used for palliative treatment to relieve symptoms of metastatic disease. In addition, local recurrences that cause pain, bleeding or other symptoms are appropriately treated with radiation therapy.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY

- **Colon Cancer**
  - Radiation Therapy is indicated for T4 tumors with penetration/perforation, intermediate/positive margins or for palliative care to relieve symptoms for Stage IV metastatic disease. Radiation therapy should not replace surgical resection.
    - 3D Conformal is recommended. 45-50 Gy in 25-28 fractions. Boost dose for positive margins an option.
    - IORT, if available, should be considered for very close or positive margins following resection, particularly for T4 or recurrent cancers, as an additional boost. Where IORT is not available, 10-20 Gy external beam radiation and/or brachytherapy to a limited volume can be considered soon after surgery but prior to adjuvant chemotherapy.
    - IMRT is not indicated as a standard treatment option and should be reserved for unique situations but may be utilized for re-irradiation of previously treated patients with recurrence. (Requires Physician Review)

Proton beam is not an approved treatment option for colorectal cancer.

- **Rectal Cancer**
  - Radiation therapy is considered a medically necessary for the following clinical indications: Preoperative or postoperative/adjuvant therapy or as primary therapy if tumor inoperable. Radiation therapy should not replace surgical resection
    - 3D Conformal Radiation Therapy recommended. 45 -54 Gy delivered 25 -30 fractions at 1.8 -2.0 Gy per fraction. Boost may be an option. Dosage exceeding 54 Gy may be necessary for unresectable tumors.
- IORT, if available, should be considered for very close or positive margins following resection, particularly for T4 or recurrent cancers, as an additional boost. Where IORT is not available, 10-20 Gy external beam radiation and/or brachytherapy to a limited volume can be considered soon after surgery but prior to adjuvant chemotherapy.

- IMRT is not indicated as a standard treatment option and should be reserved for unique situations but may be utilized for re-irradiation of previously treated patients with recurrence. (Requires Physician review)

- Proton beam is not an approved treatment option for colorectal cancer.

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:**

**Intensity Modulated Radiation Therapy (IMRT)**

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for colorectal cancer. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans.

- Provide tissue constraints for both the target and affected critical structures.

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for colorectal cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

**THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:**

*For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable*

**Pediatric Considerations**

Pediatric patients with cancer require special handling and the expertise of a pediatric oncologist. These patients are most often treated within a protocol defined by a specialty cancer center.

NIA will approve radiation therapy for malignant tumors in pediatric patients if:

- A tissue diagnosis has been made and the histology of the tumor is known to be radiation sensitive.
The radiation therapy planned is in accordance with an Institutional Review Board-approved protocol.

The radiation therapy planned is part of an Institutional Review Board-approved Clinical Trial.

Radiation therapy may be indicated in other instances that will be considered on a case by case basis, as follows:

- If the patient is treated outside of a protocol or clinical trial, the full treatment plan must be submitted for review.
- The treatment plan will be reviewed by a clinician and will be approved when consistent with clinical indications in NIA’s Radiation Oncology clinical guidelines and coding standards.
- Treatment plans that are inconsistent with NIA’s clinical guidelines and coding standards may still be approved by a physician reviewer based on additional information discussed in a peer-to-peer consultation that provides an appropriate clinical rationale in support of the treatment plan.
REFERENCES


INTRODUCTION:

The majority of endometrial cancers are adenocarcinomas, with uterine sarcomas accounting for <10%. This clinical guideline will focus primarily on adenocarcinoma of the endometrium.

After a diagnosis of endometrial cancer is made, it is followed by a staging evaluation to determine extent of disease (local, regional, or metastatic) and prognostic findings. For patients in whom cancers of the uterus are suspected, an endometrial biopsy is typically performed. A review of the pathology will determine whether or not the tumors are of epithelial origin (endometrioid, papillary serous, clear cell, or carcinosarcoma) or stromal/mesenchymal carcinoma (stromal sarcoma or leiomyosarcoma). The majority of endometrial cancers, however, are adenocarcinomas with tumor typically confined to the uterus. Thus, this disease is often localized with an excellent prognosis. Current workup, including a complete surgical assessment, includes a histological grade, depth of myometrial invasion, and extent of extrauterine involvement. Prognostic factors are based on a pathologic assessment and include the percent of myometrial invasion, myometrial thickness, tumor size and location (upper fundus or lower uterine cervical), cervix involvement, and lymphvascular space involvement. The majority of patients are treated surgically with radiation reserved for patients who are deemed at a high risk of recurrence or for those deemed medically inoperable.

This guideline outlines several methods suitable for the employment of radiation therapy. This includes the use of 3-dimensional conformal radiation therapy and/or internal radiation (brachytherapy). IMRT is not indicated as a standard treatment option for uterine cancer. External beam treatments are typically delivered using a high-energy linear accelerator. Brachytherapy is generally delivered using temporary HDR sources such as iodine 192. The purpose of this guideline is to outline the most efficient, comparatively effective, diagnostic and treatment pathway. Treatment is typically broken down into patients in whom disease is limited to the uterus, cervical involvement (either suspected or confirmed), or extrauterine disease.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS:

Post-operative

- Brachytherapy Only (HDR or LDR, 5 fx maximum)
  - Stage IA – with adverse risk factors
  - Stage IA – without risk factors (Grades G2, 3)
  - Stage IB
  - Stage II – (Grade G1)
- External Beam Radiation Therapy Only (2D, 3D-CRT, 45-50.4 Gy, 28 fx maximum)
  - Stage IA – with adverse risk factors (Grades G2, 3)
  - Stage IB – without adverse risk factors (Grade G3)
Stage IB – with risk factors
Stage II – (Grade G1)
Stage III
Stage IV
- External Beam (2D, 3D-CRT, 45-50 Gy, 28 fx maximum) and Brachytherapy (HDR or LDR, 5 fx maximum)
  - Stage IA – with adverse risk factors (Grades G2, 3)
  - Stage IB – without risk factors (Grade G3)
  - Stage IB – with risk factors
  - Stage II – (Grades G1, 2, 3)
  - Stage IIIA & IIIB & IIIC (Grades G1, 2, 3)

Medically Inoperable/ Pre-Operative
- Brachytherapy Only (HDR or LDR, 7 fx maximum)
  - Stage I & II
- External Beam Radiation Therapy Only (2D, 3D-CRT, 45-50 Gy, 28 fx maximum)
  - All Stages
- External Beam (2D, 3D-CRT, 45-50.4 Gy) and Brachytherapy (HDR or LDR, 4 fx maximum)
  - All Stages

Palliative
- Up to 10 fx

Unless otherwise indicated standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.

TREATMENT OPTIONS REQUIRING ADDITIONAL CLINICAL REVIEW:

Intensity Modulated Radiation Therapy (IMRT)

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for endometrial cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

Stereotactic Body Radiation Therapy (SBRT)
Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of endometrial cancer.
Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for endometrial cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:
For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.
REFERENCES


INTRODUCTION:

For patients with resectable gastric cancer, radiation therapy has been used both in the pre-operative and post-operative settings. External beam radiation therapy alone is of limited use for patients with locally unresectable gastric cancer with no evidence of improved survival. Combined chemoradiation, however, does result in improved survival, and thus combined modality treatment is typically supported. The role of IMRT (intensity modulated radiation therapy) may be appropriate in selected cases to reduce dose to normal structures, such as heart, lungs, kidneys and liver, but should be considered on a case by case basis.

The goal of these guidelines is to delineate appropriate indications of the employment of radiation therapy in the treatment of gastric cancer and to define suitable methods of delivery of radiation therapy for these indications.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY

Three-dimensional conformal radiation therapy (3D-CRT) is the considered medically necessary for the following with the following clinical indications:

- Pre-operative (Potentially Resectable) T2, T3, or T4 Any N, M0 or
- Primary Therapy (Unresectable/Medically Unfit) Any N, AnyT,M0 or
- Post-operative -Surgical Resection T2, T3, T4, Any N or Any T, N+ or Positive margins, or M1

Dosage Guidelines:
- 45-50.4 Gy up to 28 fractions

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Intensity Modulated Radiation Therapy (IMRT)

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for gastric cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. The role of intensity modulated radiation therapy, according to current National Comprehensive Cancer Network Guidelines may be appropriate in selected cases to reduce dose to normal structures, such as heart, lungs, kidneys and liver. However, uncertainties from variations in stomach filling and respiratory motion need to be taken into account.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:
• Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans.

• Provide tissue constraints for both the target and affected critical structures.

Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for gastric cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

Stereotactic Body Radiation Therapy
Stereotactic Body Radiation Therapy (SBRT) is not an approved treatment option for the treatment of gastric cancer.
REFERENCES


INTRODUCTION:

According to the American Society of Clinical Oncology, about 3% of all cancers in the United States occur in the head and neck. The majority of these tumors are squamous cell carcinoma, with human papilloma virus infection, tobacco and alcohol use regarded as risk factors. Due to the complexity of tumors arising from the head and neck region, it is not unusual for management to include an initial evaluation and development of a plan by a multidisciplinary team, including surgery, radiotherapy, medical oncology, and dental. Although single modality treatment with either surgery or radiotherapy is not uncommon with patients with early stage disease, combined modality therapy is appropriate for the majority of patients with locally or regionally advanced stage of disease. The primary sites for head and neck tumors include paranasal sinuses, the lip, oral cavity, salivary glands, oropharynx, hypopharynx, glottic larynx, supraglottic larynx, nasopharynx, and occult head and neck primary sites.

This guideline outlines several methods suitable for delivering radiation therapy to the head and neck area. Various radiotherapy techniques may be used as appropriate, depending on the stage, location, and expertise of the radiation oncologist. Multidisciplinary management is recommended to best achieve tumor control while reducing toxicity. These are generally accepted practice guidelines, however, cannot incorporate all possible clinical variations, and thus are not intended to replace good clinical judgment or individualization of treatments.

IMRT, 3D, 2D, and brachytherapy techniques may be used as appropriate, depending on the tumor location, stage of disease, and experience/availability of dosimetry/medical physics support. Intensely modulated radiation therapy (IMRT) has been shown to be useful in reducing long term side effects in oropharyngeal, paranasal sinus, and nasopharyngeal cancers by reducing dose to normal surrounding tissue, including the salivary gland and brain (including temporal lobes, auditory apparatus, and optic structures). The application of IMRT to other sites of the head and neck is evolving with the recommendation to use at the discretion of the treating physicians. IMRT can be delivered with various dose fractionation schemes, including simultaneous integrated boost, sequential boost, and concomitant accelerated boost. IMRT has been shown to be beneficial in treating certain head and neck cancers by reducing dose to the salivary glands, brain, auditory apparatus, and optic structures. Low dose or high dose brachytherapy may be appropriate in certain cases.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY:

2D, 3D, IMRT and Brachytherapy techniques may be used as appropriate, depending on the tumor location and stage of disease. Brachytherapy, where appropriate, may be utilized as a boost for 2D, 3D or IMRT courses of radiation therapy.

- Pre-operative radiation therapy
  - 2D/3D/IMRT – up to 35 fractions
- Definitive radiation therapy with or without concurrent chemotherapy
- 2D/3D/IMRT – up to 42 fractions
  - Hyperfractionation - 81.6 Gy, 1.2 Gy per fraction BID (up to 68 fractions)
- Post-operative radiation therapy (up to 40 fractions)
  - Presence of adverse factors
    - pT3 or pT4 primary tumors
    - N2-3
    - Perineural invasion
    - Vascular tumor embolism
    - Extracapsular spread
    - Positive surgical margin
- Palliative radiation therapy if symptomatic up to 20 fractions
- Re-irradiation may be indicated if no metastatic disease present up to 34 fractions

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

**Stereotactic Body Radiation Therapy (SBRT)**
Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of head and neck cancer. SBRT may be indicated for reirradiation.

**Proton Beam Radiation Therapy**
Proton beam is not a standard treatment option for head and neck cancer.
REFERENCES


Hitt R, Grau JJ, Lopez-Pousa A, et al. Final results of a randomized phase III trial comparing induction chemotherapy with cisplatin/5-FU or docetaxel/cisplatin/5-FU follow by chemoradiotherapy (CRT) versus...
http://meeting.ascopubs.org/cgi/content/abstract/27/15S/6009.


INTRODUCTION:

Due to the significant improvement in treatment for this disease, Hodgkin disease is further classified into classical Hodgkin lymphoma (that accounts for 95% of all Hodgkin cases) and lymphocyte predominant Hodgkin lymphoma. Staging for Hodgkin lymphoma is based on the Ann Arbor staging system (stage I-IV), further subdivided into “A” (no systemic symptoms presents) and “B” (weight loss of >10%, fevers, or night sweats). Unfavorable prognostic factors include bulky mediastinal disease, nodal mass >10 cm, numerous sites of disease, significantly elevated erythrocyte sedimentation rate, or B symptoms. Treatment recommendations are typically based on three subgroups of Hodgkin lymphoma: early stage favorable (stage I-II with no unfavorable factors), early stage unfavorable (stage I-II with any unfavorable factors as mentioned above), and advanced stage disease (stage III and IV). When radiation therapy is used for the treatment of Hodgkin disease, it is usually in combination with chemotherapy. If chemotherapy is used alone, radiation therapy can be used for relapse. Radiation therapy alone for definitive treatment is uncommon, except for lymphocyte predominant Hodgkin lymphoma.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS:

2D and 3D conformal radiation therapy techniques are considered medically necessary for treatment of Hodgkin’s Lymphoma

Stage I-II (nonbulky disease)
- Chemotherapy + radiation therapy (20-30 Gy) up to 20 fractions

Stage IB-IIB (nonbulky disease)
- Chemotherapy + radiation therapy (30 Gy) up to 20 fractions

Stage I-IV (bulky disease)
- Chemotherapy + radiation therapy (30-36 Gy) up to 24 fractions

Palliative
- Up to 10 fractions of external radiation may be indicated for symptom control.

When radiation therapy is used for the treatment of Hodgkin disease, it is usually in combination with chemotherapy. If chemotherapy is used alone, radiation therapy can be used for relapse.

Radiation therapy alone is uncommon (except for lymphocyte predominant Hodgkin lymphoma). If used, doses of 30-36 Gy (up to 20 fractions) is recommended for uninvolved regions, 25-30 Gy (up to 17 fractions)

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Intensity Modulated Radiation Therapy (IMRT)
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for Hodgkin’s lymphoma. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Stereotactic Body Radiation Therapy**

Stereotactic Body Radiation Therapy (SBRT) is not currently an approved treatment option for the treatment of Hodgkin’s lymphoma. Recent studies comparing SBRT conventional radiation therapy are limited. If requested, this would require peer to peer review to determine medical necessity.

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for Hodgkin’s Lymphoma. Proton beam has not been proven superior treatment to conventional radiation therapy.

**THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:**

For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.
REFERENCES


Chera BS, Rodriguez C, Morris CG, et al. Dosimetric comparison of three different involved nodal irradiation techniques for stage II Hodgkin's lymphoma patients: Conventional radiotherapy, intensity-


INTRODUCTION

Hyperthermia is a treatment for cancer in which body tissue is exposed to high temperatures. Research has shown that hyperthermia can damage and kill cancer cells in some circumstances when it is used with radiation therapy. It is not approvable when used alone or in conjunction with chemotherapy.

The FDA has approved hyperthermia in combination with radiation therapy for the “palliative management of certain solid surface and subservice malignant tumors (i.e. melanoma, squamous or basal cell tumors, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional radiation therapy”. The National Cancer Center Network recommends “that the use of hyperthermia be limited to treatment centers with appropriate training, expertise and equipment”.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR HYPERTERMIA WITH RADIATION THERAPY

- Superficially recurrent melanoma
- Chest wall recurrence of breast cancer
- Recurrent cervical lymph nodes from head and neck cancer

FREQUENCY OF PROCEDURE

A maximum of ten (10) hyperthermia treatments may be delivered two times per week at 7 hour intervals.

CONTRAINDICATIONS FOR HYPERTERMIA

- The use of intraluminal, endocavitary, interstitial, regional deep tissue hyperthermia exceeding 4 cm. in depth and whole body hyperthermia are considered investigational.
- There can not be any evidence of depth of tumor recurrence greater than 4 cm.
- There can be no evidence of metastatic disease for which systemic chemotherapy or hormonal therapy is planned or being given.

ADDITIONAL INFORMATION:

Local Hyperthermia - Heat is applied to a small area only. Local hyperthermia is typically administered every 72 hours (i.e., twice a week) for a total of 10 to 12 treatments using applicators that are placed close to, or in, the tumor. Local hyperthermia can be administered using various techniques: external, intraluminal or endocavitary, and interstitial.

- **External Hyperthermia** - This technique is used for cancers that are on, or just below, the skin. The tumor is heated externally using applicators that are placed on, or near to, the affected area. Heat is then applied using high-frequency energy waves generated from a device outside the body (such as a microwave or ultrasound).
• **Intraluminal or Endocavitary Hyperthermia** - This technique may be used to treat cancers that are within or near to body cavities. A sterile probe that can be heated is placed inside the cavity where the tumor is. This heats the affected area.

• **Interstitial Hyperthermia** - This is used to treat tumors that are deep within the body. Under anesthetic, probes or wires are placed within the tumor tissue and then heated. This method allows tumors to be heated to a higher temperature than external techniques.

**Regional Hyperthermia** - Various approaches may be used to heat large areas of tissue, such as a body cavity, organ, or limb. This includes **all** of the following:

  • **Deep Tissue** - This may be used to treat cancers within the body, such as cervical or bladder cancer. External applicators are positioned around the body cavity or organ to be treated, and microwave or radiofrequency energy is focused on the area to raise its temperature.
  
  • **Regional perfusion** - In this procedure, some of the patient’s blood is removed, heated, and then perfused back into the limb or organ.
  
  • **Continuous hyperthermic peritoneal perfusion (CHPP)** - This is a technique used to treat cancers within the peritoneal cavity. During surgery, heated chemotherapy drugs flow from a warming device through the peritoneal cavity. The peritoneal cavity temperature reaches 106–108°F.

**Whole-body hyperthermia** - used to treat metastatic cancer. This can be accomplished by several techniques that raise the body temperature to 107–108°F, including the use of thermal chambers or hot water blankets.

**Additional Terminology:**
Hyperthermia is also called thermal therapy or thermotherapy.
REFERENCES


INTRODUCTION:

Intensity-Modulated Radiation Therapy (IMRT) is a computer-based method of planning for, and delivery of, generally narrow, patient-specific, spatially and often temporally modulated beams of radiation to solid tumors within a patient. IMRT planning and delivery uses an approach for obtaining the highly conformal dose distributions needed to irradiate complex targets positioned near, or invaginated by, sensitive normal tissues, thus improving the therapeutic ratios. IMRT delivers a more precise radiation dose to the tumor while sparing the surrounding normal tissues by using non-uniform radiation beam intensities that are determined by various computer-based optimization techniques. The computer-based optimization process is referred to as “inverse planning.” Inverse planning develops a dose distribution based on the input of specific dose constraints for the Planned Treatment Volume (PTV) and nearby clinical structures and is the beginning of the IMRT treatment planning process. The Gross Tumor Volume (GTV), the PTV and surrounding normal tissues must be identified by a contouring procedure and the optimization must sample the dose with a grid spacing of 1 cm or less. Traditional “field-in-field technique,” which is neither MLC nor compensator-based, is not considered IMRT but rather external beam therapy.

The decision process for using IMRT requires an understanding of accepted practices that take into account the risks and benefits of such therapy compared to conventional treatment techniques. While IMRT technology may empirically offer advances over conventional or 3-D conformal radiation, a comprehensive understanding of all consequences is required before applying this technology. IMRT is not a replacement therapy for conventional radiation therapy methods.

This IMRT guideline applies to other cancers not listed below for programs that manage all cancer sites. Refer to applicable site-specific guidelines for the management of primary malignancies. Applicable site-specific guidelines may include all or some of the sites below, depending on the specific program.

- Anal Cancer
- Bone Metastases
- Breast Cancer
- Cervical Cancer
- CNS Cancer
- Colon Cancer
- Rectal Cancer
- Endometrial Cancer
- Gastric Cancers
- Head and Neck Cancer
- Lung - Non Small Cell
- Lung - Small Cell Lung Cancer
- Lymphoma - Hodgkin’s Lymphoma
- Lymphoma -Non Hodgkin’s Lymphoma
- Pancreas Cancer
- Prostate Cancers

For metastasis to the brain, regardless of primary site, refer to the NIA clinical guideline for Central Nervous System (CNS).

For metastasis to bone, refer to the NIA clinical guideline for Bone Metastases.

For all other metastases, refer to the NIA clinical guideline for Metastatic disease.
Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

### MEDICALLY NECESSARY INDICATIONS FOR INTENSITY-MODULATED RADIATION THERAPY (IMRT):

- Anal cancer
- Esophageal cancer
- Prostate cancer
- Trachea cancer
- Thyroid cancer
- Head and neck cancer
- CNS lesions with close proximity to the optic nerve, lens, retina, optic chiasm, cochlea or brain stem. (See NIA CNS Clinical Guidelines)
- Primary Bone and Articular Cartilage cancer of the skull and face, vertebral column, sacrum, and coccyx
- Treatment for repeat irradiation of a field that has received prior irradiation.
- Vulvar cancer
- Pediatric patients less than 21 years with a radiosensitive tumor

### CONDITIONS REQUIRING ADDITIONAL CLINICAL REVIEW

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for all other conditions including, but not limited to:

- Breast cancer
- Colon cancer
- Gastric cancer
- Gynecological cancer
- Lung cancer
- Lymphoma
- Pancreas cancer
- Pelvic bone cancer
- Primary or secondary liver cancer
- Rectal cancer
- Secondary bone and articular cartilage cancer
- Soft tissue sarcoma
- All other neoplasms not listed above as medically necessary

**IMRT may be indicated for the above conditions if ALL of the following are present:**

IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed when appropriate.
Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans. 3D-CRT techniques such as step-and-shoot or field-in-field should be considered for the comparison.
- Confirm the IMRT requested will be inversely planned (forward plans or ‘field-in-field’ plans are not considered IMRT).
- Provide tissue constraints for both the target and affected critical structures.
REFERENCES


Selvaraj RN, Beriwal S, Pourarian RJ, et al. Clinical implementation of tangential field intensity modulated radiation therapy (IMRT) using sliding window technique and dosimetric comparison with 3D


INTRODUCTION

Intraoperative Radiation Therapy (IORT) is a radiation treatment that is administered during surgery. It allows delivery of radiation directly to the target area for cancers that are difficult to remove during surgery or in situations in which there may be microscopic amounts of cancer remaining after removal. IORT delivers higher doses of radiation than can be used in conventional radiation therapy because the doctor can temporarily move nearby organs or shield them from radiation exposure.

IORT is often combined with conventional radiation therapy which is typically given prior to surgery.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR IORT:

Breast Cancer: Refer to NIA’s clinical guideline on Breast Cancer. IORT is considered investigational and not a medically necessary treatment option for the treatment of breast cancer.

Cervical Cancer: Refer to NIA’s clinical guideline on Cervical Cancer. IORT is indicated for local or regional recurrence of cervical cancer for centralized disease when previous radiation therapy has occurred (NCCN 2018).

Colon Cancer: Refer to NIA’s clinical guideline on Colorectal Cancer. IORT can be used as a boost for recurrent cancer of T4 tumors with penetration/perforation and intermediate/positive margins. IORT can also be used as a boost for recurrent cancer (ACR 2014).

Pancreatic Cancer: Refer to NIA’s clinical guideline on Pancreatic Cancer. IORT for pancreatic cancer requires review by a physician and may be reasonable for patients undergoing resection that may result in a closer involved margin (NCCN 2018).

Rectal Cancer: Refer to NIA’s clinical guideline on Colorectal Cancer. IORT is indicated for rectal cancer with positive or close margins for T4 lesions or recurrent disease (NCCN 2018).

Soft Tissue Sarcoma: IORT (with photons or electrons is considered medically necessary as boost treatment at time of surgery for cervical cancer, colorectal cancer, pancreatic cancer and soft tissue sarcomas if either of the following criteria is met (NCCN 2018):

- Tumor has a high risk of recurring; or
- Tumor cannot be completely removed (positive margins)

FREQUENCY OF PROCEDURE:

- A single fraction is allowed during surgery for the above situations.

CONTRAINDICATIONS FOR IORT
IORT is not indicated for any other cancer sites or scenarios other than those listed above, or when the above indications are not met. All other scenarios are considered investigational and not medically necessary.
REFERENCES

American College of Radiology (ACR) Appropriateness Criteria®.


Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

**INDICATIONS FOR THE TREATMENT OF METASTASIS:**

**BRAIN:** For metastasis to the brain, regardless of primary site, refer to the NIA clinical guideline for Central Nervous System (CNS).

**BONE:** For metastasis to bone, refer to the NIA clinical guideline for bone metastases.

**ALL OTHER SITES:** For metastasis to any other site other than brain or bone:
- Conventional 2D and 3D-CRT treatment delivery is appropriate for all other secondary malignancies up to ten (10) fractions.
  - Treatment beyond ten fractions for 2D-3D-CRT requires physician review and a clinical rationale for additional fractions.

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW**

- **IMRT** is not indicated for treatment of metastasis except for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed when appropriate.
  - Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:
    - Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans. 3D-CRT techniques such as step-and-shoot or field-in-field should be considered for the comparison.
    - Confirm the IMRT requested will be inversely planned (forward plans or ‘field-in-field’ plans are not considered IMRT).

- **Selective Internal Radiation Therapy (SIRT),** also known as radioembolization with microsphere brachytherapy device (RMBD) and transarterial radioembolization uses microscopic radioactive spheres to deliver radiation to the tumor site. Treatment is delivered through catheter injection of radioactive Yttrium-90 (90Y) microspheres into the hepatic artery. Indications for SIRT include:
  - unresectable metastatic liver tumors
  - unresectable metastatic liver tumors from primary colorectal cancer
  - unresectable primary hepatocellular carcinoma
  - unresectable neuroendocrine tumors
- All other treatment approaches require physician review with presentation of clinical rationale and documentation for the proposed treatment modality and plan.
REFERENCES


Neutron Beam Therapy

CPT Codes: 77422, 77423

INTRODUCTION

Neutron Beam Therapy (NBT) is a type of radiation treatment that uses a particle accelerator so is not readily available in most of the country. Protons from the accelerator create a neutron beam that attacks cancer cells with more power than conventional radiation therapy. Neutrons are much heavier than photons, thus appear to be more effective in destroying very dense tumors. With neutron beam treatment, the risk of side effects on healthy tissue near the cancer site is greater, requiring equipment to precisely focus the beam and block exposure to any surrounding tissue. Currently, both the availability and the criteria for use are very limited.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR NEUTRON BEAM THERAPY

- Neutron beam treatment is indicated for salivary gland cancers that are inoperable, recurrent, or are resected with gross residual disease or positive margins (ACS 2017).
- Other uses of Neutron Beam Therapy are considered investigational and therefore are not approved because its effectiveness for these indications has not been established.

ADDITIONAL INFORMATION:

NBT has been employed mainly for the treatment of the salivary gland cancers. It has also been used to treat other malignancies such as soft tissue sarcoma, lung, pancreatic, colon, kidney, and prostate cancers. Nevertheless, NBT has not gained wide acceptance because of the clinical difficulty in generating neutron particles and limited publications.

The safety and efficacy of neutron beam radiation therapy has not been established in the published medical literature. Complication rates were increased for NBT compared to other forms of external beam radiation therapy, and questions remain with regard to patient selection criteria, technical parameters, and comparative efficacy to other treatment modalities.
REFERENCES


INTRODUCTION:

The incidence of non-Hodgkin’s lymphomas has increased substantially over the past few decades due to age-related disease. The majority of non-Hodgkin’s lymphoma originates in B-lymphocytes (80-85%) with T-lymphocytes comprising 15-20%. Natural killer cell lymphomas are very rare. The classification of non-Hodgkin’s lymphoma is based on the cell of origin (large B, large T, or large NK), precursor or mature lymphocytes, as well as genetic, immunophenotype, and clinical features. Radiation therapy is typically delivered to the involved field either alone or in consolidation following chemotherapy. CT-based simulation and 3-dimensional planning is typically advised.

The use of intensity modulated radiation therapy, as well as stereotactic body radiotherapy would be unusual. If requested, this would require peer to peer review to determine medical necessity. For nodal sites, radiation therapy alone or consolidation following chemotherapy should treat the involved field in most cases. Regional/extended fields are typically not recommended.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS:

Three-dimensional conformal radiation therapy (3D-CRT) or two-dimensional (2D) radiation therapy (2D) is the appropriate technique for treatment of Non-Hodgkin’s Lymphomas. The following include radiation dose guidelines for the following lymphomas:

- Follicular lymphoma (24-30 Gy, or 36 Gy if bulky) up to 24 fractions (NCCN, 2018a)
- Mantle cell lymphoma (24-36 Gy) up to 24 fractions (NCCN, 2018a)
- MALT lymphoma – Marginal Zone (24-30 Gy) up to 20 fractions (NCCN, 2018a)
- Diffuse large B cell lymphoma (30-55 Gy) up to 37 fractions (NCCN, 2018a)
- Primary cutaneous anaplastic large cell lymphoma: 24-36 Gy up to 24 fractions (NCCN, 2018d)
- NK/T Lymphoma
  - primary treatment: 50-55 Gy up to 31 fractions
  - combined modality: 45-50.4 Gy up to 28 fractions
  - Localized chronic lymphocytic leukemia (CLL) and Small Lymphocytic Lymphoma (SLL): 24-30 Gy up to 17 fractions

- Palliative dose (up to 10 fractions) for symptom control

  Unless otherwise indicated, standard radiation fractionation consists of 1.5 Gy to 2.0 Gy per day. (NCCN, 2018a)

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Intensity modulated radiation therapy (IMRT)
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for non Hodgkin’s lymphoma. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity, or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Stereotactic Body Radiation Therapy**

Stereotactic Body Radiation Therapy (SBRT) is not currently an approved treatment option for the treatment of Non Hodgkin’s Lymphoma. Recent studies comparing SBRT conventional radiation therapy are limited.

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for non Hodgkin’s Lymphoma. Proton beam has not been proven superior treatment to conventional radiation therapy.

**THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:**

*For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.*
REFERENCES


INTRODUCTION:

Lung cancer is the leading cause of cancer-related deaths of both men and women in the United States. The World Health Organization divides lung cancer into two types: non-small cell lung cancer (NSCLC) as discussed in this guideline and small cell lung cancer (SCLC). The most common lung cancer, NSCLC, includes various histologies: squamous carcinoma, adenocarcinoma, and large cell carcinoma. Surgery alone has been the standard treatment for patients with resectable NSCLC for many years. However, patients with completely resected disease have disappointing survival rates. In some cases, relapse occurs at distant sites which suggest that NSCLC may be a systemic disease when diagnosed. Chemotherapy and radiation therapy are now treatment considerations in both the preoperative and postoperative settings.

Prognosis and treatment of NSCLC are based on the staging of the cancer which documents the extent of cancer growth and spread. The initial goal of staging is to determine if the tumor is surgically resectable. Some patients with resectable disease may be cured by surgery while others, due to contraindications to surgery, may be candidates for radiation therapy for curative intent or for local control.

This guideline outlines several methods suitable for the delivery of radiation therapy to treat lung cancer. These include the use of external beam radiation therapy such as: three-dimensional conformal radiation therapy (3D-CRT), endobronchial brachytherapy, postoperative radiation therapy (PORT) and stereotactic body radiation (SBRT). Endobronchial brachytherapy and SBRT are aggressive approaches justified, in part, for non-resectable tumors. While these advances in treatment offer a range of regimens, the goal of this guideline is to guide diagnosis and treatment to the most efficient, comparatively effective, diagnostic and treatment pathway. With the exception of medically inoperable tumors and extreme palliative circumstances, radiation treatment is performed, in most cases, in conjunction with surgical intervention.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY

1. Three-dimensional conformal radiation therapy (3D-CRT) is considered medically necessary for the following clinical indications:
   - Post Operative Radiation Therapy
     - Positive Nodes (N 1-3) or
     - Positive or close margins
   - Dosage Guidelines:
     - Extracapsular nodal extension or positive margins: 54-60 Gy up to 33 fractions
     - Gross Residual Tumor: 60-70 Gy up to 39 fractions
     - Negative margins: 50-54 Gy up to 30 fractions
   - Pre Operative Radiation Therapy
     - T3-4, N0-N1 or
     - Resectable Superior Sulcus Tumors or
N2 disease (Stage IIIA, T1-3, N2)

**Dosage Guidelines:**
- 45-54 Gy up to 30 fractions

- Inoperable – Definitive
  - Stage I disease (T1-2a, N0, M0)
  - Stage II and Stage III disease (T2b-T4, N0, M0 or T1-4, N1-3, M0)
  - or
  - Surgery Refused

**Dosage Guidelines:**
- 60-70 Gy up to 39 fractions

Palliative Radiation Therapy is considered medically necessary for Stage IV (M1) disease to relieve pain, airway or endobronchial obstruction, and other symptoms.

*Unless otherwise indicated standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.*

2. **Stereotactic body radiation therapy (SBRT)** is considered medically necessary for patients with inoperable Stage I or II disease or patients who refuse to have surgery.

**Dosage Guidelines:**
- Delivered at 5 fractions or less

3. **Endobronchial Brachytherapy** is considered medically necessary for the following clinical indications:
  - Patients with primary tumors who are not otherwise candidates for surgical resection or external-beam radiation therapy due to co-morbidities or location of the tumor
  - Palliative therapy for airway obstruction or severe hemoptyis in patients with primary, metastatic, or recurrent tumors.

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW**

**Intensity Modulated Radiation Therapy (IMRT)**

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for non small cell lung cancer. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D3D-CRT treatment planning and delivery will need to:

- Demonstrate how 2D-3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Proton Beam Radiation Therapy (PBT)**

Proton Beam is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for non small cell lung cancer.

**Stereotactic Body Radiation Therapy**
Stereotactic Body Radiation Therapy (SBRT) is not considered a standard form of treatment for NSCLC except for inoperable Stage I and II disease. Other requests for SBRT will require a peer review to make a medical necessity determination. Documentation from the radiation oncologist must include the clinical rationale for performing SBRT rather than 3-D conformal treatment.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

*For Proton Beam Radiation refer to Local Coverage Determination (LCD), if applicable.*
REFERENCES


I INTRODUCTION:

Radiation therapy may have appropriate use in several non-malignant conditions. The treatment goal in patients with non-malignant conditions is to achieve relief of the indicated condition with radiation therapy with minimal risk of radiation exposure to sensitive structures.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY

2 D or 3D Conformal (3D CRT) is considered medically necessary for several non-malignant conditions including but not limited to:
- Prevention of keloid scars as an adjunctive therapy following excisional surgery
- Heterotopic ossification
- Pterygium in cases that cannot be medically managed
- Villonodular synovitis

Stereotactic Radiation Therapy (SRS, SBRT) is considered medically necessary when used in the treatment of non-malignant cranial lesions including the following:
- Arteriovenous malformation (AVM) of the brain or spine.
- Trigeminal neuralgia that has not responded to other, more conservative, treatments.
- Non cancerous brain tumors such as acoustic neuroma, benign schwannomas, meningioma, hemangioma, pituitary adenoma, craniopharyngioma, neoplasm of the pineal gland, and chordomas

Also refer to NIA Stereotactic Radiation Therapy Guideline.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Treatment for other non-malignant conditions utilizing proton beam, stereotactic radiation therapy (SBRT), or intensity modulated radiation therapy (IMRT) modalities should be referred to physician review.
REFERENCES


INTRODUCTION:

Pancreatic cancer typically occurs later in life. Risk factors include smoking, alcohol use, obesity, diabetes, and certain chemical exposures. Pancreatitis has also been shown to have an increased risk of developing pancreatic cancer. Surgical resection is potentially the only curative approach, but most patients present with more advanced stage disease. Overall, the actuarial five-year survival rate is approximately 20%.

The goal of these guidelines is to delineate appropriate indications of the employment of radiation therapy in the treatment of pancreatic cancer and to define suitable methods of delivery of radiation therapy for these indications.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY:

2D and 3D conformal radiation therapy techniques are considered medically necessary for treatment of pancreatic cancer.

Neoadjuvant (Pre-Operative) or Resectable or Borderline Resectable without evidence of metastatic
- No standard treatment regimen currently exists for this subset of patients. If neoadjuvant radiation therapy is delivered, a dose of 45-54 Gy in 1.8-2.5 Gy fractions or 36 Gy in 2.4 fractions are viable options.

Adjuvant (Post-Operative) Resectable Without Evidence of Metastatic Disease
- For resected cases (45-46 Gy in 1.8-2 Gy fractions) to the clinical target volume, followed by boost (5-9Gy). Up to 31 fractions.

Unresectable/Locally Advanced Without Evidence of Metastatic Disease
- Radiation delivered in 45-54 Gy (1.8-2.5 Gy fractions or 36 Gy in 2.4 fractions). Up to 30 fractions.

Palliative
- Radiation delivered in 25-36 Gy in 2.4-5.0 Gy fractions is usual for patients with metastatic disease who require palliation for obstruction or pain. Up to 15 fractions.

Local Recurrence after Resection without Evidence of Systemic Metastatic Disease
- Adjuvant chemotherapy or chemoradiation if no previous radiation given. Up to 30 fractions. (NCCN, 2018)

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Intensity Modulated Radiation Therapy (IMRT)
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for pancreatic cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy
is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient specific dose volume histograms and isodose plans.

- Provide tissue constraints for both the target and affected critical structures.

**Stereotactic Body Radiation Therapy (SBRT)**
Stereotactic Body Radiation Therapy (SBRT) is not currently an approved treatment option for the treatment of pancreatic cancer. Recent studies comparing SBRT conventional radiation therapy are limited. If requested, this would require peer to peer review to determine medical necessity.

**Proton Beam Radiation Therapy**
Proton beam is not an approved treatment option for pancreatic cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.

**Intra Operative Radiation Therapy (IORT)**
The role of interoperative radiation therapy for pancreatic cancer is controversial, but may be reasonable for patients undergoing resection that may result in closer involved margins. IORT may be considered on a case by case basis.
REFERENCES


Le Scodan R, Mornex F, Girard N, et al. Preoperative chemoradiation in potentially resectable pancreatic adenocarcinoma: Feasibility, treatment effect evaluation and prognostic factors, analysis of the SFRO-


INTRODUCTION:

Prostate cancer is diagnosed by biopsy and evaluated (staged) to determine extent of disease (local, regional, or distant metastatic). Both surgery and radiation therapy is used to treat prostate cancers that are organ-confined or extend into tissues adjacent to the prostate. Daily prostate localization can be accomplished with imaging modalities, e.g., ultrasound images, computed tomography (CT) images, or implanted fiducial markers, incorporated into an image guided radiation therapy (IGRT) system.

Patients with very low risk disease should be considered for active surveillance if their life expectancy is less than or equal to 20 years. Active surveillance is as well, recommended for patients with favorable intermediate-risk prostate cancer. Observation is the preferred action for men with low-risk prostate cancer with a life expectancy of less than 10 years. Patients with intermediate risk disease may be considered for short course (4-6 months) of neoadjuvant/concomitant/adjuvant ADT. Patients with high risk disease may be considered for pelvic lymph node irradiation and 2-3 years of neoadjuvant/adjuvant ADT.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS (NCCN, 2018):

Very Low Recurrence Risk (Primary Tumor Stage [T] is T1c, PSA <10 ng/ml, and Gleason score ≤ 6, PSA density <0.15ng/ml per g, < 3biopsy cores positive with ≤ 50% cancer in each)

- Active surveillance (discussed with patient as treatment option)
- External Beam Radiation Therapy - Various fractionation and dose regimes can be considered depending on clinical scenarios
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) – with IGRT (up to 45 fractions)
- LDR (low dose-rate) or HDR (high dose-rate) Brachytherapy

Low Recurrence Risk (Primary Tumor Stage [T] is T1-T2a, PSA <10 ng/ml, and Gleason score ≤ 6)

- Active surveillance (discussed with patient as treatment option)
- External Beam Radiation Therapy - Various fractionation and dose regimes can be considered depending on clinical scenarios
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) –with IGRT (up to 45 fractions)
  - SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and not as a boost to other conventional methods of radiation treatment.
- LDR (low dose-rate) or HDR (high dose-rate) Brachytherapy

Intermediate Recurrence Risk (Primary Tumor Stage [T] T2b-T2c or PSA 10-20 ng/ml or Gleason score 7)

- External Beam Radiation Therapy - Various fractionation and dose regimes can be considered depending on clinical scenarios
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) with IGRT – (up to 45 fractions)
SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and NOT as a boost to other conventional methods of radiation treatment.

- Brachytherapy (LDR/HDR) boost combined with EBRT after 40–50 Gy

**High Recurrence Risk (Primary Tumor Stage [T] T3a or PSA >20 ng/ml or Gleason score 8–10, or two or more intermediate risk factors)**

- External Beam Radiation Therapy - *Various fractionation and dose regimes can be considered depending on clinical scenarios*
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) – with IGRT (up to 45 fractions)
- Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy

**Very High Recurrence Risk (Primary Tumor Stage [T] T3b–T4) with Gleason score 8-10 without Metastasis**

- External Beam Radiation Therapy - *Various fractionation and dose regimes can be considered depending on clinical scenarios*
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) – with IGRT (up to 45 fractions)
- Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy

**Radiation Therapy for Patients with Locally Advanced or Metastatic Prostate (T3b – T4, or any T and N1, M0 disease)**

- External Beam Radiation Therapy - *Various fractionation and dose regimes can be considered depending on clinical scenarios*
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) – with IGRT (up to 45 fractions)
- Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy

**Post-Prostatectomy**

- One of the following must be met:
  - Detectable PSA or initially undetectable PSA, but with recent detectable and rising values on 2 or more measurements with no evidence of metastatic disease
  - Positive margins
  - Seminal vesicle invasion
  - Gleason 8-10
  - Pathological T3 disease
- External Beam Radiation Therapy
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) Doses 64 – 72 Gy (up to 40 fractions) with IGRT

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:**

The radiation treatment options below require review by a physician reviewer and may include deliberation on whether or not active surveillance and surgery have been considered prior to the decision to request radiation therapy:

- Brachytherapy alone (monotherapy) may be approved for Intermediate Recurrence Risk (Primary Tumor Stage [T] T2b-T2c or PSA 10-20 ng/ml or Gleason score 7) upon review with a physician reviewer. Brachytherapy alone is not considered appropriate if the patient has unfavorable or poor prognostic risk factors intermediate risk factors and is thus higher risk.
• Proton beam is not an approved treatment option for localized prostate cancer. Studies comparing proton beam therapy alone to 3-D conformal radiation or IMRT are limited. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.
REFERENCES


CPT codes: 77520,77522,77523,77525

INTRODUCTION:

Proton beam therapy (PBT) is a type of external beam radiotherapy that uses charged particles. These particles have unique characteristics including limited lateral slide, scatter, and tissue in a defined range, going for maximum dose delivery over the last few millimeters of the particles’ range. The maximum is called the Bragg peak. Proton beam irradiation when applied to treating cancer, uses different proton energy with Bragg peaks at various steps, enabling dose escalation to the tumor, minimizing excess dose to normal surrounding tissue. Over the years, proton beam irradiation has been applied to treating tumors that require dose escalation to achieve a higher probability of care, as well as tumors requiring increased precision in dose deposition while protecting normal surrounding tissue. Proton therapy has an over 40-year history in treating cancer, yet to date, there have been few studies that show superiority to conventional photon beam irradiation, especially with modern techniques.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

MEDICALLY NECESSARY INDICATIONS FOR PROTON BEAM THERAPY:

Treatment of the following in children less than 21 years of age):

- Primary or benign solid tumors (curative intent; occasional palliative treatment) when sparing of surrounding normal tissues cannot be achieved with photon therapy

Treatment at any age (ASTRO 2017):

- Primary hepatocellular tumors treated with hypofractionated regimens
- Spinal tumors (primary or metastatic) where spinal cord has previously been treated with radiation or where the spinal cord tolerance may be exceeded with conventional treatment
- Tumors at the base of skull (chordoma, chondrosarcomas)
- Intraocular melanomas or other ocular tumors
- Patients with genetic syndromes making total volume of radiation minimization crucial, such as, but not limited to NF-1 patients and retinoblastoma patients
- Non-metastatic retroperitoneal sarcomas
- Re-irradiation cases (where cumulative critical structure dose would exceed tolerance dose)

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

For peer review purposes supporting documentation from the radiation oncologist is required and should include the clinical rationale for performing proton beam rather than 3-D conformal or IMRT or SRS

Proton beam therapy has not been proven to be superior to conventional radiation therapy for all other indications including, but not limited to:

- Prostate cancer
- Breast cancer
• Lung cancer
• Colorectal cancer
• Cervical cancer
• Metastasis
• Gliomas
• Soft tissue sarcoma
• Head and Neck
• Pelvic
• Gastric
REFERENCES


Flynn K. Brief overview: Reviews of proton beam therapy for cancer. Boston, MA: Veterans Health Administration Technology Assessment Program (VATAP); August 2007.


INTRODUCTION:

There are three main types of skin cancer:

- Basal cell carcinoma (BCC).
- Squamous cell carcinoma (SCC).
- Melanoma.

BCC and SCC are the most common forms of skin cancer and are collectively referred to as nonmelanoma skin cancers. Nonmelanoma skin cancer is the most commonly occurring cancer in the United States. BCC is the more common type of the two nonmelanoma types, accounting for about three-quarters of nonmelanoma skin cancers. The incidence of nonmelanoma skin cancer appears to be increasing in some areas of the United States. Incidence rates in the United States have likely been increasing for a number of years and at least some of this increase may be attributable to increasing skin cancer awareness and resulting increasing investigation and biopsy of skin lesions.

Melanoma is a malignant tumor of melanocytes, which are the cells that make the pigment melanin and are derived from the neural crest. Melanomas may arise from mucosal surfaces or at other sites to which neural crest cells migrate, including the uveal tract, although most melanomas arise in the skin.

Skin cancer is the most common malignancy diagnosed in the United States, with 3.5 million cancers diagnosed in 2 million people annually and the incidence increasing over the past four decades. Melanoma represents less than 5% of skin cancers but results in most deaths. Elderly men are at highest risk; however, melanoma is the most common cancer in young adults aged 25 to 29 years and the second most common cancer in those aged 15 to 29 years.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY:

**Basal & Squamous Cell Skin Cancer:**

2D or 3D-CRT EBRT (electron/ photon) are appropriate techniques for treatment of basal squamous cell skin cancer for any of the following: definitive treatment for non surgical candidates, cancer surgery would be disfiguring, further resection needed post operative or adjuvant therapy for cancers at risk for recurrence. Fractionation and treatment schedules range from single fraction to 33 fractions. Longer fractionation is associated with improved cosmetic results.

**Dosage and Schedule Guidelines**

- 30-70 Gy to up to 38 fractions (NCCN, 2018a) (NCCN, 2018c)

**Melanoma**
2D or 3D-CRT EBRT (electron/ photon) are appropriate techniques for treatment of Melanoma skin cancer for any of the following: adjuvant treatment after resection of primary site, regional disease following resection of nodes, local recurrent disease or palliative treatment

A wide range of dosage / fractionation schedules is effective up to 38 fractions (NCCN, 2018b)

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Brachytherapy

LDR, HDR, surface or interstitial brachytherapy may be considered where excision or EBRT is contraindicated. Electronic brachytherapy is considered experimental and investigational at this time.

Intensity modulated radiation therapy (IMRT)

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for skin cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans. 3D-CRT techniques such as step-and-shoot or field-in-field should be considered for the comparison.

- Confirm the IMRT requested will be inversely planned (forward plans or 'field-in-field' plans are not considered IMRT).

- Provide tissue constraints for both the target and affected critical structures.

Proton Beam Radiation Therapy

Proton beam is not an approved treatment option for skin cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.

Stereotactic Body Radiation Therapy (SBRT)

Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of skin cancer. A peer review is required with a radiation oncologist.
REFERENCES


INTRODUCTION:

The two major types of lung cancer are small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). SCLC differs significantly from NSCLC in that most patients with SCLC present with subclinical metastatic disease. Patients with SCLC are divided into those with limited- versus extensive-stage disease. Although limited-stage disease is confined to the ipsilateral hemithorax, a third of these patients have subclinical systemic disease. Extensive-stage disease is defined as disease extending beyond the ipsilateral hemithorax, including positive pleural/pericardial effusion or distant metastases. Systemic chemotherapy is an essential component of appropriate treatment for all SCLC patients, even those with limited-stage disease.

This guideline outlines methods suitable for the delivery of radiation therapy to treat SCLC. Radiation therapy may be delivered using conventional, accelerated fractionation, hyperfractionated regimens and prophylactic cranial irradiation. Three-dimensional conformal radiation therapy (3D-CRT) is the preferred technique. If image guided radiation therapy is utilized, techniques to account for respiratory motion should be performed. The goal of this guideline is to guide diagnosis and treatment to the most efficient, comparatively effective, diagnostic and treatment pathway.

SCLC is highly sensitive to initial chemotherapy and radiation therapy; however, a cure is difficult to achieve because SCLC generally has a rapid doubling time, a high growth fraction, and early development of widespread metastases.

The treatment goal in patients with limited-stage disease is to achieve a cure with chemotherapy combined with thoracic radiation therapy. In patients with extensive-stage disease, this combined modality treatment does not improve survival compared with chemotherapy alone, but radiation therapy plays a role in palliation of symptoms. All patients with SCLC require systemic chemotherapy and where radiation therapy is utilized, it should be delivered concurrently with chemotherapy. Patients with both limited- and extensive-stage disease may benefit from prophylactic cranial irradiation (PCI), decreasing the incidence of central nervous system metastases and prolonging survival. Two-dimensional, post lateral fields should be used in PCI treatment.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY

**Limited-Stage SCLC (T1-2, N1-N3 M0)**

2D or 3D Conformal Radiation Therapy (3DCRT)

- **Dosage Guidelines:**
  - Up to 39 fractions is medically necessary

**Extensive-Stage SCLC (T any, N any, M1a/b; T3-4)**

2D or 3D Conformal Radiation Therapy (3DCRT) Radiation therapy to treat symptomatic sites or treatment of cord compression
Dosage Guidelines:
- Up to 39 fractions is medically necessary

Prophylactic cranial irradiation (PCI) is indicated for Limited and Extensive SCLC. PCI is used to decrease the incidence of central nervous system metastases and prolong survival.
- 2D or 3D Conformal Radiation Therapy (3DCRT)

Dosage Guidelines
- 5 - 15 fractions is medically necessary

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Intensity Modulated Radiation Therapy (IMRT)
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for small cell lung cancer. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:
- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for small cell lung cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

Stereotactic Body Radiation Therapy (SBRT)
Stereotactic Body Radiation Therapy (SBRT) is not considered a standard form of treatment for SCLC cancer. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy. A request for SBRT will require a peer review to make a medical necessity determination.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

For Proton Beam Radiation Therapy refer to Local Coverage Determination (LCD), if applicable.
REFERENCES


INTRODUCTION:

Stereotactic radiation therapy (SRT) is a method of delivering precise high doses of radiation to small targets, while minimizing radiation-related injury in adjacent normal tissues. SRT delivers high doses of radiation in a very short time frame as, between 1 and 5 fractions. There are two types of stereotactic radiation therapy, SRS and SBRT.

Stereotactic radiosurgery (SRS) refers to treatment of any intracranial site consisting of 1 fraction only. Stereotactic body radiotherapy (SBRT) refers to use at any extracranial site or any intracranial site consisting of 2-5 fractions.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR STEREOTACTIC RADIATION THERAPY:

- Arteriovenous malformation (AVM) of the brain or spine.

- Initial or recurrent primary brain tumor (e.g. acoustic neuroma, meningioma, hemangioma, pituitary adenoma, craniopharyngioma, low grade glioma, neoplasm of the pineal gland, glioblastoma multiforme, low-grade astrocytoma etc.).

- Initial or recurrent brain metastases for patient who have good performance status (ECOG less than 3 or Karnofsky status 40 or greater with expected return to 70 or greater with treatment) and controlled systemic disease (e.g. newly diagnosed, stable systemic disease or reasonable treatment options.) Refer to the clinical guideline on Central Nervous System (CNS) metastasis.

- Non-operable spinal tumor (primary, recurrent or metastatic) that is causing compression or intractable pain.

- Trigeminal neuralgia that has not responded to other, more conservative, treatments.

- Non-Small Cell Lung Cancer and all of the following:
  a) Stage I disease; and
  The lesion cannot be removed surgically either because the tumor location makes removal difficult, the member is not a surgical candidate, or if the patient refuses surgery.

ADDITIONAL CLINICAL REVIEW REQUIRED:

Stereotactic Radiation Therapy (SRS/SBRT) has not been proven to be superior to conventional therapy and is not a standard treatment option for the treatment of the following conditions:

- Other non-central nervous system cancers unless noted above
- Lung (unless above criteria is met)
- Other cancers including but not limited, breast, colon, liver and pancreas
- Parkinson’s disease and other movement disorders (e.g. tremors)
- Epilepsy
- Chronic pain syndromes
- Treatment of functional disorders other than trigeminal neuralgia
REFERENCES


CPT Codes: 76536

INTRODUCTION:

The thyroid, parathyroid and lymph nodes are the most commonly imaged areas of the head and neck region and ultrasound is the most appropriated imaging modality. Ultrasound may also be utilized to evaluate the salivary glands, abscesses, benign and malignant masses outside the thyroid, and congenital lesions. Along with imaging, minimally invasive procedures are performed on thyroid nodules, as well as, non-thyroid abnormalities.

NIA does not review neonatal cranial ultrasounds (Echoencephalogram).

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

APPROPRIATE INDICATIONS FOR A HEAD OR NECK ULTRASOUND

Thyroid Gland:

- To assist in diagnosing thyroid autoimmune disease when the patient has a large goiter or lumpy thyroid (Choosing Wisely/Endocrine Society, 2017).
- Thyroid nodules identified via palpation or prior imaging (CT, MRI or non-thyroid US), approve for (Choosing Wisely/ACR, 2017)**:
  - High risk patients.
  - With suspicious prior imaging feature.
  - Normal risk patients when.
    - (1) < 35 years of age with normal life expectancy and nodule ≥ 1 cm.
    - (2) ≥ 35 years of age with normal life expectancy and nodule ≥ 1.5 cm.
- Follow up of thyroid nodules(s) (Durante, 2015; Gharib, 2015; Haugen/ATA, 2015; Nou, 2014)***:
  - After prior negative biopsy to confirm stability in nodule size.
  - When active surveillance of known tumor or nodule is selected (e.g. patient initially refuses biopsy, low risk tumor, high surgical risk).
- Past history of radiation in the cervical region in adult survivors of childhood cancer (Initial US 5 years after radiation, then every three years) (Briqnardello, 2016)
- Staging tumors of the thyroid (preoperative evaluation of cervical lymph nodes prior to thyroidectomy) (Haugen/ATA, 2015).
- Monitoring the thyroid bed and cervical nodal compartments after thyroidectomy (Haugen/ATA, 2015).

Parathyroid Gland:

- To localize adenomas in preparation for surgery (Gurney, 2008; Levy, 2011; Patel, 2010) (combined ultrasound and Technetium 99m sestamibi scintigraphy can be performed to increase sensitivity and accuracy of preoperative localization).
Salivary Gland:
- To localize and identify lesions within the submandibular salivary gland or superficial lobes of the parotid (Rudack, 2007).
- To help determine benign vs. malignant tumors (Alyas, 2005; Rudack, 2007).
- First line evaluation of sialolithiasis (Terraz, 2013).
- For suspected abscess (Alyas, 2005).
- Early diagnosis and staging of primary Sjogren’s syndrome (Alyas, 2005; Baldini, 2015).

Cervical Lymph Nodes (Ahuja, 2008; Chandak, 2011; Hwang, 2011):
- To identify the size and complexity of palpable cervical lymph nodes.
- To differentiate benign vs. malignant nodes, although additional cytology may be needed to identify histological origin.

Other Indication/mass:
- Follow up of an abnormality or mass seen on prior imaging or detected on physical exam (e.g. congenital masses such as cystic hygroma, branchial cleft cysts; carotid body or nerve sheath tumors, large head and neck primary or metastatic tumors).
- Initial or follow up evaluation of superficial abscess (CT more sensitive and specific for deep abscess) (Kalmovich, 2012).

ADDITIONAL INFORMATION RELATED TO HEAD AND NECK ULTRASOUND

Thyroid Gland

Thyroid nodules are common in the general population with a 3 – 7% prevalence on inspection and palpation. By ultrasound, nodules can be detected in 20% to as many as 76% of the population. Furthermore, screening and autopsy studies indicate that asymptomatic papillary microcarcinomas (PMCs) are present in at least 5–10% of the U.S. adult population (Brito, 2016). Ultrasound (US) of the thyroid gland is indicated to decipher between a benign versus malignant nodule present in or around the gland, and monitor disease progression or response to treatment. In addition to sonographic appearance, nodule location is associated with malignancy risk. Nodules in the superior pole have a four-fold higher risk of cancer than nodules in other regions (Zhang, 2018).

**According to the ACR/Choosing Wisely** **Clinical risk factors**: Patients with history of head, neck or chest radiation, family history of thyroid cancer, or diseases that increase the risk of thyroid cancer should be further evaluated regardless of nodule size. Suspicious [nodule] features on CT, MRI or US include signs of local invasion, and the presence of abnormal lymph nodes (enlarged nodes, nodes with cystic change, calcification, or increased enhancement). Size criteria for enlarged lymph nodes:
1. ≥1.5 cm in short axis for jugulodigastric nodes
2. ≥1 cm for other nodes”

“Thyrotoxic patients with nodules may also benefit from imaging. For these patients, a thyroid scan, not an ultrasound, can be used to assess the possibility of focal autonomy in a thyroid nodule” (Choosing Wisely/Endocrine Society, 2017).

According to the Endocrine Society, thyroid ultrasound in patients with abnormal thyroid function tests and no palpable abnormality of the thyroid gland should not be performed unless “the patient also has a large goiter or a lumpy thyroid” (Choosing Wisely/Endocrine Society, 2017).
***Thyroid Nodule Follow Up:*** Follow up of nodules after negative/ benign FNA results is recommended. Experts differ on the recommended follow up intervals (Durante, 2015, Gharib, 2016; Haugen/ATA, 2015; Nou, 2014). Some authors recommend repeat follow-up at 2-4 years because malignancies initially showing a negative cytology can be adequately treated at a mean 4.5 years after the initial false negative cytology (Nou, 2014). The American Thyroid Association recommended follow up intervals are based on the sonographic appearance (Haugen, 2015). Nodules with highly suspicious ultrasound pattern should be followed within 12 months. Those with low to intermediate ultrasound appearance are followed at 12-24 months. Nodules with very low suspicion sonographic features should be followed at >/= 24 months. If a nodule has a repeat (second) benign FNA, surveillance is no longer needed.

Follow up US may be undertaken without prior biopsy or for known tumors. This includes patients who initially refuse biopsy, or for nodules detected on US that do not meet criteria for FNA (e.g. small size) or when there is known malignancy and “very low-risk tumors (e.g., no clinical or radiographic evidence of invasion or metastases), patients at high surgical risk, or those with a relatively short life span expectancy in whom the benefits of intervention may be unrealized.”(Haugen, 2015). Surveillance intervals for known low risk cancers usually involves US every 6 months over the first two years then every 1-2 years thereafter. Nodules without prior negative FNA that have a suspicious US appearance should have repeat US in 6-12 months.

**Parathyroid Gland**

When hyperparathyroidism is identified clinically, US of the parathyroid gland is used to localize adenomas in preparation for surgery. US appears to be the test of choice for this preoperative procedure, due in part to the fact that US is relatively inexpensive and does not emit radiating ions, but also because there is fair evidence that US is as effective at locating the lesion as the other standard imaging technique, nuclear scintigraphy. “Crucial considerations when selecting an imaging study include availability, cost, radiation exposure, local expertise, and accuracy” (Kunstman, 2013). In a series of 29 patients undergoing preoperative localization of parathyroid adenomas, ultrasound identified the side of the adenoma in 90% of the cases versus 71% by scintigraphy (Gurney, 2008). In a study of 440, Levy et al found sensitivities for correct localization of a single parathyroid adenoma for sestamibi versus ultrasound were: 83% versus 72%. Patel, et al found the combined use of preoperative ultrasound and Technetium-99m sestamibi scintigraphy was superior to ultrasound or scintigraphy alone and had a sensitivity of 95% and accuracy of 91%.

**Salivary Glands**

Uses of US in imaging of the salivary glands are similar to those of the thyroid and parathyroid glands: to identify and/or localize masses or lesions and to assess for pathology. Because of the anatomical location of the salivary glands, only the most superficial regions can be visualized by US, namely the submandibular gland, the sublingual gland, and the superficial lobes of the parotid gland. The deep lobe of the parotid, as well as the minor salivary glands, is unable to be visualized by US. For these regions, MRI or CT is recommended as first line diagnostic modalities. In a study of 109 patients with tumor like lesions of the salivary glands Rudack, et al found that neither MRI, CT nor US is superior to diagnose tumors in the salivary glands. Therefore these modalities can be used in combination.

Ultrasound is often used as a first line examination for evaluation of salivary calculi. The technique however does not allow the reliable exclusion of small calculi (<3mm) and therefore other techniques for assessment may be utilized (Terraz, 2013).

US is also used to diagnose and stage Sjogren’s disease (Alyas, 2005; Baldini, 2015).
Masses of unknown origin
In diagnosing head and neck masses or swellings of unknown origin, US can assist in making the initial diagnosis.
REFERENCES


Zhang F. Thyroid nodule location on ultrasonography a predictor of malignancy (poster 1204). Presented at the AACE 2018, the 27th American Association of Clinical Endocrinologists Annual Scientific and Clinical Congress. May 17-20, 2018 in Boston, Massachusetts.
CPT Codes: 76700, 76705, 76770, 76775

INTRODUCTION:

An abdominal ultrasound uses reflected sound waves to produce a picture of the organs and other structures in the upper abdomen. Sometimes a specialized ultrasound is ordered for a detailed evaluation of a specific organ or section of the abdomen (e.g., upper quadrant, retroperitoneal), or as a complete study. An abdominal ultrasound can evaluate the: abdominal aorta, the gallbladder, the liver, the spleen, the pancreas, the kidneys and the spine.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR AN ABDOMEN ULTRASOUND:

Suspected appendicitis (Gale, 2016; Toorenvliet, 2010; Poortman, 2009; Smith, 2013):
- Suspected acute appendicitis if abdominal pain and tenderness to palpation is present, and at LEAST one of the following:
  - Fever
  - Elevated WBC
  - Nausea and/or vomiting
  - Anorexia
  - Guarding and/or rebound

Mass Lesions (Yaghmai, 2014):
- To determine if a lesion identified on other imaging is cystic, solid or vascular
- Abdominal mass of undetermined etiology found on physical examination.
- Follow-up of diagnosed masses under surveillance or treatment at intervals ≥ 6 months.
- To evaluate for liver metastases with elevated liver function tests and known primary tumor

Gallbladder Disease (Kiewiet, 2012; Smith, 2009; Hanbidge, 2004; Yarmish, 2013):
- Right upper quadrant or epigastric pain suggestive of gallbladder disease including at least one of the following:
  - Fever
  - Nausea, vomiting, and/or anorexia
  - Elevated WBC
  - Murphy's sign
  - Jaundice
  - History of biliary surgery
  - Known cholelithiasis

Hepatic Disease (Aghoram, 2012; Chalasani, 2012; Rotman, 2009):
- Suspected Ascites
- Suspected inflammatory or infectious process involving the liver
- Follow-up of infectious lesion(s) or fluid collections in the liver to assess resolution
• Assess liver in systemic disease involving the liver, e.g., hemachromatosis
• Assess patient with inflammatory conditions at high risk for hepatocellular carcinoma, e.g., hereditary hemochromatosis, hepatitis C, etc.
• New onset of jaundice in patient without pain.
• Evaluate for liver lesions in nonalcoholic fatty liver disease

Renal Disease:

Hematuria (Greater than 3 RBC per high-power field on urinalysis) (Davis, 2016; Sharp, 2013; Smith-Bindman, 2014):
• Hematuria (non-infectious)
• Hematuria (infectious) persisting (6) six weeks after the completion of antibiotic therapy
• Known or suspected kidney stones
• Flank pain

Acute Pyelonephritis (Colgan, 2011; Grabe, 2011; Nikolaidis, 2018)
• Failure to respond to antibiotics
• Signs of obstruction
• Suspected renal or perinephric abscess
• Immunocompromised patient
• History of renal stones
• Prior renal surgery

Renal Insufficiency and Renal Failure (Remer, 2014):
• Acute kidney injury
• Progressive kidney disease or sudden change in kidney function
• eGFR (estimated glomerular filtration rate) decline >5 ml/min/1.73 m2 within one year or >10 ml/min/1.73 m2 within 5 years
• Renal insufficiency with symptoms of urinary tract obstruction

Family History of Polycystic Kidney Disease (Srivastava, 2014; Pei, 2010):
• Screening ultrasound after age 18

Kidney Transplant (Kolofousi, 2013; Granata, 2015):
• Increase in the serum creatinine levels
• Acute signs, symptoms of inflammatory process or infection in transplanted organ.
• Pretransplantation
• Post operative/procedural

Pancreatic Disease (Tenner, 2013; Barry, 2018; Quinlan, 2014):
• Suspected acute or chronic pancreatitis
• Suspected pancreatic necrosis
• Suspected pancreatic abscess
• Suspected pancreatic pseudocysts

Splenectomy (Benter, 2011; Kaza, 2010):

Splenomegaly:
• For the measurement of spleen size to confirm splenomegaly or/and to document changes in spleen volume in patients with:
  o A known disease/condition that causes splenomegaly (e.g., myeloproliferative diseases, storage diseases, inflammatory diseases, infections, portal hypertension) OR
  o Palpable spleen OR
  o Pain on the upper left side of the abdomen

Other Splenic Disease:
• Suspected splenic infarction.
• Splenic and renal echogenicity comparison when examining left native or transplanted kidney.

Other Indications for Abdominal Ultrasound:
• Follow up of an abnormality seen on prior imaging.
• Evaluation of abdominal trauma
• Evaluation of unexplained abdominal pain after appropriate examination, laboratory tests, and trial of medical therapy
• Evaluation of unexplained weight loss

Pre-operative/procedural evaluation.
• Pre-operative evaluation for a planned surgery or procedure.

Post-operative/procedural evaluation:
• When imaging, physical, or laboratory findings indicate surgical or procedural complications.

Screening for Abdominal Aortic Aneurysm (USPSTF, 2014):
• One-time screening for abdominal aortic aneurysm (AAA) in men ages 65 to 75 years.
• One-time screening for abdominal aortic aneurysm (AAA) in women ages 65 to 75 years who have ever smoked.

Non-screening studies for Abdominal Aortic Aneurysm (Mohler, 2012):

<table>
<thead>
<tr>
<th>ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 Appropriate Use Criteria</th>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCF et al. Criteria #</td>
<td>A _ appropriate; I _ inappropriate; U _ uncertain</td>
<td></td>
</tr>
<tr>
<td>Aortic and Aortoiliac Duplex</td>
<td>Abdominal Aortic Disease - Signs and/or Symptoms</td>
<td></td>
</tr>
<tr>
<td>59.</td>
<td>• Lower extremity claudication</td>
<td>A (7)</td>
</tr>
<tr>
<td>60.</td>
<td>• Nonspecific lower extremity discomfort</td>
<td>I (3)</td>
</tr>
<tr>
<td>61.</td>
<td>• New onset abdominal or back pain</td>
<td>U (6)</td>
</tr>
<tr>
<td>62.</td>
<td>• Aneurysmal femoral or popliteal pulse</td>
<td>A (8)</td>
</tr>
<tr>
<td>63.</td>
<td>• Pulsatile abdominal mass</td>
<td>A (9)</td>
</tr>
<tr>
<td>64.</td>
<td>• Decreased or absent femoral pulse</td>
<td>A (7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>---</td>
</tr>
<tr>
<td>65.</td>
<td>Abdominal or femoral bruit</td>
<td>A (7)</td>
</tr>
<tr>
<td>66.</td>
<td>Fever of unknown origin</td>
<td>I (3)</td>
</tr>
<tr>
<td>67.</td>
<td>Lower extremity swelling</td>
<td>I (2)</td>
</tr>
<tr>
<td>68.</td>
<td>Evidence of atheroemboli in the lower extremities, including ischemic toes</td>
<td>A (8)</td>
</tr>
<tr>
<td>69.</td>
<td>Erectile dysfunction</td>
<td>U (4)</td>
</tr>
<tr>
<td>70.</td>
<td>Abnormal physiologic testing indicating aortoiliac occlusive disease</td>
<td>A (8)</td>
</tr>
<tr>
<td>71.</td>
<td>Hypertension</td>
<td>I (3)</td>
</tr>
<tr>
<td>72.</td>
<td>Abnormal abdominal x-ray suggestive of aneurysm</td>
<td>A (8)</td>
</tr>
<tr>
<td>73.</td>
<td>Presence of a lower extremity arterial aneurysm (e.g., femoral or popliteal)</td>
<td>A (8)</td>
</tr>
<tr>
<td>74.</td>
<td>Presence of a thoracic aortic aneurysm</td>
<td>A (8)</td>
</tr>
</tbody>
</table>

**New or Worsening Symptoms**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>82</td>
<td>Known abdominal aortic aneurysm (any size)</td>
<td>A (9)</td>
<td></td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year**

<table>
<thead>
<tr>
<th></th>
<th>At 3 to 5 months</th>
<th>At 6 to 8 months</th>
<th>At 9 to 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>83.</td>
<td>Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (1)</td>
<td>U (4)</td>
</tr>
<tr>
<td>84.</td>
<td>Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (1)</td>
<td>U (4)</td>
</tr>
<tr>
<td>85.</td>
<td>Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>U (4)</td>
<td>A (7)</td>
</tr>
<tr>
<td>86.</td>
<td>Aneurysm ≥ 5.5 cm in diameter</td>
<td>A (7)</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms, No or Slow Progression During First Year, Surveillance Frequency After First Year**

<table>
<thead>
<tr>
<th></th>
<th>Every 6 months</th>
<th>Every 12 months</th>
<th>Every 23 months or greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>87.</td>
<td>Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (2)</td>
<td>A (7)</td>
</tr>
<tr>
<td>88.</td>
<td>Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (2)</td>
<td>A (7)</td>
</tr>
<tr>
<td>89.</td>
<td>Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>U (5)</td>
<td>A (7)</td>
</tr>
<tr>
<td>90.</td>
<td>Aneurysm ≥ 5.5 cm in diameter</td>
<td>A (8)</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms, Rapid Progression During First Year, Surveillance Frequency After First Year**

<table>
<thead>
<tr>
<th></th>
<th>Every 6 months</th>
<th>Every 12 months</th>
<th>Every 23 months or greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>91.</td>
<td>Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>A (7)</td>
<td>A (7)</td>
</tr>
<tr>
<td>92.</td>
<td>Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>A (8)</td>
<td>A (7)</td>
</tr>
<tr>
<td>93.</td>
<td>Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>A (8)</td>
<td>A (7)</td>
</tr>
<tr>
<td>94.</td>
<td>Aneurysm ≥ 5.5 cm in diameter</td>
<td>A (9)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>
## Surveillance After Aortic Endograft or Aortoiliac Stenting

### Baseline (Within 1 Month After the Intervention)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>95.</td>
<td>• Aortic or iliac endograft</td>
<td>A (8)</td>
</tr>
<tr>
<td>96.</td>
<td>• Aortic and iliac artery stents</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

### New or Worsening Lower Extremity Symptoms After Baseline Exam

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>97.</td>
<td>• Aortic or iliac endograft</td>
<td>A (8)</td>
</tr>
<tr>
<td>98.</td>
<td>• Aortic and iliac artery stents</td>
<td>A (8)</td>
</tr>
</tbody>
</table>

### Asymptomatic or Stable Symptom After Baseline Study, Surveillance Frequency During First Year.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>99.</td>
<td>• Aortic endograft without endoleak stable and/or decreasing residual aneurysm sac size</td>
<td>I (3)</td>
</tr>
<tr>
<td>100</td>
<td>• Aortic endograft with endoleak and/or increasing residual aneurysm sac size</td>
<td>U (6)</td>
</tr>
<tr>
<td>101</td>
<td>• Aortic or iliac artery stents</td>
<td>I (2)</td>
</tr>
</tbody>
</table>

### Asymptomatic or Stable Symptom After Baseline Study, Surveillance Frequency After the First Year.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>102</td>
<td>• Aortic endograft without endoleak stable and/or decreasing residual aneurysm sac size</td>
<td>I (3)</td>
</tr>
<tr>
<td>103</td>
<td>• Aortic endograft with endoleak and/or increasing residual aneurysm sac size</td>
<td>A (8)</td>
</tr>
<tr>
<td>104</td>
<td>• Aortic or iliac artery stents</td>
<td>I (2)</td>
</tr>
</tbody>
</table>

### ADDITIONAL INDICATIONS FOR AN ABDOMEN ULTRASOUND IN CHILDREN:

#### Renal Disease (Roberts, 2011):

**Urinary Tract Infection – age < 2 months:**
- Signs/symptoms of UTI with fever

**Urinary Tract Infection – age > 2 months:**
- Signs/symptoms of UTI with fever and poor response to treatment

**Urinary Tract Infection with atypical presentation – any age:**
- Any of the following signs/symptoms:
  - Poor response to antibiotics within 48 hours
  - Sepsis
  - Urinary retention
  - Poor urine stream
  - Increased serum creatinine
  - Non-E. Coli organism
  - Recurrent UTI
**Urinary Tract – Other**
- Persistent dysuria
- Enuresis
- Urinary frequency
- Anuria, decreased urinary output, or urinary retention
- Follow up of congenital anomalies of the urinary tract
- Failure to thrive

**Spine (Kriss, 1998; Fitzgerald, 2011):**

**Spinal Dysraphism – Child less than 6 months (unless acoustic window persists):**
- Lumbosacral stigmata known to be associated with spinal dysraphism with one of the following present:
  - Midline or paramedian masses
  - Abnormal skin pigmentation
  - Skin tags
  - Hair tufts
  - Hemangiomas
  - Atypical sacral dimple
  - Sinus tract

**Other Spine Lesions**
- Caudal regression syndrome, including patients with sacral agenesis, or anal atresia or stenosis: OR
- Suspected defects such as cord tethering, diastematomyelia, hydromyelia and syringomyelia: OR
- Detection of injury, such as a hematoma after a spinal tap or birth injury, or posttraumatic leakage of cerebrospinal fluid: OR
- Visualization of fluid with characteristics of blood products within the spinal canal in patients with intracranial hemorrhage: OR
- Postoperative assessment for cord retethering.

**Other Indications for Abdominal Ultrasound in Children:**
- Suspicion of hypertrophic pyloric stenosis (Costa Dias, 2012)
- Suspicion of intussusception (Del-Pozo, 1999)

**ADDITIONAL INFORMATION RELATED TO ABDOMINAL ULTRASOUND:**

The Choosing Wisely Guidelines (2014) from the American College of Emergency Physicians: Avoid ordering CT of the abdomen and pelvis in young otherwise healthy emergency department (ED) patients (age <50) with known histories of kidney stones, or ureterolithiasis, presenting with symptoms consistent with uncomplicated renal colic. Kidney stones can cause severe pain (called renal colic) and nausea, which can usually be relieved with medication. Most stones pass spontaneously in the urine in a few days, though kidney stones often do recur. CT scans may be needed to diagnose kidney stones, and rule out other problems that may mimic the pain of kidney stones. Many patients in the ED who are less than 50 years old and who have symptoms of recurrent kidney stones do not need a CT scan unless these symptoms persist or worsen, or if there is a fever or a history of severe obstruction with previous stones. CT scans of patients in the ED with symptoms of recurrent kidney stones usually do not change.
treatment decisions, and the cost and radiation exposure can often be avoided in these cases. Close follow-
up by a primary care physician or specialist is necessary.

The Choosing Wisely Guidelines (2017) from the American Urological Association: Don’t routinely use
computed tomography (CT) to screen pediatric patients with suspected nephrolithiasis. Given the link
between radiation exposure from computed tomography (CT) in children and increased cancer risk,
imaging test selection should adhere to the principle of ALARA (as low as reasonably achievable) to
minimize radiation exposure. Ultrasonography is sufficiently sensitive and specific as an initial imaging
test in pediatric patients with suspected urolithiasis. When ultrasound results are negative or
indeterminate despite strong clinical suspicion or when proceeding with perioperative planning, CT using
a low-dose protocol is an appropriate next step.
http://www.choosingwisely.org/clinician-lists/american-urological-association-ct-to-screen-pediatric-
patients-with-suspected-nephrolithiasis/.

The Choosing Wisely Guidelines (2015) from the American Urogynecologic Society: Don’t perform
cystoscopy, urodynamics or diagnostic renal and bladder ultrasound in the initial work-up of an
uncomplicated overactive bladder (OAB) patient. The initial evaluation of an uncomplicated patient
presenting with symptoms should include history, physical examination and urinalysis. In some cases,
urine culture, post-void residual urine assessment and bladder diaries may be helpful. More invasive
testing should be reserved for complex patients, patients who have failed initial therapies (i.e., behavioral
therapies and medications), or patients who have abnormal findings on their initial evaluation.

ordering an abdominal ultrasound examination routinely in athletes with infectious mononucleosis.
Splenic enlargement is common in patients with infectious mononucleosis. The spleen is at increased risk
for splenic rupture in the first 3–4 weeks of infection. This has led many clinicians to utilize ultrasound to
determine if splenic enlargement is present. However, because individual splenic diameters vary greatly,
comparing splenic size to population norms is not a valid method to assess splenic enlargement.
http://www.choosingwisely.org/clinician-lists/american-medical-society-sports-medicine-abdominal-
ultrasound-for-infectious-mononucleosis/.
REFERENCES

Hepatic Ultrasound


Renal


**Aorta**


**Spine**


**Gallbladder and Bile Duct**


**Pancreas and Spleen**


**Appendicitis· Pyloric stenosis· Intussusception**


CPT Codes: 76856, 76857

INTRODUCTION:

A pelvic ultrasound uses reflected sound waves to produce a picture of the organs and other structures in the pelvis. Pelvic abnormalities may be the result of disease, injury, or a physiologic anomaly. A pelvic ultrasound can evaluate the bladder, ureters, uterus, and ovaries. Pelvic ultrasound can also be useful for evaluation of trauma or pelvic hernias.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR AN ULTRASOUND OF THE PELVIS:

Genitourinary conditions:
- Suspected kidney stones (Smith-Bindman, 2014)
- Urinary incontinence (Santoro, 2010)
- Bladder function abnormality (Pannu, 2014)
- Urinary tract obstruction
- Ureteral displacement or obstruction

Pain (Ackerman, 2011; Hammond, 2010; Bhosale, 2015):
- Evaluation of unexplained pelvic pain after physical examination, laboratory tests, or failure to respond to appropriate therapy.

Menstrual abnormality (AIUM, 2014):
- Dysmenorrhea (painful menses) (Osaynade, 2014)
- Amenorrhea
- Menorrhagia
- Menometrorrhagia
- Metrorrhagia (irregular uterine bleeding)
- Delayed menses
- Vaginal bleeding in a prepubertal child
- Postmenopausal bleeding
- Imperforate hymen (Kitami, 2017)

Known or suspected infection or inflammation of the pelvis (AIUM, 2014):
- Signs or symptoms of pelvic infection, inflammation, or abscess.
- Suspected appendicitis (Doria, 2006; Smith, 2013)

Pre-operative/procedural evaluation:
- Pre-operative evaluation for a planned surgery or procedure.

Post-operative/procedural evaluation:
- When imaging, physical, or laboratory findings indicate surgical or procedural complications.
Other Indications (AIUM, 2014):
• Precocious puberty (DeVries, 2006)
• Localization of an intrauterine contraceptive device (Nowitzki, 2015)
• Screening for malignancy in patients at increased risk. (Brown, 2010)
• Pelvic organ prolapse (Santoro, 2010; Pannu, 2014)
• Pelvic floor dysfunction (Pannu, 2014)
• Evaluation, monitoring, and/or treatment of infertility patients (Torre, 2010)
• Congenital anomalies (Kitami, 2017)
• Foreign body localization
• Evaluation of a hernia (Robinson, 2013; LeBlanc, 2013; Simons, 2018)
Follow up of a pelvic abnormality seen found on physical exam or prior imaging
• Known or suspected tumor or mass (Brown, 2010; Givens, 2009)
• Evaluation of pelvic trauma

ADDITIONAL INFORMATION:

The Choosing Wisely Guidelines (2014) from the American College of Emergency Physicians: Avoid ordering CT of the abdomen and pelvis in young otherwise healthy emergency department (ED) patients (age <50) with known histories of kidney stones, or ureterolithiasis, presenting with symptoms consistent with uncomplicated renal colic. Kidney stones can cause severe pain (called renal colic) and nausea, which can usually be relieved with medication. Most stones pass spontaneously in the urine in a few days, though kidney stones often do recur. CT scans may be needed to diagnose kidney stones, and rule out other problems that may mimic the pain of kidney stones. Many patients in the ED who are less than 50 years old and who have symptoms of recurrent kidney stones do not need a CT scan unless these symptoms persist or worsen, or if there is a fever or a history of severe obstruction with previous stones. CT scans of patients in the ED with symptoms of recurrent kidney stones usually do not change treatment decisions, and the cost and radiation exposure can often be avoided in these cases. Close follow-up by a primary care physician or specialist is necessary.

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patients, patients who have failed initial therapies (i.e., behavioral therapies and medications), or patients who have abnormal findings on their initial evaluation.


The Choosing Wisely Guidelines (2013) from the Society of Gynecologic Oncology (2013): Don’t screen low risk women with CA-125 or ultrasound for ovarian cancer. CA-125 and ultrasound in low risk, asymptomatic women have not led to diagnosis of ovarian cancer in earlier stages of disease or reduced ovarian cancer mortality. False positive results of either test can lead to unnecessary procedures, which have risks of complication.


Ultrasound of the pelvis should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information. In some cases, additional or specialized examinations may be necessary.

Doppler ultrasound – Doppler ultrasound is a special ultrasound technique that evaluates blood flow through a blood vessel, including the body's major arteries and veins in the abdomen, arms, legs and neck. A Doppler ultrasound study may be part of a pelvic ultrasound examination and can help the physician to see and evaluate:

- blockages to blood flow (such as clots)
- narrowing of vessels (which may be caused by plaque)
- tumors and congenital malformation

Limitations of pelvic ultrasound imaging - Ultrasound waves are disrupted by air or gas; therefore ultrasound is not an ideal imaging technique for the bowel or organs obscured by the bowel. In most cases, barium exams, CT scanning, and MRI are the methods of choice in this setting. Large patients are more difficult to image by ultrasound because tissue attenuates (weakens) the sound waves as they pass deeper into the body.

The following ultrasounds are not reviewed by NIA:

Transvaginal ultrasound - A transvaginal ultrasound is usually performed to view the endometrium or the lining of the uterus, including its thickness, and the ovaries. Transvaginal ultrasound also affords a good way to evaluate the muscular walls of the uterus, called the myometrium.

Transrectal ultrasound - Transrectal ultrasound, a special study usually done to view the prostate gland, involves inserting a specialized ultrasound transducer into the rectum.

Lower uterine segment (LUS) muscular thickness assessed by transvaginal ultrasound is more reliable than entire LUS thickness measured by the transabdominal approach. The use of three-dimensional ultrasound should be considered for better reliability.

Ultrasound of the uterus during pregnancy (addressed under OB US and/or Biophysical Profile US).
REFERENCES


CPT Codes: 76870

INTRODUCTION:

Scrotal ultrasound (US) may be useful in the identification and evaluation of structures within the scrotum. Scrotal abnormalities may be the result of disease, injury, or a physiologic anomaly.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

APPROPRIATE INDICATIONS FOR A SCROTUM AND CONTENTS ULTRASOUND (AIUM, 2015; Kitami, 2017):

- Abnormality noted on other imaging studies (e.g., computed tomography, magnetic resonance imaging, positron emission tomography)
- Intersex conditions*
- Infertility (Abdulwahed, 2013; Ammar, 2012)
- Potential scrotal hernia (Tiemstra, 2008)
- Suspected testicular torsion (Liang, 2013; Tiemstra, 2008)
- Follow up of previous indeterminate scrotal ultrasound
- Scrotal asymmetry, swelling, or enlargement
- Scrotal pain (D’Andrea, 2013; Hartman, 2014)
- Varicocele (Pauroso, 2011; Tiemstra, 2008)
- Trauma (Bhatt, 2008)
- Inguinal lymphadenopathy
- Endocrine conditions such as precocious puberty, gynecomastia, feminization, or abnormal endocrine lab tests (Faizah, 2012)

CRYPTORCHIDISM (UNDESCENDED TESTES) (Mau, 2017; Docimo, 2000; Choosing Wisely, 2017):

- Bilateral nonpalpable testes in an infant with suspected intersexuality
- Inconclusive physical exam secondary to obesity

KNOWN OR SUSPECTED MASS (Tiemstra, 2008; Toren, 2010):

- Occult primary tumor detection in patients with metastatic germ cell tumor
- Palpable inguinal or scrotal mass
- Surveillance of incidental scrotal mass found on prior imaging
- Surveillance of prior primary testicular neoplasms, leukemia, or lymphoma

PRE-OPERATIVE/PROCEDURAL EVALUATION:

- Pre-operative evaluation for a planned surgery or procedure.

POST-OPERATIVE/PROCEDURAL EVALUATION:
• When imaging, physical, or laboratory findings indicate surgical or procedural complications.

ADDITIONAL INFORMATION RELATED TO ULTRASOUND OF THE SCROTUM

The Choosing Wisely Guidelines (2017) from the American Urological Association: Don’t routinely perform ultrasound on boys with cryptorchidism. Ultrasound has been found to have poor diagnostic performance in the localization of testes that cannot be felt through physical examination. Studies have shown that the probability of locating testes was small when using ultrasound, and there was still a significant chance that testes were present even after a negative ultrasound result. Additionally, ultrasound results are complicated by the presence of surrounding tissue and bowel gas present in the abdomen.


*Intersex condition:

According to the Intersex Society of North America an intersex condition is defined as “…a general term used for a variety of conditions in which a person is born with a reproductive or sexual anatomy that doesn’t seem to fit the typical definitions of female or male”.

REFERENCES


INTRODUCTION:

A Duplex scan is an ultrasonic scanning procedure used to characterize the pattern and direction of blood flow in arteries or veins with the production of real-time images. While cerebrovascular ultrasound is a safe and widely available modality it does have its particular shortcomings and specific indications. Obtaining a high quality study requires the interplay of a number of factors. There are established criteria that are important to consider in order to ensure reliable, interpretable and meaningful results.

Complete Cerebrovascular Ultrasound studies are bilateral unless there is a specific clinical indication that warrants a limited study and investigate the common, external and internal carotid arteries as well as the vertebral arteries. 2D (Grayscale) and Doppler velocities are included.

A review of common clinical scenarios where cerebrovascular ultrasound is used follows. These scenarios are scored for appropriate use on a scale of 1-9. A median score of 7-9 indicates that this is an appropriate test for the specific indication. A median score of 4-6 indicates that there is unclear evidence as to the appropriateness of the test. A median score of 1-3 indicates that the test is not generally acceptable for the indication.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.


Section 1. Extracranial Cerebrovascular Ultrasound

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications (Refer to the “Additional Consideration” section for any clinical indication below that is followed by the letters a - e)</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation for Cerebrovascular Disease – Potential Signs and/or Symptoms</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 1.                     | - New or worsening hemispheric neurological symptoms (e.g., unilateral motor or sensory deficit, speech impairment, or amaurosis fugax) (a)  
                          - Evaluation of transient ischemic attack or stroke | A (9)                       |
| 2.                     | - Hollenhorst plaque visualized on retinal examination                                         | A (8)                       |
3. • Lightheadedness or impaired vision in the setting of upper extremity exertion
   • Evaluation for subclavian–vertebral steal phenomenon
4. • Syncope of uncertain cause after initial cardiovascular evaluation (d)
   • Suspected symptomatic vertebrobasilar occlusive disease in the symptomatic patient (e.g., vertigo, ataxia, diplopia, dysphagia, dysarthria)
5. • Evaluation for suspected carotid artery dissection (b)
   • Pulsatile neck mass
7. • Cervical bruit
   • No prior carotid artery assessment

### Evaluation for Cerebrovascular Disease—Asymptomatic With Comorbidities or Risk Factors for Carotid Artery Stenosis

| 9. | No cervical bruit
   | Atherosclerotic disease in other vascular beds (e.g., lower extremity PAD, coronary artery disease, abdominal aortic aneurysm) (c) |
|    | A (7) |

| 10. | No cervical bruit
     | History of neck irradiation ≥10 years ago |
|     | U (5) |

| 11. | Known renal fibromuscular dysplasia |
|     | U (5) |

### Prior to Open Heart Surgery

| 12. | Planned coronary artery bypass grafting (CABG) (c) |
|     | U (6) |

| 13. | Atherosclerotic disease in other vascular beds (e.g., lower extremity PAD, coronary artery disease, abdominal aortic aneurysm), or history of neck irradiation ≥10 years ago
     | Planned valve repair/replacement surgery (without CABG) (c) |
|     | U (6) |

| 14. | Atherosclerotic risk factors present
     | Planned valve repair/replacement surgery (without CABG) (c) |
|     | U (6) |

| 15. | No atherosclerotic risk factors
     | Planned valve repair/replacement surgery (without CABG) (c) |
|     | U (4) |

### Follow-Up or Surveillance for Carotid Artery Stenosis—Asymptomatic*+

| 16. | Normal prior examination (no plaque, no stenosis) (c) (e) |
|     | I (1) |

### Surveillance Frequency During First Year

<table>
<thead>
<tr>
<th>At 3 to 5 months</th>
<th>At 6 to 8 months</th>
<th>At 9 to 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.</td>
<td>Plaque without significant stenosis of the ICA (plaque, normal ICA velocity) (e)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>I (1)</td>
<td>I (1)</td>
</tr>
<tr>
<td>18.</td>
<td>Mild ICA stenosis (e.g., &lt;50%) (e)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>I (1)</td>
<td>I (1)</td>
</tr>
</tbody>
</table>
## Surveillance Frequency After First Year

<table>
<thead>
<tr>
<th>Surveillance Frequency After First Year</th>
<th>Every 6 months</th>
<th>Every 12 months</th>
<th>Every 24 months or greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>19. Moderate ICA stenosis (e.g., 50% to 69%) (e)</td>
<td>I (2)</td>
<td>U (6)</td>
<td>U (6)</td>
</tr>
<tr>
<td>20. Severe ICA stenosis (e.g., 70% to 99%) (e)</td>
<td>U (5)</td>
<td>A (7)</td>
<td>U (6)</td>
</tr>
</tbody>
</table>

## Surveillance After Carotid Artery Intervention

<table>
<thead>
<tr>
<th>Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year</th>
<th>Every 3 to 5 months</th>
<th>Every 6 to 8 months</th>
<th>Every 9 to 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>25. Baseline (within 1 month) after carotid intervention</td>
<td>A (8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26. Following normal ipsilatral ICA baseline study</td>
<td>I (2)</td>
<td>A (7)</td>
<td>A (7)</td>
</tr>
<tr>
<td>27. Following abnormal ipsilateral ICA baseline study</td>
<td>U (4)</td>
<td>A (7)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

## Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency After First Year

<table>
<thead>
<tr>
<th>Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency After First Year</th>
<th>Every 6 months</th>
<th>Every 12 months</th>
<th>Every 24 months or greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>28. Following normal ipsilatral ICA baseline study</td>
<td>I (2)</td>
<td>A (7)</td>
<td>U (5)</td>
</tr>
<tr>
<td>29. Following abnormal ipsilateral ICA baseline study</td>
<td>U (4)</td>
<td>A (7)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

### Table 2.1 30-33

Limited Screening Study for Carotid Artery Plaque—Asymptomatic

#### Indication

- Low Framingham risk score
- No prior risk assessment imaging study, such as coronary calcium scoring or carotid IMT measurement

#### Appropriate Use Score (1–9)

I (2)
Indication

31. • Intermediate Framingham risk score
   • No prior risk assessment imaging study, such as coronary calcium scoring or carotid IMT measurement

32. • Low or intermediate Framingham risk score
   • Normal prior risk assessment imaging study, such as coronary calcium scoring or carotid IMT measurement

33. • High Framingham risk score

*In the setting of interval development of clinical symptoms in a previously asymptomatic patient or for rapid progression of stenosis during subsequent follow-up (e.g., stenosis category change during a limited period of time), more intensive surveillance may be indicated.

Periodic surveillance duplex ultrasound should be performed according to the severity of stenosis of the contralateral side.

LIMITED STUDY INDICATIONS (CPT code: 93882)

A limited study (unilateral) is indicated under the following circumstances:

1) Post intervention surveillance where the contralateral carotid is free of disease.
2) Post intervention where the contralateral carotid has less than 70% stenosis and the surveillance period on the contralateral carotid has been less than 6 month (Ballota, 2007).
3) Emergent or urgent requests in the immediate postoperative or postprocedural period.

ADDITIONAL CONSIDERATIONS (Mohler 2012)

a. Cerebrovascular ultrasound is rated as Appropriate for evaluation of vertebrobasilar occlusive disease. Other Ultrasound protocols including Transcranial Doppler and other imaging modalities such as MRI or CT may be indicated.

b. Carotid Ultrasound is rated as Appropriate for Carotid artery dissection. This is in the scenario of suspected carotid dissection as a continuation of dissection of the aortic arch or ascending aorta and is Inappropriate in the setting of trauma where distal dissection and intracranial extension cannot be diagnosed by Ultrasound. CT and MRI are used in this scenario.

c. The appropriateness for cerebrovascular duplex is rated as Uncertain for all scenarios prior to cardiac surgery. This excludes patients with cerebrovascular symptoms. In patients with cerebrovascular symptoms (prior hemispheric stroke, TIA, etc.) cerebrovascular duplex would be Appropriate. Routine scanning of asymptomatic patients and particularly those without atherosclerotic comorbidities is Inappropriate.

d. The use of Carotid Duplex in the evaluation for syncope without cardiac cause is rated as Uncertain. Cerebrovascular disease is a rare cause of syncope, but can be seen in severe and usually bilateral internal carotid stenosis, in severe vertebral basilar disease and in subclavian steal syndrome.
Without cardiovascular risk factors or demonstrated atherosclerotic disease elsewhere the yield of Carotid Duplex in the evaluation of syncope is very low.

e. Clinical management of asymptomatic patients with demonstrated atherosclerotic disease requires periodic ultrasound surveillance. Any follow-up in patients with a normal baseline carotid ultrasound is Inappropriate. The frequency and appropriateness of testing intervals can change in the setting of new abnormalities on a surveillance study.

f. Screening studies are Inappropriate in the setting of a low Framingham risk score. Screening studies are also Inappropriate in patients with low or intermediate Framingham risk scores who have undergone other risk assessment imaging such as carotid IMT measurement or coronary artery calcium scoring.

ADDITIONAL INFORMATION (Mohler, 2012)

Definitions:

Claudication: Reproducible muscle discomfort or fatigue occurring with exertion at the same workload and relieved with rest, typically due to arterial obstruction.

Cold extremity: Reduced temperature from patient history or observed on physical examination by physician.

Physiological testing: Evaluation of the peripheral circulation based on measurement of limb blood pressures with pulse volume recordings or Doppler waveforms, or other parameters without utilizing data from direct imaging of the blood vessels.

Resistant hypertension: The failure to normalize blood pressure on 3 or more drug regimen with medications at maximum doses and at least 1 of the medications being a diuretic agent.

Abbreviations:

ABI - ankle-brachial index
ACE - angiotensin-converting enzyme inhibitor
ARB - angiotensin II receptor blocker
CABG - coronary artery bypass graft
CT - computed tomography
GI - gastrointestinal
ICA - internal carotid artery
ICAVL - Intersocietal Commission for the Accreditation of Vascular Laboratories
IMT - intima-media thickness
PAD - peripheral artery disease
PVR - pulse volume recording
REFERENCES


CPT codes: 93886, 93888

**INTRODUCTION:**

Transcranial doppler ultrasonography (TDU) is a non-invasive technology that uses a handheld pulsed low-frequency doppler transducer that enables recording of blood velocities from intra-cranial arteries through selected cranial foramina and thin regions of the skull. Analysis of the doppler spectra allows display and calculation of peak systolic, peak diastolic and mean velocities and pulse indices. Mapping of the sampled velocities as a color display of spectra in lateral, coronal and horizontal views locates the major brain arteries in three dimensions.

A complete transcranial study includes the investigation of the middle cerebral, anterior cerebral, posterior cerebral, terminal ICA, ICA siphon, ophthalmic artery, vertebral artery and basilar artery bilaterally where applicable. A study could be limited because of the limitations of the technique which have to do with obtaining adequate ultrasound windows. Patient factors that influence skull thickness such as race, age and gender influence the success of the technique.

Resistance, velocity and pulse all vary with changes in blood viscosity and variations in respiration. With hypoventilation vasodilatation occurs reducing resistance and increasing velocity. Anemia lowers viscosity and increases velocity. In a sickle cell patient a mean velocity in the MCA of greater than 200 cm/sec is abnormally high and is accompanied by a 40% stroke risk within 3 years.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

**Transcranial doppler (TCD) or transcranial doppler ultrasonography (TDU) is indicated in the following scenarios:**

- The assessment of stroke risk of children 2-16 years of age with sickle cell anemia (rescreening at 6 month intervals) (NIH, 2014; Yawn, 2015).
- Management of infants of less than 32 weeks gestation and very low birth weight (<1500 g) preterm infants (Buckley, 2017; Gabriel, 2010).
- For screening of cerebral vasospasm after aneurysmal subarachnoid hemorrhage prior to other imaging (MRA, CTA, Cerebral angiography) (ACR, 2016).

**ADDITIONAL INFORMATION:**

The 2014 Expert Panel Report from the NIH titled *Evidence-Based Management Of Sickle Cell Disease* recommends that children with sickle cell disease be screened with annual transcranial doppler starting at two years and continuing until adolescence to assess the risk of stroke (NIH, 2016). In children with elevated middle cerebral artery peak systolic velocities (> 200cm/sec) prophylactic transfusion therapy to decrease hemoglobin S (HbS) below 30% is associated with a significant reduction in the risk of stroke.

In premature and low birth weight infants cerebral hemodynamic changes related to impaired vascular autoregulation of the immature vasculature assessed by transcranial doppler, particularly abnormalities in the resistive index, are associated with the development of intraventricular hemorrhage and hypoxic
ischemic encephalopathy. According to Eisenhut et al “arterial development is completed initially in [the] brainstem and cerebellum (20–24 weeks) followed by the basal ganglia and diencephalon by 24–28 weeks and finally the cortex and germinal matrix”. The fragility of the germinal matrix capillaries and “immature vasoregulation coupled with rises in arterial pressure due to the stresses of postnatal adaption coupled with the extreme premature delivery contributes to the pathogenesis of IVH” (Eisenhut, 2017).

Transcranial doppler is useful in the assessment of many other cerebral vascular conditions but in general other modalities are regarded as superior. Right to left cardiac shunts are better assessed by transesophageal echo (TEE) and extracranial ICA stenosis is better depicted by ultrasound or MRA. Intracranial steno-occlusive disease is also better evaluated by MRA and CTA. The ability of TCD to predict outcomes in vertebrobasilar distribution stroke requires study as does the ability to predict hemorrhagic transformation of ischemic strokes, the occurrence of stroke leading to neurocognitive impairment following CABG, or the evaluation of cerebral thrombolytic therapy (Sloan, 2004) American Academy of Neurology). Although TCD evidence of vasospasm following aneurysmal subarachnoid hemorrhage is highly predictive of delayed cerebral ischemia it is not a mandated standard of care due to a paucity of evidence on clinically relevant outcomes (Kumar, 2016).
REFERENCES


Ferro JL, Canhao P. Etiology, clinical features, and diagnosis of cerebral venous thrombosis. Last reviewed February 2013. UpToDate Inc. Waltham, MA.


Suwanwela N. Moyamoya disease: Etiology, clinical features, and diagnosis. Last reviewed January 2012. UpToDate Inc. Waltham, MA.


INTRODUCTION:

A Duplex scan is an ultrasonic scanning procedure used to characterize the pattern and direction of blood flow in arteries or veins with the production of real-time images. While duplex ultrasound is a safe and widely available modality it does have its particular shortcomings and specific indications. Obtaining a high quality study requires the interplay of a number of factors. There are established criteria that are important to consider in order to ensure reliable, interpretable and meaningful results.

A complete lower extremity arterial study is comprised of imaging of the common femoral, deep femoral (profunda), proximal mid and distal superficial femoral artery popliteal and trifurcation vessels (anterior, posterior tibial and peroneal arteries) in both legs. Duplex with spectral waveforms are included. Bypass grafts or interventional sites are investigated. The Ankle-Brachial index is included. Performance of ABI studies alone do not fall under this guideline.

A review of common clinical scenarios where ultrasound is used follows. These scenarios are scored for appropriate use on a scale of 1-9. A median score of 7-9 indicates that this is an appropriate test for the specific indication. A median score of 4-6 indicates that there is unclear evidence as to the appropriateness of the test. A median score of 1-3 indicates that the test is not generally acceptable for the indication.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.


Section 5. Lower Extremity Artery Testing Using Multilevel Physiological Testing Alone or Duplex. Ultrasound With Single-Level ABI and PVR.

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications A _ appropriate; I _ inappropriate; U _ uncertain</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation for Lower Extremity Atherosclerotic Disease – Potential Signs and/or Symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>105.</td>
<td>Lower Extremity claudication</td>
<td>A (9)</td>
</tr>
<tr>
<td>106.</td>
<td>Leg/foot/toe pain at rest</td>
<td>A (9)</td>
</tr>
<tr>
<td>107.</td>
<td>Foot or toe ulcer or gangrene</td>
<td>A (9)</td>
</tr>
<tr>
<td>108.</td>
<td>Infection of leg/foot without palpable pulses</td>
<td>A (9)</td>
</tr>
<tr>
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</tr>
<tr>
<td>109.</td>
<td>• Suspected acute limb ischemia (e.g., cold, painful limb with pallor, pulselessness, paresthesia)</td>
<td>A (9)</td>
</tr>
</tbody>
</table>
| 110. | • Nocturnal leg cramps  
• Normal pulses | I (2) |
| 111. | • Lack of hair growth on dorsum of foot or toes  
• Normal pulses | I (2) |
| 112. | • Evidence of atheroemboli in the lower extremities | A (8) |
| 113. | • Lower Extremity Swelling  
• Normal pulses | I (2) |
| 114. | • Diabetes with peripheral neuropathy  
• Normal pulses | I (3) |

**Surveillance of Known Lower Extremity PAD**

**New or Worsening Symptoms**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td>115.</td>
<td>• Normal Baseline Study</td>
</tr>
<tr>
<td>116.</td>
<td>• Abnormal baseline ABI (i.e., ABI ≤ 0.90)</td>
</tr>
</tbody>
</table>

**No Change in Symptom Status (No revascularization)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 117. | • Normal baseline ABI (no stenosis) | I (1)  
I (1)  
I (1) |
| 118. | • Mild or moderate disease (e.g., ABI >0.4) | I (2)  
I (2)  
U (4) |
| 119. | • Severe (e.g., ABI <0.4) | I (3)  
U (5)  
U (5) |

**Symptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency After First Year**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 120. | • Normal baseline ABI (no stenosis) | I (1)  
I (1)  
I (2) |
| 121. | • Mild or moderate disease (e.g., ABI >0.4) | I (2)  
I (2)  
U (4) |
| 122. | • Severe (e.g., ABI <0.4) | U (4)  
U (4)  
I (3) |

**Surveillance of Lower Extremity PAD After Revascularization (Duplex/ABI)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>123.</td>
<td>• Baseline surveillance (within 1 month)</td>
</tr>
</tbody>
</table>

**New or Worsening Symptoms**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>124.</td>
<td>• After revascularization (angioplasty ± stent or bypass)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 125. | • After angioplasty ± stent placement | I (2)  
U (6)  
U (6) |
126. • After vein bypass graft & A (8)
127. • After prosthetic bypass graft & U (6)*
128. • Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency After First Year & Every 6 months
129. • After vein bypass graft & Every 12 months
130. • After prosthetic bypass graft & Every 24 months or greater

Lower Extremity Artery Testing With Duplex Ultrasound Only
131. Evaluation for Groin Complication After Femoral Access
132. • Pulsatile groin mass & A (9)
133. • Bruit or thrill over the groin & A (8)
134. • Ecchymosis & A (4)
135. • Significant hematoma & A (4)
136. • Severe pain within groin post procedure & A (&)

ADDITIONAL CONSIDERATIONS *

Duplex ultrasound of the lower extremities is INDICATED for the following:
- The diagnosis of the anatomic location of stenosis in peripheral vascular disease patients where the Ankle Brachial Index has been found to be .9 or less (Conte, 2015; Hirsch, 2006; Mohler, 2012).
- Baseline surveillance within 1 month of revascularization (vein or synthetic graft) (Mohler, 2012).
- Routine surveillance after femoral-popliteal or femoral-tibial-pedal bypass with a:
  - Venous conduit: Minimal surveillance intervals are, in addition to within 1 month baseline (Mohler, 2012; Conte, 2015), at 3, 6 and 12 months then yearly (Conte, 2015, Hirsch, 2006).
  - Prosthetic bypass graft: Surveillance, in addition to within 1 month baseline (Mohler, 2012), at 6 month then yearly after the first year (Mohler, 2012) when other imaging has not been performed (Hirsch, 2006).
- The evaluation of patients with acute lower extremity ischemia.

Duplex Ultrasound MAY BE INDICATED for the following but generally other imaging studies will be performed, making the ultrasound redundant or unnecessary (Hirsch, 2006).
- To select patients as candidates for endovascular intervention
- To select patients as candidates for surgical bypass and to select sites for anastomosis.
- Routine surveillance after femoral-popliteal bypass with a synthetic conduit.

ADDITIONAL INFORMATION (Mohler, 2012):

Definitions:
Claudication: Reproducible muscle discomfort or fatigue occurring with exertion at the same workload and relieved with rest, typically due to arterial obstruction.
Cold extremity: Reduced temperature from patient history or observed on physical examination by physician.
**Physiological testing:** Evaluation of the peripheral circulation based on measurement of limb blood pressures with pulse volume recordings or Doppler waveforms, or other parameters without utilizing data from direct imaging of the blood vessels.

**Resistant hypertension:** The failure to normalize blood pressure on 3 or more drug regimen with medications at maximum doses and at least 1 of the medications being a diuretic agent.

**Abbreviations:**

- **ABI** - ankle-brachial index
- **ACE** - angiotensin-converting enzyme inhibitor
- **ARB** - angiotensin II receptor blocker
- **CABG** - coronary artery bypass graft
- **CT** - computed tomography
- **GI** - gastrointestinal
- **ICA** - internal carotid artery
- **ICAVL** - Intersocietal Commission for the Accreditation of Vascular Laboratories
- **IMT** - intima-media thickness

Scanning protocols may be developed by the vascular laboratory but are based upon technical recommendations from appropriate societies (Intersocietal Commission for the Accreditation of Vascular Laboratories, ICVL or American College of Radiology, ACR). Interpretation of studies are performed by a physician according to standard diagnostic criteria adapted from the Ultrasound literature and are validated internally for accuracy as part of an ongoing quality assurance program. Testing should be performed by a credentialed Technologist (RVT or RVS) and interpreted by a credentialed physician (RVPI, ACR or RVT). Documentation of the use of optimal angle correction techniques and appropriate sample volume placement are necessary.

**Literature Review:**

Duplex ultrasound of the lower extremities is used in the diagnosis of arterial occlusive disease. It is not a cost effective screening tool and should only be utilized in patients with significant clinical evidence of peripheral vascular disease as determined by physical exam findings such as abnormal Ankle-Brachial Index or non-invasive testing.

Although duplex ultrasound produces images in either shades of black and white (2D or Greyscale) or color (Color Doppler), the majority of the important clinical information is gained through analysis of the velocity of blood flow. Quantitative criteria are used based on flow velocity (peak systolic velocity, peak systolic velocity ratios) before, within, and beyond a stenosis are compared. The presence of turbulence, pulsatility and plaque morphology are more qualitative observations.

Peak systolic velocity ratios are the most accurate method for diagnosing stenosis greater than 50%. A ratio of 2 is commonly used to diagnose a stenosis greater than 50%. Measurement of peak systolic velocity is operator dependent. The probe must be correctly oriented and the Doppler gate must be correctly aligned. Calcifications, stents and tortuous vessels can confound the measurement. The sensitivity and specificity for the diagnosis of a stenosis greater than 50% from the Iliac to the popliteal arteries is approximately 90-95%.

Duplex ultrasound has been evaluated for use as a preintervention tool. It has been shown to be an accurate method to predict the suitability of a lesion for angioplasty, 84-94%. It has been used as a substitute for intraoperative angiography to select a distal bypass site in infrapopliteal (infragenicular)
bypass operations. This has been shown to be inferior to angiography and has shown no differences in outcomes.

Duplex ultrasound has been used for postrevascularization surveillance of graft patency with mixed results. Vein grafts fail either from the development of stenosis at the anastomoses, in the body of the graft or from proximal or distal disease progression. These may occur and be detectable by ultrasound even if the patient is asymptomatic and the ABI is unchanged. It has been shown that revision of these threatened grafts results in better outcomes. Duplex surveillance of vein grafts is widely accepted and necessary.

Duplex surveillance of synthetic grafts has not been as well defined. However, the multisociety (Mohler, 2012) guideline provides an appropriateness rating of “7” within one month of revascularization, then at six month and yearly. When other imaging modalities such as CTA are utilized ultrasound is however redundant (Hirsch, 2006). Several studies have failed to show an improved outcome where duplex guided the clinical decision making. Other studies have found some improvement in patency where duplex was used for graft surveillance. The lack of consistency of these studies represents not only the marginal utility of duplex in the surveillance of synthetic grafts but also technical factors inherent when a synthetic conduit is used.

Duplex surveillance of angioplasty procedures is of questionable value. Several studies have shown that increased velocities exist after a PTA procedure and that this does not influence patency. There are contradictory studies that suggest patency is influenced adversely by these increased velocities and predict early failure. Although it seems logical to assume that early detection of restenosis could improve outcomes this is unsupported by the literature at this point.
REFERENCES


93930 – Upper Extremity Arterial Duplex Scan

93930 – Bilateral or Complete
93931 - Unilateral or Limited

INTRODUCTION:

A Duplex scan is an ultrasonic scanning procedure used to characterize the pattern and direction of blood flow in arteries or veins with the production of real-time images. While duplex ultrasound is a safe and widely available modality it does have its particular shortcomings and specific indications. Obtaining a high quality study requires the interplay of a number of factors. There are established criteria that are important to consider in order to ensure reliable, interpretable and meaningful results.

A complete upper extremity arterial study is comprised of imaging of the subclavian, axillary, brachial, ulnar and radial arteries. Duplex with spectral waveforms are included. Bypass grafts or interventional sites are investigated. The ankle-brachial index is usually not included.

A review of common clinical scenarios where ultrasound is used follows. These scenarios are scored for appropriate use on a scale of 1-9. A median score of 7-9 indicates that this is an appropriate test for the specific indication. A median score of 4-6 indicates that there is unclear evidence as to the appropriateness of the test. A median score of 1-3 indicates that the test is not generally acceptable for the indication.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

ACCF/ACR/AIUM/ASE/ASN/ICA/SCAI/SCCT/SIR/SVM/SVS 2012 Appropriate Use Criteria

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 8. Upper Extremity Arterial Testing – Physiological Testing or Duplex Ultrasound Study</td>
<td>Evaluation for Upper Extremity PAD – Potential Signs and/or Symptoms</td>
<td>A _ appropriate; I _ inappropriate; U _ uncertain</td>
</tr>
<tr>
<td>142.</td>
<td>Arm or hand claudication</td>
<td>A (8)</td>
</tr>
<tr>
<td>143.</td>
<td>Finger discoloration or ulcer</td>
<td>A (8)</td>
</tr>
<tr>
<td>144.</td>
<td>Unilateral cold painful hand</td>
<td>A (8)</td>
</tr>
<tr>
<td>145.</td>
<td>Raynaud's phenomenon</td>
<td>U (5)</td>
</tr>
<tr>
<td>146.</td>
<td>Suspected positional arterial obstruction (e.g., thoracic outlet syndrome).</td>
<td>A (7)</td>
</tr>
<tr>
<td>147.</td>
<td>Upper extremity trauma with suspicion of vascular injury</td>
<td>A (8)</td>
</tr>
<tr>
<td>148.</td>
<td>Discrepancy in arm pulses or blood pressure discrepancy of &gt;20mm Hg between arms.</td>
<td>U (6)</td>
</tr>
<tr>
<td>149.</td>
<td>Periclavicular bruit</td>
<td>U (5)</td>
</tr>
<tr>
<td>150.</td>
<td>Pre-op radial artery harvest (e.g., for CABG)</td>
<td>A (7)</td>
</tr>
<tr>
<td>151.</td>
<td>Presence of pulsatile mass or hand ischemia after upper extremity vascular access.</td>
<td>A (8)</td>
</tr>
<tr>
<td>152.</td>
<td>• Presence of bruit after upper extremity access for intervention.</td>
<td>A (8)</td>
</tr>
<tr>
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</tr>
<tr>
<td><strong>Table 8.2 Surveillance of Upper Extremity PAD After Revascularization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>153.</td>
<td>• Baseline (within 1 month)</td>
<td>A (8)</td>
</tr>
<tr>
<td><strong>New or Worsening Symptoms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>154</td>
<td>• After revascularization (stent or bypass)</td>
<td>A (8)</td>
</tr>
<tr>
<td>155</td>
<td>• Post trauma</td>
<td>A (8)</td>
</tr>
<tr>
<td><strong>Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year</strong></td>
<td>At 3 to 5 months</td>
<td>At 6 to 8 months</td>
</tr>
<tr>
<td>156.</td>
<td>• After vein bypass graft</td>
<td>U (6)</td>
</tr>
<tr>
<td>157.</td>
<td>• After prosthetic bypass graft</td>
<td>I (3)</td>
</tr>
<tr>
<td><strong>Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency After First Year</strong></td>
<td>Every 6 months</td>
<td>Every 12 months</td>
</tr>
<tr>
<td>158.</td>
<td>• After vein bypass graft</td>
<td>U (4)</td>
</tr>
<tr>
<td>159.</td>
<td>• After prosthetic bypass graft</td>
<td>U (4)</td>
</tr>
</tbody>
</table>

**ADDITIONAL CONSIDERATIONS (Mohler, 2012):**

The **appropriate** indications for upper extremity arterial testing included claudication, ulcer, unilateral cold painful hand, suspected positional arterial obstruction, and trauma with suspicion of vascular injury.

The presence of Raynaud’s phenomenon was an “**Uncertain**” indication. A preoperative evaluation for a procedure such as radial artery harvest or suspected complication after an upper extremity arterial intervention was also **appropriate** indications for testing.

Similar to the lower extremity, a baseline study after revascularization and new or worsening symptoms are **appropriate** indications for upper extremity arterial testing.

The most **appropriate** initial surveillance time interval after upper extremity revascularization with either vein or prosthetic bypass graft was at 12 months. A surveillance period of every 6 months after initial postoperative evaluation was most **inappropriate** for asymptomatic patients.

**ADDITIONAL INFORMATION (Mohler, 2012):**

**Definitions:**

**Claudication:** Reproducible muscle discomfort or fatigue occurring with exertion at the same workload and relieved with rest, typically due to arterial obstruction.

**Cold extremity:** Reduced temperature from patient history or observed on physical examination by physician.

**Physiological testing:** Evaluation of the peripheral circulation based on measurement of limb blood pressures with pulse volume recordings or Doppler waveforms, or other parameters without utilizing data from direct imaging of the blood vessels.

**Resistant hypertension:** The failure to normalize blood pressure on 3 or more drug regimen with medications at maximum doses and at least 1 of the medications being a diuretic agent.
Abbreviations:

**ABI** = ankle-brachial index  
**ACE** = angiotensin-converting enzyme inhibitor  
**ARB** = angiotensin II receptor blocker  
**CABG** = coronary artery bypass graft  
**CT** = computed tomography  
**GI** = gastrointestinal  
**ICA** = internal carotid artery  
**ICAVL** = Intersocietal Commission for the Accreditation of Vascular Laboratories  
**IMT** = intima-media thickness  
**PAD** = peripheral artery disease  
**PVR** = pulse volume recording
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INTRODUCTION:

A duplex scan is an ultrasonic scanning procedure used to characterize the pattern and direction of blood flow in arteries or veins with the production of real-time images. While duplex ultrasound is a safe and widely available modality it does have its particular shortcomings and specific indications. Obtaining a high quality study requires the interplay of a number of factors. There are established criteria that are important to consider in order to ensure reliable, interpretable and meaningful results.

Interpretation of venous duplex examinations must use validated criteria to assess the presence and extent of venous thrombosis, vessel patency, valvular competence, and/or calf muscle pump function. Duplex ultrasonography for venous evaluation includes transverse gray scale imaging with transducer compressions and long axis spectral doppler evaluation, with or without color imaging.

The interpretation and report must state the presence or absence of abnormalities in the vessels that were investigated. Disease if present, must be characterized according to its location, extent, severity, and in the case of venous thrombosis, age when possible.

A review of common clinical scenarios where ultrasound is used follows. These scenarios are scored for appropriate use on a scale of 1-9. A median score of 7-9 indicates that this is an appropriate test for the specific indication. A median score of 4-6 indicates that there is unclear evidence as to the appropriateness of the test. A median score of 1-3 indicates that the test is not generally acceptable for the indication.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.


Section 1: Upper Extremity Venous Duplex Ultrasound

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venous Duplex of the Upper extremities for Patency and Thrombosis</td>
<td>A = appropriate; M = maybe appropriate; R = rarely appropriate</td>
<td></td>
</tr>
<tr>
<td>Limb Swelling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Unilateral – Acute</td>
<td>A (9)</td>
<td></td>
</tr>
<tr>
<td>2. Unilateral – chronic, persistent</td>
<td>A (7)</td>
<td></td>
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</tr>
</tbody>
</table>
| 3. | • Bilateral – acute  
• Suspected central venous obstruction | A (8) |
| 4. | • Bilateral—chronic, persistent  
• No alternative diagnosis identified (e.g., no CHF or anasarca from hypoalbuminemia)  
• Suspected central venous obstruction | A (7) |
|   | **Limb Pain (without swelling)** |   |
| 5. | • Nonarticular pain in the upper extremity (no indwelling upper extremity venous catheter) | M (5) |
| 6. | • Nonarticular pain in the upper extremity with indwelling upper extremity venous catheter | A (7) |
| 7. | • Tender, palpable cord in the upper extremity | A (8) |
|   | **Shortness of Breath** |   |
| 8. | • Suspected pulmonary embolus (no indwelling upper extremity venous catheter) | M (4) |
| 9. | • Suspected pulmonary embolus with indwelling upper extremity venous catheter | M (6) |
| 10. | • Diagnosed pulmonary embolus (no indwelling upper extremity venous catheter) | M (4) |
| 11. | • Diagnosed pulmonary embolus with indwelling upper extremity venous catheter | M (6) |
|   | **Fever** |   |
| 12. | • Fever of unknown origin (no indwelling upper extremity venous catheter) | R (2) |
| 13. | • Fever with indwelling upper extremity venous catheter | R (4) |
|   | **Known Upper Extremity Venous Thrombosis** |   |
| 14. | • New upper extremity pain or swelling while on anticoagulation. | A (7) |
| 15. | • New upper extremity pain or swelling not on anticoagulation (i.e., contraindication to anticoagulation) | A (7) |
| 16. | • Before anticipated discontinuation of anticoagulation treatment | M (5) |
| 17. | • Shortness of breath in a patient with known upper extremity DVT | R (3) |
| 18. | • Surveillance after diagnosis of upper extremity superficial phlebitis.  
• Not on anticoagulation, phlebitis location ≤ 5 cm from deep vein junction. | M (6) |
| 19. | • Surveillance after diagnosis of upper extremity superficial phlebitis.  
• Not on anticoagulation, phlebitis location ≥5 cm from deep vein junction. | M (4) |
|   | **Vein Mapping Prior to Bypass Surgery (Coronary or Peripheral)** |   |
| 20. | • In the absence of adequate leg vein for harvest | A (8) |
| 21. | • In the presence of adequate leg vein for harvest. | M (4) |
### Screening Examination for Upper Extremity DVT (Screening examination performed in the absence of upper extremity pain or swelling)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>R (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>22.</td>
<td>Prior to pacemaker or implantable cardiac defibrillator placement</td>
<td></td>
</tr>
<tr>
<td>23.</td>
<td>Prolonged ICU stay (e.g., &gt;4 days)</td>
<td>R (2)</td>
</tr>
<tr>
<td>24.</td>
<td>Prolonged ICU stay (e.g., &gt;4 days) with indwelling upper extremity venous catheter</td>
<td>R (3)</td>
</tr>
<tr>
<td>25.</td>
<td>Monitoring indwelling upper extremity venous catheter that is functional</td>
<td>R (2)</td>
</tr>
<tr>
<td>26.</td>
<td>In those with high risk: acquired, inherited, or hypercoagulable state.</td>
<td>R (2)</td>
</tr>
<tr>
<td>27.</td>
<td>Positive D-dimer test in a hospital inpatient</td>
<td>R (1)</td>
</tr>
</tbody>
</table>

### SECTION 2: VENOUS DOPPLER FOR LOWER EXTREMITIES

#### Venous Duplex of the Lower Extremities for Patency and Thrombosis

**Limb Swelling**

<p>| | | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>28.</td>
<td>Unilateral – Acute</td>
<td>A (9)</td>
</tr>
<tr>
<td>29.</td>
<td>Unilateral – chronic, persistent</td>
<td>A (7)</td>
</tr>
<tr>
<td>30.</td>
<td>Bilateral – acute</td>
<td>A (8)</td>
</tr>
<tr>
<td>31.</td>
<td>Bilateral—chronic, persistent</td>
<td>M (6)</td>
</tr>
<tr>
<td></td>
<td>No alternative diagnosis identified (e.g., no CHF or anasarca from hypoalbuminemia)</td>
<td></td>
</tr>
</tbody>
</table>

**Limb Pain (without swelling)**

<p>| | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>32.</td>
<td>Nonarticular pain in the lower extremity (e.g., calf or thigh)</td>
<td>A (7)</td>
</tr>
<tr>
<td>33.</td>
<td>Knee pain</td>
<td>M (4)</td>
</tr>
<tr>
<td>34.</td>
<td>Tender, palpable cord in the lower extremity</td>
<td>A (8)</td>
</tr>
</tbody>
</table>

**Shortness of Breath**

<p>| | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>35.</td>
<td>Suspected pulmonary embolus</td>
<td>A (8)</td>
</tr>
<tr>
<td>36.</td>
<td>Diagnosed pulmonary embolus</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**Fever**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>37.</td>
<td>Fever of unknown origin (no indwelling lower extremity venous catheter)</td>
<td>M (5)</td>
</tr>
<tr>
<td>38.</td>
<td>Fever with indwelling lower extremity venous catheter</td>
<td>M (5)</td>
</tr>
</tbody>
</table>

**Known Lower Extremity Venous Thrombosis**

<p>| | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>39.</td>
<td>Surveillance of calf vein thrombosis for proximal propagation in patient with contraindication to anticoagulation (within 2 weeks of diagnosis)</td>
<td>A (7)</td>
</tr>
<tr>
<td>40.</td>
<td>New lower extremity pain or swelling</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**Duplex Evaluation for Venous Incompetency**

**Venous Insufficiency (Venous Duplex with Provocative Maneuvers for Incompetency)**

<p>| | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>56.</td>
<td>Active venous ulcer</td>
<td>A (9)</td>
</tr>
<tr>
<td>57.</td>
<td>• Healed venous ulcer</td>
<td>A (7)</td>
</tr>
<tr>
<td>58.</td>
<td>• Spider veins (telangiectasias)</td>
<td>R (3)</td>
</tr>
<tr>
<td>59.</td>
<td>• Varicose veins, entirely asymptomatic</td>
<td>M (5)</td>
</tr>
<tr>
<td>60.</td>
<td>• Varicose veins with lower extremity pain or heaviness</td>
<td>A (7)</td>
</tr>
<tr>
<td>61.</td>
<td>• Visible varicose veins with chronic lower extremity swelling or skin changes of chronic venous insufficiency (e.g., hyperpigmentation, lipodermatosclerosis)</td>
<td>A (7)</td>
</tr>
<tr>
<td>62.</td>
<td>• Skin changes of chronic venous insufficiency without visible varicose veins (e.g., hyperpigmentation, lipodermatosclerosis)</td>
<td>A (7)</td>
</tr>
<tr>
<td>63.</td>
<td>• Lower extremity pain or heaviness without signs of venous disease</td>
<td>M (5)</td>
</tr>
<tr>
<td>64.</td>
<td>• Mapping prior to venous ablation procedure</td>
<td>A (8)</td>
</tr>
<tr>
<td>65.</td>
<td>• Prior endovenous (great or small) saphenous ablation procedure with new or worsening varicose veins in the ipsilateral limb</td>
<td>A (8)</td>
</tr>
<tr>
<td>66.</td>
<td>• Prior endovenous (great or small) saphenous ablation procedure with no residual symptoms</td>
<td>R (3)</td>
</tr>
</tbody>
</table>

**ADDITIONAL CONSIDERATIONS (Gornik, 2013):**

Lower extremity venous duplex ultrasound is **Appropriate** in the setting of limb swelling, non articular lower extremity pain with or without a palpable cord, pulmonary embolism, or when new pain or swelling occurs in the presence of known lower extremity DVT. Testing with duplex ultrasound is also **Appropriate** in certain surveillance situations, such as calf vein thrombosis where anticoagulation is contraindicated and for early follow up of venous ablation surgery (first 10 days). Duplex ultrasound is **Appropriate** for surveillance of patients with superficial venous thrombosis where the thrombus is adjacent to its deep junction. Duplex ultrasound is an **Appropriate** study when evidence of venous obstruction exists from venous physiologic testing (plethysmography). In these situations CPT code 93971 should be used where only the symptomatic limb is scanned.

Duplex ultrasound is felt to be **Appropriate** in the evaluation of suspected paradoxical embolism in a patient with an atrial septal defect or patent foramen ovale.

Lower extremity venous mapping prior to coronary or peripheral bypass surgery is **Appropriate**, but generally constitutes a limited study, (CPT code 93971).

Screening for DVT with duplex ultrasound in an asymptomatic patient is so rarely productive as to make it **Inappropriate**. These scenarios include, patients with prolonged ICU stay, positive D-Dimer, following orthopedic surgery, and those with a hypercoagulable state. Evaluation of patients with fever of unknown origin may possibly be appropriate but there is little evidence to support this.
Duplex ultrasound evaluation for venous valvular insufficiency or venous reflux, with provocative maneuvers such as distal limb augmentation and/or Valsalva is **Appropriate** in the setting of significant clinical signs and symptoms of venous disease. These are active or healed ulcers, varicosities with lower extremity discomfort, swelling or chronic skin changes.

Duplex ultrasound **May Be Appropriate** for evaluation of the patient with significant though asymptomatic varicose veins or for the patient with lower extremity pain and swelling.

Duplex ultrasound is **Inappropriate** in the evaluation of patients with spider veins (telangiectasia) without other stigmata of venous disease. Duplex ultrasound is also **Inappropriate** for the patient with prior vein ablation and no residual symptoms (follow up duplex is indicated within 10 days of the procedure).

---

**ADDITIONAL INFORMATION (Gornik, 2013):**

**Definitions:**

**Physiological testing:** Evaluation of the peripheral venous circulation based on measurement of limb blood flow using plethysmographic sensors (e.g., air, strain gauge, or photoplethysmography) with physiological maneuvers (e.g., limb positioning, limb exercise, tourniquet application), or other parameters, without utilizing data from direct imaging of the blood vessels.

**Screening examination:** Testing conducted to determine the presence or absence of disease in an asymptomatic patient.

**Surveillance examination:** Testing conducted to monitor disease progression based solely on the passage of time since initial diagnosis or revascularization (e.g., calf vein thrombosis with contraindication to anticoagulation). It is assumed that baseline testing has already been conducted.

**Abbreviations:**

- ACR = American College of Radiology
- AVF = autogenous arteriovenous fistula (including venous transpositions)
- AVG = prosthetic arteriovenous graft
- CHF = congestive heart failure
- DVT = deep vein thrombosis
- IAC = Intersocietal Accreditation Commission
- ICU = intensive care unit
- IVC = inferior vena cava
- RPVI = registered physician in vascular interpretation
- RVT = registered vascular technologist
- RVS = registered vascular sonographer
- TIPS = transjugular intrahepatic portosystemic shunt
REFERENCES


CPT Codes:
93975 – Bilateral or Complete
93976 - Unilateral or Limited

INTRODUCTION:

A Duplex scan is an ultrasonic scanning procedure used to characterize the pattern and direction of blood flow in arteries or veins with the production of real-time images.

While duplex ultrasound is a safe and widely available modality it does have its particular shortcomings and specific indications. Obtaining a high quality study requires the interplay of a number of factors. There are established criteria that are important to consider in order to ensure reliable, interpretable and meaningful results.

A review of common clinical scenarios where doppler ultrasound is used follows. These scenarios are scored for appropriate use on a scale of 1-9. A median score of 7-9 indicates that this is an appropriate test for the specific indication. A median score of 4-6 indicates that there is unclear evidence as to the appropriateness of the test. A median score of 1-3 indicates that the test is not generally acceptable for the indication.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

For evaluation of the aorta (CPT codes 93978 & 93979) refer to guideline # 335 for AORTA, INFERIOR VENA CAVA, ILIAC DUEPLEX SCAN (US)

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal and Mesenteric Artery Duplex</td>
<td>A _ appropriate; I _ inappropriate; U _ uncertain</td>
<td>____________________________</td>
</tr>
<tr>
<td>Evaluation of Renal Artery Stenosis – Potential Signs and/or Symptoms</td>
<td>Creatinine Evaluation and/or Hypertension</td>
<td>____________________________</td>
</tr>
<tr>
<td>34.</td>
<td>• Malignant Hypertension</td>
<td>A (8)</td>
</tr>
<tr>
<td>35.</td>
<td>• Resistant Hypertension</td>
<td>A (8)</td>
</tr>
<tr>
<td>36.</td>
<td>• Worsening blood pressure control in long standing hypertensive patient.</td>
<td>A (8)</td>
</tr>
<tr>
<td>37.</td>
<td>• Hypertension in younger patient (age &lt;35 years)</td>
<td>A (8)</td>
</tr>
<tr>
<td>38.</td>
<td>• Unexplained size discrepancy between kidneys (&gt;1.5 cm; in longest dimension)</td>
<td>A (7)</td>
</tr>
<tr>
<td>39.</td>
<td>• Unknown cause of azotemia (e.g., unexplained increase in creatinine)</td>
<td>A (7)</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Category</td>
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</tr>
<tr>
<td>40.</td>
<td>Increased creatinine (&gt;50% baseline or above normal levels) after the administration of ACE/ARBs.</td>
<td>A (8)</td>
</tr>
<tr>
<td>41.</td>
<td>Acute renal failure with aortic dissection</td>
<td>A (8)</td>
</tr>
<tr>
<td>42.</td>
<td>Epigastric bruit</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**Heart Failure of Unknown Origin**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Category</th>
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</thead>
<tbody>
<tr>
<td>43.</td>
<td>Refractory CHF</td>
<td>A (7)</td>
</tr>
<tr>
<td>44.</td>
<td>“Flash” pulmonary edema</td>
<td>A (8)</td>
</tr>
</tbody>
</table>

**Screening for Renal Artery Stenosis - Asymptomatic**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Category</th>
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</thead>
<tbody>
<tr>
<td>45.</td>
<td>Atherosclerotic vascular disease in other beds (e.g., peripheral artery disease) and well-controlled hypertension</td>
<td>I (3)</td>
</tr>
<tr>
<td>46.</td>
<td>Unexplained size discrepancy between kidneys (&gt;1.5 cm; in longest dimension) as discovered by CT or ultrasound</td>
<td>U (4)</td>
</tr>
</tbody>
</table>

**Evaluation for Mesenteric Artery Stenosis – Potential Signs and/or Symptoms**

**Symptomatic**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>47.</td>
<td>Evaluation for acute abdominal pain &quot;out of proportion to exam&quot;</td>
<td>I (3)</td>
</tr>
<tr>
<td></td>
<td>Leukocytosis, “thumbprinting” pneumatosis or hemoconcentration, and acidosis with or without elevated amylase, alkaline phosphatase, or CPK</td>
<td></td>
</tr>
<tr>
<td>48.</td>
<td>Postprandial pain or weight loss not otherwise explained</td>
<td>A (8)</td>
</tr>
<tr>
<td></td>
<td>GI evaluation previously completed</td>
<td></td>
</tr>
<tr>
<td>49.</td>
<td>Postprandial pain or discomfort</td>
<td>U (5)</td>
</tr>
<tr>
<td></td>
<td>GI evaluation not yet undertaken</td>
<td></td>
</tr>
<tr>
<td>50.</td>
<td>Chronic constipation or diarrhea</td>
<td>I (3)</td>
</tr>
<tr>
<td></td>
<td>GI evaluation not yet undertaken</td>
<td></td>
</tr>
<tr>
<td>51.</td>
<td>Unexplained or unintended weight loss</td>
<td>U (5)</td>
</tr>
<tr>
<td>52.</td>
<td>Abdominal or epigastric bruit</td>
<td>U (4)</td>
</tr>
</tbody>
</table>

**Follow-Up Testing for Renal Artery Stenosis - Asymptomatic**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Category</th>
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</thead>
<tbody>
<tr>
<td>53.</td>
<td>Prior imaging indicates renal artery stenosis</td>
<td>A (7)</td>
</tr>
<tr>
<td></td>
<td>Determine hemodynamic significance</td>
<td></td>
</tr>
<tr>
<td>54.</td>
<td>Surveillance of known renal artery stenosis</td>
<td>U (6)</td>
</tr>
</tbody>
</table>

**Surveillance After Renal or Mesenteric Artery Revascularization**

**Asymptomatic**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>55.</td>
<td>Baseline surveillance (within 1 month) after revascularization</td>
<td>A (8)</td>
</tr>
</tbody>
</table>

**New or Worsening Symptoms After Baseline**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>56.</td>
<td>After renal or mesenteric artery revascularization</td>
<td>A (8)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year**

| Description                                                                 | At 3 to 5 months | At 6 to 8 months | At 9 to 12 months |
|---|------------------------------------------------------------------------------|------------------|------------------|-------------------|
| 57. | During first 12 months after endovascular revascularization                  | I (3)            | U (6)            | U (6)             |

**Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency After First Year**

| Description                                                                 | Every 6 months | Every 12 months | Every 23 months or greater |
|---|------------------------------------------------------------------------------|----------------|-----------------|----------------------------|
| 58. | After first 12 months after endovascular revascularization                   | I (3)          | A (7)           | U (5)                       |
### ACCF/ACR/AIUM/ASE/IAC/SCAI/SCVS/SIR/SVM/SVS/SVU 2013 Appropriate Use Criteria

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A _ appropriate; M _ maybe inappropriate; R _ rarely appropriate</td>
<td></td>
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</tr>
</tbody>
</table>

#### Duplex of the Hepatoportal System (Portal Vein, Hepatic Veins, Splenic Vein, Superior Mesenteric Vein, Inferior Cava) for Patency, Thrombosis, and Flow Direction

**Evaluation of Hepatic Dysfunction or Portal Hypertension**

| 86. | • Abnormal liver function tests.  
• No alternative diagnosis identified (e.g., medication related or infectious hepatitis) | M (6) |
| 87. | • Cirrhosis with or without ascites | A (7) |
| 88. | • Jaundice  
• As an initial diagnostic test | R (3) |
| 89. | • Jaundice  
• No alternative diagnosis identified after initial evaluation (e.g., no biliary obstruction) | M (6) |
| 90. | • Hepatomegaly and/or splenomegaly | A (7) |
| 91. | • Portal hypertension | A (7) |

**Surveillance Following Portal Decompression Procedure**

| 92. | • Follow-up of a TIPS | A (8) |

**Evaluation of other Symptoms or Signs of Abdominal Vascular Disease**

| 93. | • Abdominal pain | M (4) |
| 94. | • Fever of unknown origin | R (3) |

**Evaluation of Other Symptoms or Signs of Abdominal Vascular Disease**

| 95. | • Pulmonary symptoms (suspected pulmonary embolus) | R (3) |
| 96. | • Cor Pulmonale | R (3) |

**Duplex of the Renal Veins for Patency and Thrombosis**

| 97. | • Gross hematuria | R (3) |
| 98. | • Acute renal failure | M (5) |
| 99. | • Acute flank pain | M (5) |
Evaluation of Cardiac and/or Pulmonary Symptoms

100. Pulmonary symptoms (suspected pulmonary embolus) R (3)

Evaluation of Other Symptoms or Signs of Abdominal Vascular Disease

101. Drug-resistant hypertension (suspected renal artery stenosis) R (3)
102. Microscopic hematuria (prior to urological evaluation) R (2)
103. Fever of unknown origin R (2)
104. Epigastric bruit R (2)

*Testing indications refer to evaluation of native renal veins only for patency (i.e., renal transplant sites and renal arteries excluded).

Scrotal Duplex

- Testicular trauma
- Acute testicular pain
- Suspected testicular torsion
- Varicocele

ADDITIONAL CONSIDERATIONS:

Renal artery
Duplex ultrasound is **Appropriate** in the evaluation of hypertension, increasing or elevated serum creatinine, and heart failure as described in the tables above. It is **Inappropriate** for screening in an asymptomatic patient. Duplex ultrasound is also **Inappropriate** in the surveillance of known stenotic lesions in the absence of changing symptoms or laboratory findings.

Mesenteric/Celiac artery
The only **Appropriate** indication for evaluation of the mesenteric and celiac arteries for stenosis is postprandial pain and weight loss in patients who have undergone a gastrointestinal evaluation.

Surveillance after Renal, Mesenteric or Celiac artery revascularization
Surveillance after renal, mesenteric or celiac revascularization (surgical or endovascular) is **Appropriate** at 1 month following the procedure to establish a baseline and any time there are new signs or symptoms. Yearly surveillance is **Appropriate** after 12 months from the procedure.

Duplex evaluation of the Hepatoportal System
Duplex ultrasound evaluation is **Appropriate** for the evaluation of cirrhosis with or without ascites, hepatomegaly and/or splenomegaly, and portal hypertension. Duplex scanning is **Appropriate** in the surveillance after a transjugular intrahepatic portosystemic shunt (TIPS) procedure. Duplex ultrasound is **Not Appropriate** in the initial evaluation of jaundice, but **May Be Appropriate** in cases where there are elevated liver enzymes and jaundice without a diagnosis identified after other evaluations. Hepatoportal duplex scanning is **Rarely Appropriate** in the initial evaluation of fever of unknown origin, cor pulmonale or pulmonary symptoms.

Duplex Ultrasound evaluation of the renal venous system
Isolated renal vein pathology is uncommon as a cause of genitourinary symptoms or signs. There are **no** clinical indications rated as **Appropriate** for assessment of the native renal veins with duplex ultrasound. For indications of acute renal failure, acute flank pain and symptoms compatible with renal vein thrombosis, renal venous duplex scanning is **Maybe Appropriate**.
Renal venous duplex is **Rarely Appropriate** for the evaluation of microscopic hematuria, fever of unknown origin and pulmonary symptoms. Renal venous duplex is **Rarely Appropriate** for evaluation of abdominal bruits and hypertension where an arterial study would be more appropriate.

---

**ADDITIONAL INFORMATION:**

**Definitions:**

**Claudication:** Reproducible muscle discomfort or fatigue occurring with exertion at the same workload and relieved with rest, typically due to arterial obstruction.

**Cold extremity:** Reduced temperature from patient history or observed on physical examination by physician.

**Physiological testing:** Evaluation of the peripheral circulation based on measurement of limb blood pressures with pulse volume recordings or Doppler waveforms, or other parameters without utilizing data from direct imaging of the blood vessels.

**Resistant hypertension:** The failure to normalize blood pressure on 3 or more drug regimen with medications at maximum doses and at least 1 of the medications being a diuretic agent.

**Abbreviations:**

ABI = ankle-brachial index  
ACE = angiotensin-converting enzyme inhibitor  
ACR = American College of Radiology  
ARB = angiotensin II receptor blocker  
AVF = autogenous arteriovenous fistula (including venous transpositions)  
AVG = prosthetic arteriovenous graft  
CABG = coronary artery bypass graft  
CHF = congestive heart failure  
CT = computed tomography  
DVT = deep vein thrombosis  
GI = gastrointestinal  
ICA = internal carotid artery  
ICAVL = Intersocietal Commission for the Accreditation of Vascular Laboratories  
IMT = intima-media thickness  
IVC = inferior vena cava  
PAD = peripheral artery disease  
PVR = pulse volume recording  
RPVI = registered physician in vascular interpretation  
RVT = registered vascular technologist  
RVS = registered vascular sonographer  
TIPS = transjugular intrahepatic portosystemic shunt
REFERENCES


Reviewed / Approved by Caroline Carney, MD, Chief Medical Officer
INTRODUCTION:

A Duplex scan is an ultrasonic scanning procedure used to characterize the pattern and direction of blood flow in arteries or veins with the production of real-time images. While duplex ultrasound is a safe and widely available modality it does have its particular shortcomings and specific indications. Obtaining a high quality study requires the interplay of a number of factors. There are established criteria that are important to consider in order to ensure reliable, interpretable and meaningful results.

A standard screening exam images the native aorta with 2D ultrasound beginning at the diaphragm and documents the maximal transverse and AP diameter. Color may be used to access patency and define the lumen. A gray scale image of the aorta should be recorded.

A review of common clinical scenarios where ultrasound is used follows. These scenarios are scored for appropriate use on a scale of 1-9. A median score of 7-9 indicates that this is an appropriate test for the specific indication. A median score of 4-6 indicates that there is unclear evidence as to the appropriateness of the test. A median score of 1-3 indicates that the test is not generally acceptable for the indication.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.


Section 4. Aortic and Aortoiliac Duplex

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A _ appropriate; I _ inappropriate; U _ uncertain</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Aortic and Aortoiliac Duplex**

**Abdominal Aortic Disease - Signs and/or Symptoms**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>59.</td>
<td>• Lower extremity claudication</td>
<td>A (7)</td>
</tr>
<tr>
<td>60.</td>
<td>• Nonspecific lower extremity discomfort</td>
<td>I (3)</td>
</tr>
<tr>
<td>61.</td>
<td>• New onset abdominal or back pain</td>
<td>U (6)</td>
</tr>
<tr>
<td>62.</td>
<td>• Aneurysmal femoral or popliteal pulse</td>
<td>A (8)</td>
</tr>
<tr>
<td>63.</td>
<td>• Pulsatile abdominal mass</td>
<td>A (9)</td>
</tr>
<tr>
<td>64.</td>
<td>• Decreased or absent femoral pulse</td>
<td>A (7)</td>
</tr>
<tr>
<td>65.</td>
<td>• Abdominal or femoral bruit</td>
<td>A (7)</td>
</tr>
<tr>
<td>66.</td>
<td>• Fever of unknown origin</td>
<td>I (3)</td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
<tr>
<td>---</td>
<td>-----------------------------------------------------------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>67.</td>
<td>Lower extremity swelling</td>
<td>I (2)</td>
</tr>
<tr>
<td>68.</td>
<td>Evidence of atheroemboli in the lower extremities, including ischemic toes</td>
<td>A (8)</td>
</tr>
<tr>
<td>69.</td>
<td>Erectile dysfunction</td>
<td>U (4)</td>
</tr>
<tr>
<td>70.</td>
<td>Abnormal physiologic testing indicating aortoiliac occlusive disease</td>
<td>A (8)</td>
</tr>
<tr>
<td>71.</td>
<td>Hypertension</td>
<td>I (3)</td>
</tr>
<tr>
<td>72.</td>
<td>Abnormal abdominal x-ray suggestive of aneurysm</td>
<td>A (8)</td>
</tr>
<tr>
<td>73.</td>
<td>Presence of a lower extremity arterial aneurysm (e.g., femoral or popliteal)</td>
<td>A (8)</td>
</tr>
<tr>
<td>74.</td>
<td>Presence of a thoracic aortic aneurysm</td>
<td>A (8)</td>
</tr>
<tr>
<td>75.</td>
<td>Men age &gt;60 years</td>
<td>A (8)</td>
</tr>
<tr>
<td></td>
<td>First degree relative with an abdominal aortic aneurysm</td>
<td>A (8)</td>
</tr>
<tr>
<td>76.</td>
<td>Women age &gt;60 years</td>
<td>A (8)</td>
</tr>
<tr>
<td></td>
<td>First degree relative with an abdominal aortic aneurysm</td>
<td>A (8)</td>
</tr>
<tr>
<td>77.</td>
<td>Men age 65 to 75 years</td>
<td>A (8)</td>
</tr>
<tr>
<td></td>
<td>Current or former smoker</td>
<td>A (8)</td>
</tr>
<tr>
<td>78.</td>
<td>Women age 65 to 75 years</td>
<td>A (7)</td>
</tr>
<tr>
<td></td>
<td>Current or former smoker</td>
<td>A (7)</td>
</tr>
<tr>
<td>79.</td>
<td>Age &gt;75 years</td>
<td>A (7)</td>
</tr>
<tr>
<td></td>
<td>Current or former smoker</td>
<td>A (7)</td>
</tr>
<tr>
<td>80.</td>
<td>Age ≥65 years</td>
<td>U (5)</td>
</tr>
<tr>
<td></td>
<td>No history of smoking</td>
<td></td>
</tr>
<tr>
<td>81.</td>
<td>Age &lt;65 years</td>
<td>I (3)</td>
</tr>
<tr>
<td></td>
<td>No history of smoking</td>
<td></td>
</tr>
</tbody>
</table>

**New or Worsening Symptoms**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>82.</td>
<td>Known abdominal aortic aneurysm (any size)</td>
<td>A (9)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>At 3 to 5 months</th>
<th>At 6 to 8 months</th>
<th>At 9 to 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>83.</td>
<td>Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (1)</td>
<td>U (4)</td>
<td>A (7)</td>
</tr>
<tr>
<td>84.</td>
<td>Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (1)</td>
<td>U (4)</td>
<td>A (7)</td>
</tr>
<tr>
<td>85.</td>
<td>Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>U (4)</td>
<td>A (7)</td>
<td>A (7)</td>
</tr>
<tr>
<td>86.</td>
<td>Aneurysm ≥ 5.5 cm in diameter</td>
<td>A (7)</td>
<td>A (7)</td>
<td>U (6)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms, No or Slow Progression During First Year, Surveillance Frequency After First Year**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Every 6 months</th>
<th>Every 12 months</th>
<th>Every 23 months or greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>87.</td>
<td>Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (2)</td>
<td>A (7)</td>
<td>A (7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>---</td>
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<td></td>
</tr>
<tr>
<td>88.</td>
<td>• Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (2)</td>
<td>A (7)</td>
<td>A (7)</td>
</tr>
<tr>
<td>89.</td>
<td>• Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>U (5)</td>
<td>A (7)</td>
<td>U (6)</td>
</tr>
<tr>
<td>90.</td>
<td>• Aneurysm ≥ 5.5 cm in diameter</td>
<td>A (8)</td>
<td>A (7)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms, Rapid Progression During First Year, Surveillance Frequency After First Year**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>91.</td>
<td>• Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>A (7)</td>
<td>A (7)</td>
</tr>
<tr>
<td>92.</td>
<td>• Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>A (8)</td>
<td>A (7)</td>
</tr>
<tr>
<td>93.</td>
<td>• Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>A 8)</td>
<td>A (7)</td>
</tr>
<tr>
<td>94.</td>
<td>• Aneurysm ≥ 5.5 cm in diameter</td>
<td>A (9)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

**Surveillance After Aortic Endograft or Aortoiliac Stenting**

**Baseline (Within 1 Month After the Intervention)**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>95.</td>
<td>• Aortic or iliac endograft</td>
<td>A (8)</td>
</tr>
<tr>
<td>96.</td>
<td>• Aortic and iliac artery stents</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**New or Worsening Lower Extremity Symptoms After Baseline Exam**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>97.</td>
<td>• Aortic or iliac endograft</td>
<td>A (8)</td>
</tr>
<tr>
<td>98.</td>
<td>• Aortic and iliac artery stents</td>
<td>A (8)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptom After Baseline Study, Surveillance Frequency During First Year.**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>99.</td>
<td>• Aortic endograft without endoleak stable and/or decreasing residual aneurysm sac size</td>
<td>I (3)</td>
</tr>
<tr>
<td>100.</td>
<td>• Aortic endograft with endoleak and/or increasing residual aneurysm sac size</td>
<td>U (6)</td>
</tr>
<tr>
<td>101.</td>
<td>• Aortic or iliac artery stents</td>
<td>I (2)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptom After Baseline Study, Surveillance Frequency After the First Year.**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>102.</td>
<td>• Aortic endograft without endoleak stable and/or decreasing residual aneurysm sac size</td>
<td>I (3)</td>
</tr>
<tr>
<td>103.</td>
<td>• Aortic endograft with endoleak and/or increasing residual aneurysm sac size</td>
<td>A (8)</td>
</tr>
<tr>
<td>104.</td>
<td>• Aortic or iliac artery stents</td>
<td>I (2)</td>
</tr>
</tbody>
</table>
Section 3: Duplex Evaluation of the Inferior Vena Cava and Iliac Veins

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>75.</td>
<td>Prior to IVC filter placement</td>
<td>M (6)</td>
</tr>
<tr>
<td>76.</td>
<td>Lower extremity swelling – unilateral or bilateral as a “stand-alone test” without venous duplex of the lower extremities</td>
<td>R (3)</td>
</tr>
<tr>
<td>77.</td>
<td>Lower extremity swelling – unilateral or bilateral combined routinely with a venous duplex of the lower extremities</td>
<td>M (4)</td>
</tr>
<tr>
<td>78.</td>
<td>Lower extremity swelling – unilateral or bilateral performed selectively – when the lower extremity venous duplex is normal</td>
<td>M (6)</td>
</tr>
<tr>
<td>79.</td>
<td>Lower extremity swelling – unilateral or bilateral performed selectively – when the lower extremity venous duplex is positive for acute proximal DVT</td>
<td>A (7)</td>
</tr>
<tr>
<td>80.</td>
<td>Selectively – when the flow pattern in 1 or both common femoral veins is abnormal</td>
<td>A (8)</td>
</tr>
<tr>
<td>81.</td>
<td>Pulmonary symptoms (suspected pulmonary embolus) as a “stand-alone test” without a venous duplex of the lower extremities</td>
<td>R (2)</td>
</tr>
<tr>
<td>82.</td>
<td>Pulmonary symptoms (suspected pulmonary embolus) – combined routinely with a venous duplex of the lower extremities</td>
<td>M (4)</td>
</tr>
</tbody>
</table>

ADDITIONAL CONSIDERATIONS (Gornik, 2013):

Duplex ultrasound is used for assessment of the Iliac Veins and Inferior Vena Cava most often in conjunction with an abnormal Lower extremity venous duplex. Scanning of the iliac veins is Appropriate.
when there is acute proximal femoral thrombus thought to extend superior to the inguinal ligament. An obstructive flow pattern, which is associated with lack of augmentation of femoral venous flow with expiration, suggests proximal obstruction. In patients with this finding during a lower extremity venous duplex study a scan of the iliac veins and IVC is warranted. Most often these are limited and/or unilateral studies as generally it is not necessary to fully evaluate the arterial system or scan the unaffected side.

Duplex evaluation of the iliac veins and IVC is Not Appropriate as a stand alone test for shortness of breath, limb swelling, or abdominal pain. It has some utility in the preprocedural planning in patients being considered for placement of a Vena Caval filter.

**ADDITIONAL INFORMATION (Gornik, 2013):**

**Definitions:**

Claudication: Reproducible muscle discomfort or fatigue occurring with exertion at the same workload and relieved with rest, typically due to arterial obstruction.

Cold extremity: Reduced temperature from patient history or physical examination by physician.

Physiological testing: Evaluation of the peripheral circulation based on measurement of limb blood pressures with pulse volume recordings or Doppler waveforms, or other parameters without utilizing data from direct imaging of the blood vessels.

**Abbreviations:**

ABI = ankle-brachial index  
ACE = angiotensin-converting enzyme inhibitor  
ACR = American College of Radiology  
ARB = angiotensin II receptor blocker  
AVF = autogenous arteriovenous fistula (including venous transpositions)  
AVG = prosthetic arteriovenous graft  
CABG = coronary artery bypass graft  
CHF = congestive heart failure  
CT = computed tomography  
DVT = deep vein thrombosis  
GI =gastrointestinal  
ICA = internal carotid artery  
ICAVL = Intersocietal Commission for the Accreditation of Vascular Laboratories  
IMT = intima-media thickness  
IVC = inferior vena cava  
PAD = peripheral artery disease  
PVR = pulse volume recording  
RPVI = registered physician in vascular interpretation  
RVT = registered vascular technologist  
RVS = registered vascular sonographer  
TIPS = transjugular intrahepatic portosystemic shunt
REFERENCES


INTRODUCTION:

A Duplex scan is an ultrasonic scanning procedure used to characterize the pattern and direction of blood flow in arteries or veins with the production of real-time images. While duplex ultrasound is a safe and widely available modality it does have its particular shortcomings and specific indications. Obtaining a high quality study requires the interplay of a number of factors. There are established criteria that are important to consider in order to ensure reliable, interpretable and meaningful results.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR VENOUS DUPLEX ULTRASONOGRAPHY (AIUM, 2011):

- Erectile dysfunction, impaired erection or complete impotence. (Patel, 2012)
- Penile trauma (Nicola, 2014)
- Dorsal vein thrombosis (Nazir, 2017)
- Priapism (Shigehara, 2016)
- Penile fibrosis and/or penile curvature (Peyronie’s disease; Kalokairinou, 2012)
- Penile tumors (Rocher, 2012)
- Urethral stricture, diverticulum, or cyst (AUA, 2016)
- Penile or urethral calculus or foreign body (Kim, 2007)

INDICATIONS FOR PENILE COLOR CODED DUPLEX SONOGRAPHY (CCDS)* or DYNAMIC PENILE COLOR DUPLEX ULTRASOUND (D-PCDU) (Altinkilic, 2004):

- Evaluation of patients with erectile dysfunction unresponsive to oral medications when ordered by Urologist.

* Penile color coded duplex sonography (CCDS) combined with the pharmaco-erection test represents an acceptable method of evaluating penile arterial and veno-occlusive function. Peak systolic velocity and a change in cavernous artery diameter are indicators of arterial inflow, while the pathologic end diastolic velocity and resistance index point out veno-occlusive dysfunction.
REFERENCES


CPT Codes: 93990

INTRODUCTION:

A duplex scan is an ultrasonic scanning procedure used to characterize the pattern and direction of blood flow in arteries or veins with the production of real-time images. While duplex ultrasound is a safe and widely available modality it does have its particular shortcomings and specific indications. Obtaining a high quality study requires the interplay of a number of factors. There are established criteria that are important to consider in order to ensure reliable, interpretable and meaningful results.

The following table includes situations in which ultrasound duplex assessment of hemodialysis access sites is indicated. Note that NIA does not review requests for ultrasound studies to determine appropriate INITIAL placement of an access site (“Assessment Prior to Access Site Placement” (Gornik, 2013)); NIA reviews only requests for studies of hemodialysis sites already in place.

These scenarios are scored for appropriate use on a scale of 1-9. A median score of 7-9 indicates that this is an appropriate test for the specific indication. A median score of 4-6 indicates that there is unclear evidence as to the appropriateness of the test. A median score of 1-3 indicates that the test is not generally acceptable for the indication.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.


Section 5: Hemodialysis Vascular Access Duplex Ultrasound

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-Operative Assessment of a Vascular Access Site</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Failure to Mature</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>107.</td>
<td>“Failure to mature” on basis of physical examination 0-6 weeks after placement</td>
<td>M (6)</td>
</tr>
<tr>
<td>108.</td>
<td>“Failure to mature” on basis of physical examination &gt;6 weeks after placement</td>
<td>A (8)</td>
</tr>
<tr>
<td><strong>Symptoms and Signs of Disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>109.</td>
<td>Signs of access site malfunction during dialysis (e.g., low blood flows, kt/V, recirculation times, or increased venous pressure)</td>
<td>A (8)</td>
</tr>
<tr>
<td>110.</td>
<td>Mass associated with an AVF/AVG</td>
<td>A (8)</td>
</tr>
<tr>
<td>111.</td>
<td>Loss of palpable thrill of AVF/AVG</td>
<td>A (8)</td>
</tr>
</tbody>
</table>
112.  • Arm swelling  

113.  • Hand pain, pallor, and/or digital ulceration (i.e., evaluation for suspected arterial steal syndrome)  

114.  • Cool extremity  
• Without pain, pallor, or ulceration  

115.  • Difficult cannulation by multiple personnel on multiple attempts  

116.  • Routine surveillance of a functioning AVF or AVG  

**Asymptomatic**

**ADDITIONAL CONSIDERATIONS (Gornik, 2013):**

Duplex ultrasound is **Appropriate** for vascular assessment of hemodialysis access when performed within three months of the access placement. It is **Inappropriate** to perform scans earlier than 3 months prior to access placement due to the potential for interval development of vascular lesions such as venous thrombosis. Following access placement the need for scans are largely dictated by clinical findings and performance of the access during dialysis.

Determination of failure to mature is **Appropriate** 6 weeks following access placement. Evaluation of signs of access malfunction in mature, previously functional access sites is **Appropriate** as is evaluation of a mass, loss of thrill, and arm swelling. Hand pain, pallor and ulceration are signs and symptoms of arterial steal which results from reversal of flow in the palmer arteries. It is **Appropriate** to use duplex ultrasound in the evaluation of that scenario. It is **Inappropriate** to use duplex ultrasound for surveillance of normal functioning access.

**ADDITIONAL INFORMATION (Gornik, 2013):**

**Definitions:**

**Claudication:** Reproducible muscle discomfort or fatigue occurring with exertion at the same workload and relieved with rest, typically due to arterial obstruction.

**Cold extremity:** Reduced temperature from patient history or observed on physical examination by physician.

**KT/V = Kt/V** is another test that tells you how well dialysis is cleaning your blood. Kt/V is considered more accurate than URR (urea reduction ratio) because it takes into account your size, treatment time, blood flow rate, how much urea your body makes during dialysis and the extra urea and fluid removed in your dialysis session

**Physiological testing:** Evaluation of the peripheral circulation based on measurement of limb blood pressures with pulse volume recordings or Doppler waveforms, or other parameters without utilizing data from direct imaging of the blood vessels.

**Resistant hypertension:** The failure to normalize blood pressure on 3 or more drug regimen with medications at maximum doses and at least 1 of the medications being a diuretic agent.

**Abbreviations:**
ACR = American College of Radiology
AVF = autogenous arteriovenous fistula (including venous transpositions)
AVG = prosthetic arteriovenous graft
CHF = congestive heart failure
DVT = deep vein thrombosis
IVC = inferior vena cava
RPVI = registered physician in vascular interpretation
RVT = registered vascular technologist
RVS = registered vascular sonographer
TIPS = transjugular intrahepatic portosystemic shunt
REFERENCES


Reviewed / Approved by Caroline Carney, MD, Chief Medical Officer
INTRODUCTION:

Treatment of sleep disorders is often managed during standard evaluation and management services. The “Sleep Disorder Treatment Initiation and Management” service can be used when the only purpose for the office visit is for the implementation of, or issue resolution related to, a Positive Airway Pressure (PAP) device. Devices include Continuous Positive Airway Pressure (CPAP), Bi-Positive Airway Pressure (BiPAP), Auto-Adjusting Positive Airway Pressure (APAP), and Variable Positive Airway Pressure (VPAP).

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR SLEEP DISORDER TREATMENT INITIATION AND MANAGEMENT (ATS, 2010; Epstein, 2009; Kushida, 2006, 2008):

- The patient has been previously diagnosed by a physician with a sleep disorder that would benefit from treatment using a PAP device, AND the chief purpose of the office visit with the physician is to initiate PAP device treatment or address issues related to the PAP device, AND
- The patient requires education or problem solution related to the PAP device, AND
- The visit does not include discussion of other health issues beyond initiation and management of a PAP device.

ADDITIONAL INFORMATION RELATED TO SLEEP DISORDER TREATMENT INITIATION AND MANAGEMENT:

- This service should not occur for the same patient on the same date as an evaluation and management service.
REFERENCES


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699173.


INTRODUCTION:

Attended sleep tests or polysomnography (PSG) are used to assess sleep related disorders. This guideline provides criteria for attended sleep studies for initial and repeat diagnosis as well as follow-up of therapeutic interventions for these conditions for adult and pediatric patients:

- Obstructive sleep apnea
- Narcolepsy
- Parasomnias and seizure disorder
- Periodic limb movement disorder

Sleep studies refer to the continuous and simultaneous recording of various physiological parameters of sleep followed by physician review and interpretation, performed in the diagnosis and management of sleep disorders. Sleep studies have been classified based on the number and type of physiologic variables recorded and whether or not the study is attended by a technologist or performed with portable equipment in the home or some other unattended setting. (See “Additional Information” below.)

Polysomnography requires a minimum of the following channels: Electroencephalogram (EEG), Electrooculogram (EOG), chin Electromyogram (EMG), air-flow, oxygen saturation, respiratory effort and heart rate, attended by a technologist (AASM, 2017).

INDICATIONS FOR SLEEP STUDY, ATTENDED – ADULTS:

An attended sleep study can be approved for patients who require a sleep assessment and have contraindications for an unattended sleep test (Home Sleep Test).

Unattended (home) sleep studies are considered medically necessary for patients with symptoms suggestive of OSA when the home sleep study is used as part of a comprehensive sleep evaluation, using a Type II, Type III, or Type IV device measuring airflow.

An attended sleep study (polysomnography (PSG)) is approvable when the patient has:

- At least one of the following co-morbid conditions that reduce the accuracy of portable monitoring (Collop, 2007; Qaseem, 2014; Kapur, 2017):
  - Moderate to severe pulmonary disease (for example, COPD or asthma) (with nocturnal oxygen use or daytime hypercapnia with documented arterial blood gases showing \( pO_2 \) less than 60 or \( pCO_2 \) greater than 45)
  - Neuromuscular disease (e.g., Parkinson’s disease, spina bifida, myotonic dystrophy, amyotrophic lateral sclerosis)
  - History of stroke
  - Epilepsy
  - Congestive heart failure (NYHA class III or IV or LVEF less than 45%)
- Obesity with BMI >45, or pulmonary function studies show obesity hypoventilation syndrome (BMI >35 plus arterial blood gas with PCO$_2$ >45, or BMI >35 plus inability to lie flat in bed);
- Awake hypoventilation or suspicion of sleep-related hypoventilation
- Chronic opioid medication use
- Severe insomnia

OR

- One or more of the following suspected sleep disorders (See detailed criteria in following sections)
  - Periodic limb movement disorder
  - Parasomnias that are unusual or Narcolepsy,
  - Central sleep apnea or complex sleep apnea;

OR

- Negative or technically inadequate portable (Home) monitoring results; or
- Low pretest probability of obstructive sleep apnea (BMI <30, normal airway, no snoring, and neck circumference <17 inches in men and <16 inches in women and Epworth Score <10) but likely has other sleep disorders not identified during unattended (Home) study; or
- Patient lacks the mobility or dexterity to use portable monitoring equipment safely at home.

**Indications for evaluating suspected obstructive sleep apnea (OSA)**

- Individuals who present with clinical features suggestive of moderate to severe OSA as follows:
  - Excessive daytime sleepiness (EDS) and ONE of the following:
    - BMI >30: or
    - Excessive sleepiness while driving: or
    - Loud/intense snoring: or
    - Epworth Sleepiness Scale (ESS) score of 10 or greater (Johns, 1991, 1997): or
    - Witnessed nocturnal apnea, choking, and/or gasping.
- Unattended (home) sleep studies are considered medically necessary for patients with symptoms suggestive of OSA unless criteria for an attended sleep study (e.g., comorbid conditions, chronic opioid use, suspected non-OSA sleep disorder) are also met.

See preceding section.

**Indications for a split night sleep study** (Kawaja, 2010; Kushida, 2008):

Where attended PSG is indicated, a split-night study PSG is considered medically necessary. The initial 2 or more hours of the PSG is used to diagnose OSA and the final portion is used to titrate continuous positive airway pressure (CPAP) if the Apnea Hypopnea Index (AHI) is >15 in first 2 hours. There must be 3 hours available to perform the CPAP titration (Kapur, 2017).

**Indications for a follow-up attended sleep study after a split night study:**

- An additional full-night attended sleep study for CPAP/BiPAP titration is considered medically necessary only
  - If the diagnostic portion of the split night study fails to demonstrate an AHI of >15, but the overall study reaches this threshold due to events occurring later in the night, or
  - If patient has AHI between 5 and 15, and significant daytime sleepiness, or
  - If during the titration portion of the split night the titration is not successful (there are residual apneas or hypopneas).

**Indication for an Attended Sleep Study following a Home Sleep Test:**

- An Attended Sleep Study following a Home Sleep Test (HST) is considered medically necessary
  - If a home study is technically inadequate (e.g., loss of signal through the night, bad recording due to patient device interface problem, etc.), or
- If the Home Sleep Test is positive (AHI>15) and an attended sleep study is needed for CPAP/BiPAP titration.

**Indications for repeat sleep studies in patients with diagnosed OSA:**
- If repeat testing is indicated, attended full-channel nocturnal polysomnography (PSG) (Type I device) performed in a healthcare facility is considered medically necessary the individual meets criteria for attended PSG (above); otherwise, unattended (home) sleep studies are considered medically necessary.
- Repeat sleep studies may be indicated up to twice a year for:
  - Determining if treatment is objectively effective in patients continuing to report symptoms (e.g. daytime sleepiness or snoring) despite adequate adherence (4 hours a night for 70 percent of nights over a 30 day period), or
  - Patients requiring a change of device due to intolerance of current device
  - Determining if positive airway pressure treatment settings need to be changed; or
  - Determining if continued treatment with positive airway pressure treatment is necessary, such as following a significant weight loss or recurrent symptoms, or
  - Assessing treatment response after upper airway surgical procedures, or initial treatment with oral appliances.

**Indications for evaluation of patients with Narcolepsy/Idiopathic CNS Hypersomnia (Dauvillers, 2004; Guilleminault, 1998):**
- A multiple sleep latency test (MSLT) is indicated for patients suspected of having narcolepsy as evidenced by:
  - Excessive daytime sleepiness
  - Cataplexy
  - Hypnogogic hallucinations
  - Sleep paralysis
- MSLT is also indicated for the evaluation of suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy (Aurora, 2012; Duvallier, 2004; Littner, 2005; Thorpy, 1992).
- *All other indications are considered experimental and investigational since effectiveness for other indications have not been established.*

**Indications for the evaluation of patients with parasomnias and seizure disorders (Cao, 2010; Guilleminault, 2005):**
- Polysomnography with expanded bilateral montage and video recording is indicated for evaluation of patients WITH inconclusive EEG results AND with sleep behaviors suggestive of parasomnias (such as sleep disruptions thought to be sleep-related seizures or paroxysmal arousals) that are unusual or atypical because of:
  - The patient’s age at onset
  - The time, duration or frequency of occurrence
  - Behaviors that are violent or otherwise potentially injurious to the patient or others
  - Features of the particular motor patterns in question, (e.g., stereotypical, repetitive, or focal)

**Indications for the evaluation of patients with periodic limb movement disorder (Martin, 2008; Montgomery-Downs, 2005; Montplaisir, 1997):**
- Polysomnography is indicated when patient or an observer report repetitive limb movements during sleep with the following:
  - Frequent awakenings, or
  - Difficulty maintaining sleep, or
  - Excessive daytime sleepiness, and
  - Movements are not associated with moderate or high pre-test probability of OSA

- Habitual snoring during sleep to differentiate primary snoring from obstructive sleep apnea syndrome (OSAS)
- Hypersomnia
- Suspected narcolepsy as suggested by the presence of:
  - Excessive daytime sleepiness
  - Cataplexy
  - Hypnagogic hallucinations
  - Sleep paralysis
- Suspected parasomnia or seizure disorders:
  - When NREM parasomnias, epilepsy, or nocturnal enuresis exist, if suspicion for co-morbid sleep disorder such as sleep-disordered breathing has been identified.
  - When there is snoring and craniofacial features that predispose to sleep disordered breathing.
- Suspected restless leg syndrome or periodic limb movement disorder
  - When patient or an observer report repetitive limb movements during sleep and frequent awakenings, fragmented sleep, difficulty maintaining sleep, or excessive daytime sleepiness, or
  - To document periodic limb movements when this disorder is suspected.
- Suspected congenital central alveolar hypoventilation syndrome
- Suspected sleep related hypoventilation due to neuromuscular disorders or chest wall deformities
- Following an apparent life-threatening event where there is clinical evidence of sleep-related breathing disorder.
- Children being considered for adenotonsillectomy to treat OSAS.
- Following an adenotonsillectomy or other pharyngeal surgery for OSAS when any of the following is met (study should be delayed 6 to 8 weeks postoperatively):
  - Age younger than 3 years; or
  - Cardiac complications of OSAS (e.g., right ventricular hypertrophy); or
  - Craniofacial anomalies; or
  - Failure to thrive; or
  - Neuromuscular disorders; or
  - Obesity; or
  - Prematurity; or
  - Recent respiratory infection; or
  - Severe OSAS was present on preoperative PSG (a respiratory disturbance index of 19 or greater); or
  - Presence of symptoms of OSAS persisting after treatment.
- The following are experimental or investigational:
  - Videotaping
  - Nocturnal pulse oximetry
  - Daytime nap PSG
  - Measurements of a) circulating adropin, b) plasma pentraxin 3, c) plasma TREM 1
  - Home (unattended) sleep studies

**Indications for repeat sleep studies in pediatric patients**

- To titrate level to titrate positive pressure therapy
- To determine if pressure requirements are appropriate in presence of ongoing symptoms
- If child has had rapid maxillary development (change in craniofacial abnormalities)
- In child with oral appliance to assess response to treatment
• Neurologic disorders (e.g., Down syndrome, Prader Willi syndrome) and persistent snoring or other symptoms following treatment
• Significant weight change or significant growth and development.

ADDITIONAL INFORMATION RELATED TO SLEEP STUDY, ATTENDED:

CPAP titration: A cardiorespiratory sleep study without EEG recording is not recommended for CPAP titration. CPAP titration should include sleep staging and the ability to identify arousals to appropriately titrate CPAP with a goal of the elimination or near elimination of apneas, hypopneas and respiratory related arousals in REM and NREM sleep, including REM sleep with the patient in the supine position.

Daytime nap polysomnography (sometimes referred to as “PAP-nap”) is not considered medically necessary.

Maintenance of wakefulness test is considered investigational for members with symptoms suggestive of OSA because its effectiveness for this indication has not been established:


Home sleep test (HST): When a Sleep Study, Unattended (i.e. Home Sleep Test, or HST) is a covered benefit, the health plan may require use of the unattended study unless the patient has contraindications or co-morbidities that would require an attended sleep study. (See separate clinical guideline for “Sleep Study, Unattended” when that procedure requires authorization.)

Narcolepsy: For Narcolepsy, PSG may be done on the night preceding MSLT to rule out other sleep disorders and to document adequate nocturnal sleep time prior to daytime MSLT to help confirm diagnosis of narcolepsy and determine severity of daytime sleepiness
  ▪ Multiple Sleep Latency Testing (MSLT) includes minimum channels of EEG, EOG, chin EMG and ECG)
  ▪ The use of MSLT to support a diagnosis of narcolepsy is suspect if Total Sleep Time on prior night sleep study is less than 6 hours
  ▪ MSLT should not be performed after a split night sleep study

OSA: Obstructive sleep apnea is characterized by recurrent episodes of upper airway obstruction and is linked with reductions in ventilation, resulting in repeated arousals and episodic oxyhemoglobin desaturations during sleep.

Parasomnias and seizure disorders: Polysomnography for evaluation of parasomnias and seizure disorders includes minimum channels of EEG, EOG, chin EMG; (EEG using an expanded bilateral montage; and anterior tibialis or extensor digitorum EMG for body movements) and video with documented technologist observations.
  ▪ PSG is used to assist in the diagnosis of paroxysmal arousals or other sleep disruptions that are thought to be sleep related seizures when initial clinical evaluation and standard EEG are inconclusive.
  ▪ PSG is not routinely indicated in cases of typical, uncomplicated, non-injurious parasomnias when the diagnosis is clearly delineated.
For pediatric patients, studies have indicated that there is a significant prevalence of sleep disordered breathing, ranging from 58% to 100% on PSG in children with chronic NREM parasomnias.

**Periodic limb movement disorder:** Polysomnography for the evaluation of periodic limb movement disorder includes minimum channels of EEG, EOG, chin EMG, and left and right anterior tibialis EMG AND respiratory effort, airflow and oximetry.

**Split-night study:** A split-night study must be used unless criteria are met for a second night titration study (see above in “split night study” section). A split night study is expected for most attended PSGs. In a split night sleep study, the diagnosis of OSA is established in the first half of the night and the optimal CPAP pressure is determined during the second half of the night, if the Apnea+ Hypopnea Index (AHI) is >15 in the first 2 hours of the diagnostic portion of the study.

**Types/Levels:** The types of sleep studies are as follows:

<table>
<thead>
<tr>
<th>Type(Level)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Standard polysomnography (PSG) with a minimum of 7 parameters measured, including EEG, EOG, chin EMG, and ECG, as well as monitors for airflow, respiratory effort, and oxygen saturation. A sleep technician is in constant attendance.</td>
</tr>
<tr>
<td>II</td>
<td>Comprehensive portable PSG studies that measure the same channels as type I testing, except that a heart rate monitor can replace the ECG and a sleep technician is not necessarily in attendance.</td>
</tr>
<tr>
<td>III</td>
<td>Monitor and record a minimum of 4 channels and must record ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. A sleep technician is not necessarily in constant attendance but is needed for preparation.</td>
</tr>
<tr>
<td>IV</td>
<td>Three or more channels, one of which is airflow. Other measurements include oximetry and at least 2 other parameters (e.g. body position, EOG, peripheral arterial tonometry (PAT) snoring, actigraphy, airflow). A sleep technician is not necessarily in attendance but is needed for preparation.</td>
</tr>
</tbody>
</table>
REFERENCES


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699173.


http://www.aasmnet.org/Resources/PracticeParameters/PP_MSLTMWT.pdf.


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2276827.


INTRODUCTION:

Obstructive sleep apnea (OSA) is a common disorder and is associated with significant morbidity and mortality. Recent epidemiologic data have demonstrated that the prevalence of moderate to severe sleep-disordered breathing is 10% among 30-49-year-old men; 17% among 50-70-year-old men; 3% among 30-49-year-old women; and 9% among 50-70 year-old women. These percentages are substantially increased from previously reported studies (Young, 1993; Peppard, 2013). OSA is caused by recurrent complete or partial upper airway obstruction during sleep resulting in loud snoring or apnea frequently reported by a bed partner, episodes of gasping or choking, and associated frequent awakenings from sleep. The increase in prevalence of OSA is likely largely attributable to the rising rates of obesity resulting in the United States, as obesity is often associated with a narrowed upper airway.

The diagnosis of OSA is made by clinical evaluation and confirmed by sleep testing. Unattended home sleep studies are indicated to confirm the diagnosis of sleep apnea as part of a comprehensive sleep evaluation. This guideline outlines the indications and contra-indications for unattended home sleep studies in adults with suspected OSA.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR HOME SLEEP STUDY, UNATTENDED- ADULTS (Collop, 2007; Kapur, 2017)

Indications for the evaluation of suspected Obstructive Sleep Apnea in adults >18 years old:
Home sleep studies are indicated if the patient meets the following criteria and there are no contraindications to a home sleep study (Collop, 2007) (see “Contraindications to Home Sleep Study” below).

- Witnessed apnea during sleep OR any two of the following
  - Habitual loud snoring punctuated by choking, gasping, or grunting episodes
  - Epworth Sleepiness Scale score >10 (See “Additional Information”)
  - Headache upon awakening
  - Decreased concentration, memory, or daytime alertness
  - Sleep fragmentation or sleep maintenance insomnia (difficulty maintaining sleep)
  - Obesity (BMI > 35kg/m2)
  - Large neck circumference (> 17 inches in men, >16 inches in women)
  - Craniofacial or upper airway soft tissue abnormalities, including:
    1) Adenotonsillar enlargement
    2) Modified Mallampati score of 3 or 4 (See “Additional Information”)
    3) Retrognathia
    4) Lateral peritonsillar narrowing
    5) Elongated/enlarged uvula
    6) High arched/narrow hard palate
    7) Nasal abnormalities (polyps, deviation, valve abnormalities, turbinate hypertrophy)
- Hypertension
- Congestive Heart Failure: NYHA class I or II (see “Additional Information”)

CONTRAINDICATIONS FOR HOME SLEEP STUDY, UNATTENDED - ADULTS

<table>
<thead>
<tr>
<th>Comorbid Medical Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Moderate to severe COPD-FEV1/FVC 0.7 and FEV1 less than 80% predicted</td>
</tr>
<tr>
<td>• Chronic opiate medication use</td>
</tr>
<tr>
<td>• Neuromuscular disease (e.g. Parkinson’s disease, ALS)</td>
</tr>
<tr>
<td>• Congestive Heart Failure: NYHA class III or IV (see “Additional Information”)</td>
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<tr>
<td>• Stroke</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbid Sleep Disorders suspected</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Periodic Limb Movement disorder</td>
</tr>
<tr>
<td>• Parasomnia</td>
</tr>
<tr>
<td>• REM behavior disorder</td>
</tr>
<tr>
<td>• Nocturnal seizures</td>
</tr>
<tr>
<td>• Narcolepsy or idiopathic hypersomnia</td>
</tr>
<tr>
<td>• Circadian Rhythm Disorder</td>
</tr>
<tr>
<td>• Central sleep apnea or complex sleep apnea</td>
</tr>
<tr>
<td>• Hypoventilation</td>
</tr>
<tr>
<td>• Sleep-related hypoxemia</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Technical Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inability to follow instructions or lack of mobility or dexterity to use portable equipment and the absence of a competent care giver</td>
</tr>
<tr>
<td>• Previous negative or technically inadequate home sleep study</td>
</tr>
</tbody>
</table>

INDICATIONS FOR REPEAT HOME SLEEP STUDY IN PATIENTS WITH DIAGNOSED OSA

A repeat home sleep study is indicated in patients with diagnosed OSA if there is no contraindication listed in the table above and a re-evaluation is required for:
- Appropriateness of PAP pressure settings because of persistent symptoms of disturbed sleep or daytime sleepiness despite AH1 ≤ 5 on initial titration AND documented compliance with PAP > 4 hrs/night for ≥ 5 nights/week.
- Response to upper airway surgical procedures
- Response after initial treatment with oral appliances
- Appropriateness of PAP after either gain or loss of ≥ 10% of body weight

ADDITIONAL INFORMATION RELATED TO SLEEP STUDIES

- Types/Levels: Sleep studies refer to the continuous and simultaneous recording of various physiological parameters of sleep and breathing. Sleep studies have been classified based on the number and type of physiologic variables recorded and whether or not the study is attended by a technologist or performed using portable equipment in the home or some other unattended setting.

The types of sleep studies are as follows:
<table>
<thead>
<tr>
<th>Type (Level)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Standard polysomnography (PSG) with a minimum of 7 parameters measured, including EEG, EOG, chin EMG, and ECG, as well as monitors for airflow, respiratory effort, and oxygen saturation. A sleep technician is in constant attendance.</td>
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<tr>
<td>II</td>
<td>Comprehensive portable PSG studies that measure the same channels as type I testing, except that a heart rate monitor can replace the ECG and a sleep technician is not necessarily in attendance.</td>
</tr>
<tr>
<td>III</td>
<td>Monitor and record a minimum of 4 channels and must record ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. A sleep technician is not necessarily in constant attendance but is needed for preparation.</td>
</tr>
<tr>
<td>IV</td>
<td>Three or more channels, one of which is airflow. Other measurements include oximetry and at least 2 other parameters (e.g. body position, EOG, peripheral arterial tonometry (PAT) snoring, actigraphy, airflow). A sleep technician is not necessarily in attendance but is needed for preparation.</td>
</tr>
</tbody>
</table>

Type II, Type III and Type IV devices are used for unattended home sleep studies. When Type III and Type IV devices are used, which do not include sleep EEG recording channels, AHI is calculated by dividing the total number of apneas + hypopneas by the total recording time.

- **CPAP Titration**: A cardiorespiratory sleep study without EEG recording is not recommended for CPAP titration. CPAP titration should include sleep staging and the ability to identify arousals to appropriately titrate CPAP with a goal of the elimination or near elimination of apneas, hypopneas and respiratory related arousals in REM and NREM sleep, including REM sleep with the patient in the supine position (Epstein 2009).


- **Mallampati Score**: The Mallampati score was first described by an anesthesiologist and colleagues (Mallampati, 1985) to describe difficulty of intubation of patients going to surgery. The score actually describes the degree of patency of the posterior pharynx. The more patent the posterior airway, the easier the intubation. The original Mallampati score had only 3 gradations, but the more commonly used system has four classifications. The Modified Mallampati scores are described as follows:
  - Class I: Soft palate, uvula, fauces, pillars visible.
  - Class II: Soft palate, uvula, fauces visible.
  - Class III: Soft palate, base of uvula visible.
  - Class IV: Only hard palate visible

The scoring is done with the patient opening his mouth wide and sticking out his tongue. Proceeding from Class I to Class IV, there is less and less of an opening observed at the back of the mouth/throat, implying a narrower airway due to excessive tissue or anatomic variation.

**New York Heart Association (NYHA) Functional Classes** (Dolgin, 1994)

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (Mild)</td>
<td>Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs, etc.</td>
</tr>
</tbody>
</table>
### Class II (Mild)
- Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

### Class III (Moderate)
- Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20–100 m).
- Comfortable only at rest.

### Class IV (Severe)
- Severe limitations. Experiences symptoms even while at rest.
- Mostly bedbound patients.

- **Unattended Sleep Study - Home Sleep Test (HST) vs. Attended Sleep Study**: When a Sleep Study, Unattended (i.e. Home Sleep Test, or HST) is a covered benefit, the health plan may require use of the unattended study unless the patient has contraindications or co-morbidities that would require an attended sleep study. Home Sleep Tests are considered inappropriate for testing people with co-morbid conditions, people who are suspected of having sleep disorders other than Obstructive Sleep Apnea (OSA), and those who are not in the category of high risk for moderate to severe OSA. There may be some situations in which Home Sleep Test may require follow-up with an attended test when the home test is negative or there are other factors that contribute to a HST failure.

- **AHI/RDI**: After physician review and interpretation of the data recorded in sleep studies, the total number, type, and rate of occurrence of apneas (cessation of breathing for at least 10 seconds) and hypopneas (reduction, but not cessation of airflow with an associated fall in oxygen saturation of 3 to 4% or an arousal) are reported and the number of events per hour, the Apnea/Hypopnea Index (AHI) or respiratory disturbance index (RDI) is calculated to classify the severity of OSA:

<table>
<thead>
<tr>
<th>Severity of OSA in adults &gt; 18 years old</th>
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</thead>
<tbody>
<tr>
<td>AHI= 5-15/hr</td>
<td>Mild OSA</td>
</tr>
<tr>
<td>AHI= 15-30/hr</td>
<td>Moderate OSA</td>
</tr>
<tr>
<td>AHI= &gt;30/hr</td>
<td>Severe OSA</td>
</tr>
</tbody>
</table>

An AHI of 15 or more/hr of sleep even in the absence of sleep related symptoms is sufficient for the diagnosis of sleep apnea and warrants treatment due to a greater association of this level of sleep disordered breathing with consequences such as increased cardiovascular risk (Epstein, 2009).

The terms RDI/AHI have been defined differently when used with Home Sleep Testing than when used with Polysomnography (PSG). RDI/AHI is the number of apneas + hypopneas/total recording time, rather than the total sleep time since sleep parameters are not recorded with type III and IV devices. As a result, Home Sleep Testing is more likely to underestimate the severity of events compared to the RDI/AHI by PSG. Due to this risk of false negative HST tests, in laboratory PSG should be performed in cases where HST is technically inadequate or fails to establish the diagnosis of OSA in patients with a high pre-test probability.

- **Treatment of OSA**: Treatment of OSA requires the use of positive airway pressure devices to provide a pneumatic splint to maintain upper airway patency during sleep. PAP devices can deliver continuous positive airway pressure (CPAP), bi-level positive airway pressure (BPAP), where there is a difference in inspiratory and expiratory positive pressure, or automatically titrating positive pressure (APAP). Prior to the initiation of PAP therapy with CPAP or BPAP, pressure levels must be titrated in an attended setting, either at the time of a diagnostic attended sleep study (so called Split night testing) or on a separate PAP titration study.
• **Consequences of OSA:** The most significant consequences of sleep apnea include neurocognitive and cardiovascular effects. Excessive daytime sleepiness, difficulties with concentration and memory, decreased libido, and irritability result from OSA and sleep fragmentation. Motor vehicle accidents are more common among patients with sleep apnea compared with normal controls and the degree of driving impairment is similar to what is seen in drivers who are impaired by alcohol consumption (Tragear, 2009). Patients with OSA are at increased risk for cardiovascular consequences including hypertension, coronary artery disease and heart failure, nocturnal cardiac arrhythmias, stroke, and death (Shahar, 2001).
REFERENCES


Policy Statement
Active care services have sufficient evidence to support superior outcomes when used alone or in combination with manual-based treatments and/or passive care services.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose
These guidelines will assist the evidence based physical medicine provider to properly choose the correct service/s when indicated for proper overall case management.

Scope
This policy will apply to all physical medicine participating network practitioners who provide active procedures, data/claims processing, and peer reviewers. Physical medicine practitioners include chiropractors, physical therapists, occupational therapists, and speech language pathologists.

Definition
The following services are considered “active” meaning the patients themselves take part in the completion of the service. This is opposed to “passive”, where the patient passively receives health care services without any physical input or effort.

All services outlined in this section require the provision of skilled services and direct (one on one) provider-patient contact.

Clinical Reasoning
The current valid literature indicates the necessity of incorporating active care measures into treatment programs. Interventions chosen to treat the patient’s symptoms or conditions should be selected based on the most effective and efficient means of achieving the patient’s functional goals.

Timing of Introduction
Acute care cases: The literature supports the introduction and management of active care procedures as soon as clinically possible once the patient has sufficient range of motion/functional ability. For the care to be considered beneficial and effective, active care services should generally be provided within the first two weeks of intervention. For the purpose of these guidelines, an acute care case is when a patient is seen for treatment within seven days of the onset of the illness, injury, and/or medical intervention.

Subacute care cases: Similar to acute care cases, the literature support the introduction and management of active care procedures as soon as clinically possible once the patient has sufficient range of motion/functional ability. For the care to be considered beneficial and effective, active care services should generally be provided within the first two weeks of intervention. For the purpose of these guidelines, a subacute care case is when a patient is seen for treatment between 7 to 21 days after the onset of an illness, injury, and/or medical intervention.
Chronic care cases - The literature supports the introduction and management of active care procedures at the onset of intervention, either the first or second visit. For the purpose of these guidelines, a chronic care case is when a patient is seen for treatment beyond 21 days after the onset of an illness, injury, and/or medical intervention. Chronic conditions that have intermittent episodes will also be considered chronic in nature for purpose of these guidelines.

Documentation Requirements
Documentation must support the medical necessity for the services requested and why the skills of a licensed professional are needed to render the service. The provider must outline the patient-specific rationale/need for care intervention as it relates to the patient’s condition and resultant functional limitations in activities of daily living, as well as mobility and safety, as identified in a comprehensive evaluation. Based on these findings, a plan of care is developed that includes specific and measurable goals that support the need for the identified interventions.

Documentation must include a timeframe for initiating, progressing and discharging the patient from skilled services. Documentation must also include specific treatment parameters to support the intervention, in addition to applicable precautions. This includes the specific type of procedure, instruction and/or exercise performed, area of body and muscle groups treated, and time component.

Billing Units
This organization follows Medicare rules for reporting timed units. Billing units are based on 15 minutes per unit for time based codes and the Medicare minimum time requirement for a service to be justifiably billed.

1 unit - 8 minutes to 22 minutes
2 units - 23 minutes to 37 minutes
3 units - 38 minutes to 52 minutes
4 units - 53 minutes to 67 minutes
5 units - 68 minutes to 82 minutes
6 units - 83 minutes to 98 minutes

NOTE: Individual states may have varying statutory guidelines for reporting timed units that supersede this organization’s requirements.
CPT Code Definitions, Examples, and Requirements

97110 - Therapeutic Exercise

Definition:
Although not exclusive by definition, therapeutic exercise is any exercise planned and performed to attain a specific goal. Goals would be to increase strength, endurance, range of motion, and flexibility. Therapeutic procedures/exercise could be applied to one or more areas and billed in units as noted above.

Parameters for Use:

I. The following requirements must be documented in the medical record to support and justify the use of all therapeutic procedures/exercises:
   a. Evidence to support medical necessity
   b. Plan of care with specific and measurable goals and timeframe for initiating, progressing, and discharging the patient from skilled medical services to an independent home program.
   c. Detailed description of active care services including:
      i. What exercise(s) were provided
      ii. What area and muscle groups the exercise(s) were provided to
      iii. Amount and type of resistance, repetitions, sets and time component.
   d. Evidence to support the need for skilled services by a licensed professional in direct contact with one patient.


III. Based on the definition and guidelines for services that are medically necessary, the expectation is for the provision of the therapeutic procedures/exercises that are not for the convenience of the patient or health care provider or more costly than an alternative form of treatment.

Guidelines regarding the Use of Fitness Machines (MedX Extension Machine, Isostation B-220 Lumbar Dynamometer, Cybex Back System etc). There is insufficient evidence that they are more efficacious than standard exercise equipment or that their use improves clinical outcomes to a greater extent than standard programs. Thus documentation must support the following:
   a. It must be clear that the intervention is medically necessary.
   b. Evidence to support number of visits that are often in excess of community standards for treatment of musculoskeletal conditions
   c. Evidence of functional improvement as a result of the increased muscle strength
   d. It must be clear skilled service is being provided (as defined in Guideline III above)
   e. Evidence for why the skills of a therapist are needed beyond progressing weights and repetitions.
   f. Evidence for why the skills of a therapist are needed beyond a few visits to establish a program
   g. Their use should be part of a comprehensive rehab program
   h. Plan of care is driven by impairments, not the intervention itself
   i. It must be clear that increasing muscle strength is the treatment of choice (e.g. strength building may be detrimental in an individual with movement restrictions).
Examples
Strengthening of select muscle groups (beginning in gravity-eliminated plane, if needed) progressing to anti-gravity plane utilizing body weight with progressive resistive exercises utilizing theraband, exercise ball, free weights etc. (Closed chain exercises are often preferable to open chain exercises in preventing shearing forces and simulating functional activities); monitored graded exercise following cardiac or pulmonary surgery or heart attack; selective stretching to increase joint range of motion (ROM).

Note: The Precor Stretching Station is not considered least costly as this service must be performed in the office setting. Once a patient is educated regarding stretching and demonstrates proper form, they should be able to continue stretching in the home setting.

Support for this service
I. Indications must be documented for loss or restriction of joint motion, reduced strength, and functional capacity or mobility concerns. The clinical records must show objective (quantitative if possible) loss of ROM, strength, flexibility or mobility. The code is generally not reimbursable for increasing a patient’s endurance without deficits, promotion of overall fitness, weight loss, return to sports, and/or sports and aerobic conditioning.

II. Documentation must include evidence of the skilled services required to support the use of therapeutic exercise. It is considered a skilled service that would require proper licensure/credentials of the clinician. Without evidence in the documentation to support the need for skilled services, the records would suggest the patient is “working out” in the clinical setting, which is generally not medically necessary and not eligible for reimbursement.

III. Most programs should only entail up to one to three units at any time to ensure competency and compliance with instructions. The clinical rationale for more than three units would need to be clearly supported by the documentation. As this service should be seen in the acute phase, the patient should not then require more than three units at any time. If more than three units are seen, this might suggest the patient is “working out” in the clinical setting, which is generally not medically necessary as the service can be performed in a less costly arena (home or health club setting).

IV. Patient non-compliance with active home instructions will not result in further in-office instruction being considered medically necessary. The patient should instead be discharged for non-compliance/acting against medical advice. One to three sessions of in-office exercise should be sufficient, for the non-surgical patient, to ensure competency and compliance with a home exercise program. If in-office repetitive exercise continues after 3 sessions, the record must clearly document why the patient is not able to participate in a home exercise program. Any active care program may include periodic review of the program as part of case management in regard to monitoring continued therapeutic benefit and progression in specific exercises/instructions. This ongoing case management should outline patient compliance, necessary alterations to any active home care program, progression in specific active home care program, and anticipated term date for the need for skilled in-office services.

97112 - Neuromuscular reeducation
Definition:
Neuromuscular re-education of movement, balance, coordination, kinesthetic sense, posture, and proprioception (defined as the three modalities of joint position: sense, sense of movement and sense of
Injuries can be seen after stroke, closed head injury, spinal cord injury, tumor, congenital disorders such as cerebral palsy or secondary to degenerative joint disease, musculoskeletal injury such as ankle sprain, post orthopedic surgery, or prolonged immobilization. Neuromuscular re-education may be considered medically necessary if at least one of the following conditions is present and documented:

- the patient has the loss of deep tendon reflexes and vibration sense accompanied by paresthesia, burning, or diffuse pain of the feet, lower legs, and/or fingers;
- the patient has nerve palsy, such as peroneal nerve injury causing foot drop; or
- the patient has muscular weakness or flaccidity as a result of a cerebral dysfunction, a nerve injury or disease, or has had a spinal cord disease or trauma.

**Examples**

Treatment involves the stimulation of reflexes, sensation, posture, proprioception and motor activity through rocker/BAPS board, mini-trampolines, targeted exercises to spastic or rigid muscles, balance training, Proprioceptive Neuromuscular Facilitation (PNF), Feldenkreis, Bobath, Neurodevelopmental Treatment (NDT), and desensitization techniques.

**Support for this service**

Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.

An indication of the lesion of the neuromusculoskeletal system needs to be documented and the exact procedure must be noted. Instructions for home care should be seen within a reasonable timeframe and the service discontinued with proper education and instruction given to the patient.

**97113 -Aquatic Therapy**

**Definition**

A therapy program utilizing therapeutic exercise techniques with the properties of water; designed and carried out in a suitably heated hydrotherapy pool by a qualified clinician specifically for an individual to improve function. Examples: Tai Chi, Aquatic PNF, the Bad Ragaz Ring Method, Fluid Moves, the Halliwick Concept, Swim Stroke Training and Modification, Task Type Training Approach and Watsu. Treatment to address improved circulation and decreased venous pooling, increased endurance facilitated through the availability of cardiovascular training with less stress on weight-bearing joints or working with enhancement of balance and coordination as a result of the buoyancy obtained from an aquatic environment.

**Support for this Service**

Documentation must support the need for skilled services by a licensed professional in direct contact with one patient. The patient would need to be immersed in a pool of water for this code to apply.

The provider must also indicate the medical necessity for the buoyancy, hydrostatic pressure, and heat properties that are present in a pool setting versus standard therapeutic exercise or activities. This is often used to transition the patient to a land based program.

**97116 -Gait Training**

**Definition**

Training the patient in specific activities that will facilitate ambulation on varied surfaces and stair climbing with or without an assistive device. This includes training in rhythm, speed, sequencing and safety instructions.

**Examples**
Gait training can be useful for people with any condition needing to re-learn proper ambulation. Common conditions include: Amputation; Osteoarthritis; Muscular Dystrophy; Cerebral Palsy; Stroke; Parkinson’s disease; Multiple Sclerosis; Brain/Spinal Cord injuries; post-surgical; sports injury; Low Back Pain.

**Support for this Service**
Documentation must support the need for skilled services by a licensed professional in direct contact with one patient as opposed to just “walking the patient.”

Deficits in gait parameters including walking speed, cadence, stride length and balance, and Functional Ambulation Category scores must be documented. The provider would need to document if body-weight support (BWS) systems, unweighting devices, or assistive devices are used. The record must denote the assessment of the phases of gait to include stance phase, stride length, balance issues and what the ankle, knee, hip and low back are doing during the phases of gait cycle.

### 97760 - Orthotics Management and Training

**Definition**
Orthotic(s) management and training, including assessment and fitting when not otherwise reported as a separate L HCPCS code (L-code), fitting and training, upper extremity or extremities, lower extremity or extremities, and/or trunk, each 15 minutes.

**Explanation**
This code applies to custom-fabricated orthotics and for adjustments to over-the-counter orthotics. The orthotics management portion of this code refers to time spent assessing the need for the orthotic and the type of orthotic as well as the fitting and the fabrication if the fabrication is done in the presence of the patient. The Training portion of this code includes training in the care and use of the orthotic device.

This code cannot be used if the orthotic is fabricated/formed without the patient being present. Supplies and time for the actual orthotic fabrication is typically reported under L-codes. If an L-code is NOT used to report the orthotic, then the time assessing and fitting/fabricating would be reported under code 97760.

**Support for this Service**
The need for an orthotic requires documented support. This would include a proper examination (not just a vendor specific evaluation) along with the outline of the causal nexus to justify inclusion for any complaints other than foot based. Foot based complaints need a detailed notation as to the fault/deficit present that requires custom orthotics, versus usage of a heel lift or over-the-counter orthotic. This service should typically not be seen more than once per calendar year for one set of orthotics. Orthotic use is based on plan benefit.

Documentation must also support why the skills of a licensed professional are needed for the training in care and use of the orthotic.

### 97761 - Prosthetic Training

**Definition**
Functional mobility and ADL assessment, training with prosthesis, upper and/or lower extremity. This would include instruction and practice in use of prosthesis.

**Support for this Service**
The patient would need to be the recipient of a recent prosthetic device. Surgical records would need to be supplied in support. Code 97760 cannot be reported with gait training (97116).
97763 - Checkout for Orthotic/Prosthetic Use, Established Patient

Definition
Orthotic(s)/prosthetic(s) management and/or training, upper extremity or extremities, lower extremity or extremities, and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes.

Support for this Service
Documentation must clearly support the skilled need of a licensed professional for the adjustments.

97530 - Therapeutic Activities

Definition
This code includes the use of dynamic activities in teaching and training the patient to improve functional performance in a progressive manner.

Examples
Activities that address quantifiable deficits (e.g. loss of ROM, strength or functional capacity) resulting in a deficit in functional mobility. Functional mobility may include bending, reaching, lifting, carrying, pushing, pulling, bed mobility and transfers.

Support for this Service
Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.

In order for therapeutic activities to be covered, the following requirements must be met:
- the patient has a condition for which therapeutic activities can reasonably be expected to restore or improve functioning;
- the patient’s condition is such that he/she is unable to perform therapeutic activities except under the direct supervision of a physician, optometrist or physical therapist; and
- there is a clear correlation between the type of exercise performed and the patient’s underlying medical condition for which the therapeutic activities were prescribed.

The code is generally not reimbursable for increasing a patient’s endurance without deficits, promotion of overall fitness, weight loss, return to sports, and/or sports and aerobic conditioning.

97127 - Cognitive Skills Development

Definition
Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact.

Examples
Individuals with inherited learning disabilities, individuals who have lost cognitive skills as a result of illness or brain injury

Support for this Service
Cognitive deficits would need to be present and quantifiably documented. Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.

97533 - Sensory Integration

Definition
Treatment techniques designed to enhance sensory processing and adaptive responses to environmental demands.

The goal of sensory integration therapy is to improve the way the brain processes and adapts to sensory information as a foundation for later, more complex learning behavior.

**Examples**
Sensory integration (SI) therapy has been proposed as a treatment of developmental disorders in patients with established dysfunction of sensory processing (e.g., children with autism, attention deficit hyperactivity disorder (ADHD), fetal alcohol syndrome, and neurotransmitter disease). Sensory integration disorders may also be a result of illness or brain injury.

Therapy usually involves activities that provide vestibular, proprioceptive, and tactile, visual and auditory stimuli, which are selected to match specific sensory processing deficits of the child. For example, swings are commonly used to incorporate vestibular input, while trapeze bars and large foam pillows or mats may be used to stimulate somatosensory pathways of proprioception and deep touch. Tactile reception may be addressed through a variety of activities and surface textures involving light touch.

Sensory integration differs from 97112 as 97112 focuses on training to restore the ability to perform the particular activities.

**Support for this Service**
Sensory integration therapy is usually provided by occupational and physical therapists who are certified in sensory integration therapy.

Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.

97535 -Self-care/Home Management Training
**Definition**
Instructing and training the patient in self-care and home management activities (activities of daily living or ADL). This includes compensatory training, safety procedures and instruction in the use of assistive technology devices/adaptive equipment.

**Examples**
Activities that address quantifiable deficits resulting in functional limitations in activities of daily living (ADL). ADLs include toileting, continence, bathing, dressing, personal hygiene, housecleaning, eating and meal preparation.

**Support for this Service**
Documentation must support the need for skilled services by a licensed professional in direct contact with one patient. Documentation should relate the ADL instruction to the patient’s expected functional goals and indicate that it is part of an active treatment plan directed at a specific goal.

97537 -Community Work Reintegration — typically not a covered service
**Definition**
Services are instructing and training the patient in community and/or work re-integration activities. These activities could include shopping, safely accessing transportation sources, money
management, avocational activities and/or work environment/modification analysis, work task analysis, and use of assistive technology devices and/or/adaptive equipment.

**Example**

Community reintegration is often performed in conjunction with other therapeutic procedures such as gait training and self-care/home management training. The payment for community reintegration training is often bundled into the payment for those other services. Therefore, those other services are not usually separately reimbursable.

Services provided to issue, modify, adjust, and/or educate the patient on assistive technology devices and/or adaptive equipment typically will not be covered if the adaptive equipment and/or assistive technology device(s) are not covered by the third-party payer.

Generally, services which are related solely to specific employment opportunities, work skills, or work settings are not reasonable and necessary for the diagnosis and treatment of an illness or injury and are excluded from coverage by Section 1862(a)(1) of the Social Security Act.

**Support for this Service**

Documentation would need to provide evidence to support the medical necessity and the need for skilled services provided to the patient.

**97542 - Wheelchair Management and Training**

*Definition*

Includes assessment, fitting and adjustment of the wheelchair and seating; instructing the patient and/or caregiver on how to propel and safely operate the wheelchair (97001 and 97002 cannot be billed with this code).

**Support for this Service**

Documentation should include the recent event that prompted the need for a skilled wheelchair assessment; the result of any previous wheelchair assessments; most recent prior functional level; the interventions that were tried by nursing staff, caregivers or the patient to address poor seating or positioning; and any functional deficits or applicable impairments such as ROM, strength, sitting balance, skin integrity, sensation and tone.

The documentation must correlate the training provided to the expected functional goals that are attainable by the patient and/or caregiver, along with the response of the patient to the instruction or fitting.

The documentation must clearly support that the services rendered required the skills and expertise of a licensed therapist.

**97545 - Work Hardening/Conditioning** – initial 2 hours, use 97546 for each additional hour and use in conjunction with 97545 – typically not a covered service

*Definition*

Work hardening includes job simulation tasks and educational activities related to a safe return to work for the patient. Often, work hardening programs incorporate an interdisciplinary approach to restore physical, behavioral, and/or vocational functions. Work conditioning includes exercises directed towards safely returning the patient to work related activities or to commence with vocational rehabilitation services. In general, work conditioning programs are designed to address neuromuscular functions such as flexibility, strength, endurance, and/or range of motion as well as cardiopulmonary functions.
**Example**
A work induced injury and/or impairment was present that resulted in the need for therapeutic exercises/procedures. Once the patient has completed acute medical care including chiropractic or rehabilitation treatment, the patient may require a comprehensive, intensive, and individualized program for safely returning to work activities. Subsequently, the patient may begin a work hardening and/or work conditioning program. Typically, the patient will participate in a program for at least two hours a day, three days a week to as much as eight hours a day, five days a week. The activities performed by the patient in the program may include and exercise regimen, simulation of specific or general work requirements, training and/or modifications of activities of daily living, injury prevention training, cognitive-behavioral pain management training, and/or occupational/educational training aspects.

**Support for this Service**
The documentation would need to support that the patient had an injury and/or impairment within the last 12 months, has received acute rehabilitation services, and is expected to return to his/her previous employment. Furthermore, the documentation should clearly report the patient’s limitations for returning to work; the patient’s willingness to participate in the program; a highly structured, goal oriented plan of care including reference to return to work and discharge from skilled services; identified systemic neuromusculoskeletal deficits that interfere with work; documentation to support that care is at the point of resolution for the initial or principal injury so that participation in the conditioning process would not be prohibited; and, if applicable, the identification of psychosocial and/or vocation problems and evidence of a referral to the appropriate professional.

**ADDITIONAL INFORMATION RELATED TO ACTIVE PROCEDURES:**

A qualified health care provider is an individual who by education, training, and licensure/regulation performs a professional service within his/her scope of practice and reports a professional service. These providers are distinct from ‘clinical staff’ (e.g., physical therapy aide or speech language assistant). A clinical staff member is a person who works under the supervision of a qualified health care provider and who is allowed by law or regulation to perform or assist in the performance of a specified professional service. Examples of qualified health care providers for the purpose of this policy include chiropractors, physical therapists, occupational therapists, physician assistants, speech therapists, physical therapy assistants, and occupational therapy assistants.

Skilled care services are not required to effect improvement or restoration of function when a patient suffers a transient and easily reversible loss or reduction of function, which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Skilled care services furnished in such situations are not considered reasonable and necessary for the treatment of the individual’s illness or injury.

While an individual’s particular medical condition is a valid factor in making decisions about health care, the diagnosis or prognosis cannot be the sole basis in deciding that skilled care services are reasonable and necessary. The key judgment is whether the skills of a qualified health care provider are needed to treat the illness or injury or whether the services can be carried out by unskilled personnel.

Regardless of the expectation of improvement, reasonable and necessary skilled care services must be provided by a qualified health care provider and require a high level of complexity and sophistication or the condition of the patient is such that the services can be safely and effectively performed only by a
qualified health care provider. Services that do not require the performance or supervision of a qualified health care provider are not skilled and are not considered reasonable or necessary services, even if they are performed or supervised by a qualified professional. Therefore, if a service can be self-administered or safely and effectively furnished by an unskilled person or caregiver, without the direct or general supervision of a qualified health care provider, the service cannot be regarded as skilled even if a qualified professional actually furnishes the service. Further, the unavailability of a competent person to provide a non-skilled service, despite the importance of the service to the patient, does not make it a skilled service when a qualified health care provider furnishes the service. A clinician may not merely supervise, but must apply the skills of a professional by actively participating in the treatment of the patient. In addition, a provider’s skills may be documented, for example, by the clinician’s descriptions of their skilled treatment, the changes made to the treatment due to a clinician’s assessment of the patient’s needs on a particular treatment day, or changes due to progress the clinician judged sufficient to modify the treatment toward the next more complex or difficult task.

Services related to activities for the general good and welfare of patients (e.g., general exercises to promote overall fitness and flexibility and activities to provide diversion or general motivation) do not constitute skilled care services. Services provided by practitioners/staff who are not qualified health care providers are not skilled intervention services. Unskilled services are palliative procedures that are repetitive or reinforce previously learned skills or services performed to maintain function.

Objective Evidence: Consists of serial standardized assessment tools/instruments, outcome measurements, and or measurable assessments of functional outcome used to quantify patient progress and support justification for continued treatment. Examples of objective evidence include:
- Functional assessment from standardized and validated outcomes instruments; or
- Functional assessment scores from tests and measurements that are validated in the professional literature, which are appropriate for the condition/function being measured. Physical measures (e.g., range of motion or manual muscle strength testing) are generally not considered to be ‘objective evidence’ of functional assessment.

Rehabilitative (Restorative) Services: Are services designed to address recovery or improvement in function and, when possible, restoration to a previous level of health and well-being. Improvement is evidenced by successive objective measurements whenever possible (e.g. impairments, pain, functional status, etc.). If an individual’s expected rehabilitation potential is insignificant in relation to the extent and duration of therapy services required to achieve such potential, rehabilitative therapy is not reasonable and necessary. Rehabilitative care must require the skills and level of sophistication of a qualified health care provider. Services that can be safely and effectively furnished by non-skilled personnel or caregivers are not rehabilitative care services.

Skilled rehabilitative care services must be part of a documented treatment plan provided to improve or restore lost or impaired physical function resulting from illness, injury, neurologic disorder, congenital defect or surgery. These skilled care services are intended to enhance rehabilitation and recovery by clarifying a patient’s impairments and functional limitations as well as by identifying interventions, treatment goals, and precautions.

Reasonable and Necessary: The services shall be of such a level of complexity and sophistication or the condition of the patient shall be such that the services required can only be performed safely and effectively by a qualified health care provider. Services that do not require the performance of a qualified health care provider are not skilled and are not considered reasonable or necessary.
REFERENCES


**Policy Statement**
This policy will be used to provide a listing of procedures considered experimental, investigational by any physical medicine practitioner. Services listed in the policy are not eligible for reimbursement.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

**Purpose**
To provide a listing of procedures considered experimental, investigational, or unproven services by any physical medicine practitioner, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

**Scope**

**Coverage**
Coverage is subject to the terms of an enrollee’s benefit plan. To the extent there is any inconsistency between this medical policy and the terms of an enrollee’s benefit plan, the terms of the enrollee’s benefit plan documents will always control. Investigational services are not covered under enrollee’s health plan.

**Definition**
A service is considered experimental/investigation if any of the following criteria is met:

1. The services, procedures or supplies requiring Federal or other Governmental body approval, such as drugs and devices, do not have unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.

2. There is insufficient or inconclusive medical and scientific evidence to evaluate the therapeutic value of the service, procedure, or supply.

3. There is inconclusive medical and scientific evidence in peer-reviewed medical literature that the service, procedure, or supply has a beneficial effect on health outcomes.

4. The service, procedure, or supply under consideration is not as beneficial as any established alternatives.

5. There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, the service, procedure, or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives.

Experimental and investigational services include the use of a service, procedure, or supply that is not recognized as standard clinical care for the condition, disease, illness, or injury being treated. A service, procedure, or supply includes, but is not limited to the diagnostic service, treatment, facility, equipment,
or device. This organization will determine whether a service, procedure, or supply is considered experimental and investigational.

The following is a partial listing of experimental and investigational services:

- Advanced BioStructural Correction (ABC)
- Alphabiotics
- Applied Kinesiology or any of its derivations
- Applied Spinal Biomechanical Engineering
- BioEnergetic Synchronization Technique (B.E.S.T)
- Chiropractic Biophysics (CBP, Clinical Biomechanics of Posture, CBP Mirror Image Technique)
- Coccygeal Meningeal Stress Fixation
- Cold Laser Therapy
- Computerized muscle testing or analysis
- Craniosacral Therapy (CST)
- Directional Non-force Technique
- Hako-Med electrotherapy (horizontal electrotherapy)
- Hippotherapy
- Impulse adjusting instrument
- Intersegmental traction and Autotraction
- Kinesio taping (Elastic Therapeutic Taping)
- Live Cell Analysis or hair analysis
- Manipulation under Anesthesia (MUA)
- Moire Contourographic Analysis
- Nambudripad’s Allergy Elimination Technique (NAET)/ other Allergy Testing
- National Upper Cervical Chiropractic Association (NUCCA technique)/Grostitc technique
- Network Chiropractic, NeuroEmotional Technique (NET)
- Neurocalometer, Nervoscope, Nerve Conduction Velocity, Surface EMG, Paraspinal Electromyography, Spinoscopy or other nerve conduction testing for non-specific neck and back pain
- Neural Organizational Technique, Contact Reflex Analysis (CRA), Whole System Scan
- Nimmo Receptor-Tonus method
- Pettibon, including, but not limited to wobble chair/board treatment and posture pump
- Preventive Care, Maintenance Care, Corrective Care
- Pro-Adjuster
- Sacro Occipital Technique, Neurocranial Restructuring (NCR), Cranial Manipulation
- Sound Assisted Soft Tissue mobilization
- Spinal Diagnostic Ultrasound
- Chiropractic services directed at controlling progression and/or reducing scoliosis, including but not limited to the SpineCor brace and CLEAR scoliosis treatment
- Repeat imaging to determine the progress of conservative treatment
- Thermography
- Upledger Technique
- Vascular Studies, including, but not limited to, Doppler ultrasound analysis and plethysmography
- VAX-D, Lordex, LTX3000, DRX-9000, DRS (Decompression Reduction Stabilization System), or other back traction devices charged at a higher rate than mechanical traction (97012)
- Whole Body Vibration (WBV), Vibration Plate, Vibration Therapy
- Any lab work for which the office is not CLIA Certified or falls outside of the scope of practice, including, but not limited to: drug testing, therapeutic drug assays, and organ or disease oriented panels
• Treatment for brachioradial pruritis
• Dry Needling

Professional societies have published position statements concluding that diagnostic spinal ultrasound is investigational for non-operative spinal and paraspinal conditions in adults. The 2014 policy statement of the American Institute of Ultrasound in Medicine indicates: “There is insufficient evidence in the peer-reviewed medical literature establishing the value of non-operative spinal/paraspinal ultrasound in adults (for study of intervertebral discs, facet joint and capsules, central nerves and fascial edema, and other subtle paraspinous abnormalities) for screening, diagnostic evaluation, including pain or radiculopathy syndromes, and for monitoring of therapy has no proven clinical utility.”

There is insufficient peer-reviewed published scientific evidence that computerized muscle testing leads to better patient outcomes. There is insufficient evidence to support any specific therapeutic effect of craniosacral therapy. While there is emerging evidence for the effectiveness of whole body vibration in treating some medical conditions, the evidence for whole body vibration as a treatment for LBP remains equivocal.

A 2015 systematic review found that low level laser therapy is an effective method for relieving pain in non-specific chronic low back pain patients. However, no significant treatment effect was identified for disability scores or spinal range of motion outcomes. Yelden and colleagues concluded that there is no fundamental difference between LLLT and placebo LLLT when they are supplementing an exercise program for rehabilitation of patients with shoulder impingement syndrome (Yelden, 2009). Ay and colleagues found no differences between laser and placebo laser treatments on pain severity and functional capacity in patients with acute and chronic low back pain caused by lumbar disc herniation (Ay, 2010). The Blue Cross and Blue Shield Association Technology Evaluation Center (2010) concluded that LLLT for either carpal tunnel syndrome or for chronic neck pain does not meet the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria. Furthermore, the Work Loss Data Institute's clinical practice guideline on "Carpal tunnel syndrome" (2011) does not recommend LLLT as a therapeutic option. The effectiveness of LLLT in reducing acute and chronic neck pain was examined in 2013. The authors concluded that this systematic review provided inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. They stated that the benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference (Kadhim-Saleh, 2013). The best available current evidence does not support the effectiveness of low level laser therapy as a therapy for patients with knee osteoarthritis (Huang, 2015).

There is insufficient evidence to support the clinical value of the Pettibon System. Posture Pump is deemed experimental and investigational because the effectiveness of this device has not been proven by adequate scientific studies, published in peer-reviewed scientific journals. There is insufficient evidence to support the clinical value of the Therapeutic (Wobble) Chair/Board.

The appropriateness and effectiveness of chiropractic manipulation as a preventive or maintenance therapy has not been established by clinical research and is not covered.

 Thermography has not been shown to provide sufficient reliable characterizing information about neurologic dysfunction or deficit to accept it as a proven evaluative procedure for the clinical diagnosis or characterization of: neck or back pain; musculoskeletal pain; entrapment neuropathy; headache; or transient cerebral ischemia and stroke.
High-density surface electromyography (HD-sEMG), surface scanning EMG, paraspinal surface EMG, or macro EMG are considered experimental and investigational as a diagnostic test for evaluating low back pain or other thoracolumbar segmental abnormalities, such as soft tissue injury, intervertebral disc disease, nerve root irritation and scoliosis, and for all other indications because the reliability and validity of these tests have not been established. Surface EMG devices are also experimental and investigational for diagnosis and/or monitoring of nocturnal bruxism and all other indications because the reliability and validity of these tests have not been demonstrated. The Neurophysiologic Pain Profile (NPP) and the spine matrix scan (lumbar matrix scan) are considered experimental and investigational because the reliability and validity of these tests has not been established.

There is insufficient evidence to conclude that nerve conduction studies are beneficial for health outcomes in patients with non-specific neck or back pain. Non-invasive automatic or portable nerve conduction monitoring systems that test only distal motor latencies and conduction velocities are unproven and not medically necessary for the purpose of electrodiagnostic testing.

Plethysmography is used to diagnose deep vein thrombosis and arterial occlusive disease. Plethysmography is used as the sole diagnostic modality for these conditions or as an initial evaluation to determine the need for venography or arteriography. Body Plethysmography evaluates total lung capacity and residual volume. Since treatment of cardiovascular and lung conditions falls outside of the scope of chiropractic, patients should be referred for testing if these conditions are suspected.

**Procedure**

1. **Guidelines**
   a. If such services are to be provided, the practitioner will inform the member, in writing, that such services will be the member’s responsibility. None of these services are to be performed in lieu of an appropriate examination or without consideration of an appropriate referral.
   b. There is limited scientific evidence that the use of experimental, investigational and unproven services provides an improved or more accurate diagnosis, nor do they result in an improved clinical outcome.
   c. Scientific literature will continue to be reviewed and any significant changes in published literature will be taken into consideration for modification of this policy.

2. **Exclusions/Limitations (not limited to)**
   Refer to enrollee’s Certificate of Coverage or Summary Plan Description.

3. **Removal of a service from the Experimental and Investigations Policy**
   At least annually, a review of the current literature will be evaluated to determine if there is additional research in support of any of the services listed under this policy. This evaluation will include the following criteria:
   - **Safety** – Is the potential benefit superior to the potential harm?
   - **Health Outcomes** – Is there evidence the service will provide, at minimum, equal outcomes and at best, superior outcomes to currently available services?
   - **Patient Management** – Will the service improve clinical decision making?
   - **Clinical Performance** – Is the reliability as well as predictive value of the service equal or superior to the current “gold standard” for such services?
   - **Cost-effectiveness** – Is the service equal to or lower cost than currently utilized services for similar diagnosis and treatment?
All criteria will be based on peer-reviewed scientific literature and internationally and nationally accepted and published guidelines. Peer-reviewed scientific studies must be published in or accepted for publication by medical journals meeting national requirements for scientific publication (http://www.icmje.org). The medical literature must meet the National Institutes of Health Library of Medicine for indexing (http://www.nlm.nih.gov). Medical journals that publish most of their scientific manuscripts by the editorial staff of a journal will not be considered for review. If the majority of funding for research is published by the device manufacturer or organization sponsoring a technique the results will not be considered for review.

If the service appears to be safe and cost-effective, this organization will present these results to our health plan partners for consideration of coverage and/or payment. Final authority for such coverage determinations rests with the health plan.
REFERENCES


Gose EE, Naguszewski WK. Vertebral axial decompression therapy for pain associated with herniated or degenerated discs or facet syndrome. *J Neuro Res.* 1998; 20:186-190.


Hazell TJ, Olver TD, Hamilton CD, et al. Addition of synchronous whole-body vibration to body mass resistive exercise causes little or no effects on muscle damage and/or inflammation. *J Strength Cond Res*. April 23, 2013.


Troyanovich SJ. Motion palpation it’s time to accept the evidence. *J Manip Physiol Ther.* 1998; 21:568-571.


Measureable Progressive Improvement

Policy Statement
Outcome measures and/or pre-determined treatment goals that are specific, measurable, and/or functional must be used with each patient. These goals and outcome measures must be clearly defined in the patient record to ascertain the amount or degree of change over time. The documentation must also provide evidence of lasting, sustainable, progress with treatment.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose
This policy will be used to provide minimal clinical thresholds using specific-measurable, and functional treatment goals and/or outcome measures in the determination of improved, lasting, and sustained outcomes. These thresholds will assist in medical necessity reviews of billed clinical services by network practitioners.

Scope
Physical medicine practitioners, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

Definition

Treatment Goals
Determined with the patient and clinician at the initial encounter for each episode of care. Unique for each patient's clinical presentation based on the evaluation/examination findings, outcome assessment tool results, and personal preferences.

Episode of Care
Consultation or treatment preceded and followed by at least 3 months without treatment for the same complaint

Specific, Measurable, and Functional Goals
Clearly defined goals of treatment that allow measurement of the amount and/or degree of meaningful change over time. These goals are often determined by the use of functional outcome assessment tools, as defined in Clinical Guideline, Plan of Care.

Outcome Measures
Objective, measurable, assessments by the clinician to determine patient progress with treatment. The use of standardized tests and measures at the onset of care establishes the baseline status of the patient, providing a means to quantify change in the patient's functioning. Outcome measures, along with other standardized tests and measures used throughout the episode of care, as part of periodic reexamination, provide information about whether predicted outcomes are being realized. Outcomes measurement refers to the systematic collection and analysis of information that is used to evaluate the efficacy of an intervention. Systematic collection means that data are gathered at multiple time points using the same methods or instruments. Analysis refers to the process of condensing and examining the data to identify meaningful trends or changes. The World Health Organization defines an outcome measure as a “change in the health of an individual, group of people, or population that is attributable to an intervention or series of interventions.”
**Lasting, Sustainable Progress**
Documentation must provide evidence to support that progress made by the patient has been maintained at a reasonable level over a reasonable period of time.

**Minimally Clinically Important Change (MCIC)**
The smallest change in the outcome assessment score that the patient perceives as beneficial, i.e. clinically meaningful improvement.

**Minimal Detectable Change-MDC**
The minimal detectable change is the smallest change in score than can be detected beyond random error and is dependent upon sample distribution.

**Minimal Clinically Important Difference-MCID**
MCID is the smallest change in an outcome that a patient would identify as important.

**Maximum Therapeutic Benefit-MTB**
Maximum Therapeutic Benefit (MTB) is determined following a sufficient course of care, where demonstrable improvement would be expected in a patient’s health status and one or more of the following are present:
- The patient has returned to pre-clinical/pre-onset health status
- Meaningful improvement has occurred; however, there is no basis for further meaningful improvement
- Meaningful improvement has occurred and there is no basis for further in-office treatment
- The patient no longer demonstrates meaningful clinical improvement, as measured by standardized outcome assessment tools
- Meaningful improvement, as measured by standardized outcome assessment tools, has not been achieved
- There is insufficient information documented in the submitted patient record to reliably validate the response to treatment

It is the responsibility of the treating practitioner to maintain a patient record that includes periodic measures of treatment response by employing valid, reliable, and relevant outcome assessment tools. Further, it is the responsibility of the treating practitioner to include sufficient clinical documentation, so that a peer reviewer can render a reasonable determination on baseline functional status and/or treatment response. Further, meaningful improvement can occur only when there is a potential for MCIC. When progress towards goals is such that outcome measures approximate normative data for asymptomatic populations or are indicative of mild deficits, which can typically be managed through home exercise or other self-care, then a determination of MTB is appropriate. Most individuals can expect to notice measurable improvement in pain and/or disability within 2 to 6 weeks after beginning treatment. If improvement has not occurred with 6 weeks of treatment, it is highly unlikely that continuing treatment will be helpful. When initial improvement did occur, many studies showed no additional lasting improvement beyond 6 to 12 weeks of treatment. Most flare-ups resolve quickly – within a few days to 3 weeks. The timelines for improvement may not be applicable to some types of post-surgical care. (Axen, 2005; Leboeuf, 2005; Kohlbeck, 2005; Hurwitz, 2006; Newell, 2007; Bove, 1998; Moraska, 2007; Borman, 2008; Thiel, 2008).

**Patient Acceptable Symptom State (PASS):**
Defined as the point at which the patient considers themselves well, recovered, and satisfied with treatment.
Acceptable Thresholds of Measurable Improvement:
Meaningful clinical change (Minimal Clinically Important Change-MCIC; Minimal Clinically Important Differences-MCID; Minimal Detectable Change-MDC) has been calculated for most common standardized outcome assessment tools. The application of valid and reliable outcome assessment tools in the management of neuromusculoskeletal disorders is generally considered as “best practice”.

In order to make a valid and reliable determination of meaningful progress toward goals (MCIC) and/or Maximum Therapeutic Benefit (MTB), it is essential that the record include a relevant standardized outcome assessment tool. Progress towards goals should be assessed at predetermined time periods, supported by anticipated meaningful clinical change based on treatment plan goals. Typically, recovery patterns for neuromusculoskeletal conditions involving the low back, neck, and headache disorders show that >50% of the overall improvement with care occurs within 4-6 weeks. When patients are categorized via predictive modeling, the percentage of those showing significant improvement within 6 weeks rises considerably. Studies have consistently shown that short term treatment response is predictive of long term outcomes. McGorry showed that exacerbations of LBP resolved within a few days (52%); within a week (16%); within two-three weeks (26%); even severe flare-ups usually resolved within nine days (McGorry, 2000). After a review of the scientific evidence, this organization has concluded all practitioner records must evaluate and document whether treatment is resulting in progressive and sustained improvement.

The practitioner records must demonstrate clear, specific and measurable improvement in the patient’s pain and function every two weeks, or at regular intervals as appropriate for the documented condition, as measured by one or more of the following examples of methods for each anatomic region. If no functional tool is available for the patient’s condition it is expected the practitioner will develop specific, measurable, and functional goals:

- 6-Minute Walk test (6MWT) for Older Adults
  - MDC (calculated from standard error of measurement (SEM)) = 58.21 m (190.98 ft) (Perera, 2006)
  - SEM Older people with limited mobility: 21 m (Perera, 2006)
  - Older people with stroke: 22 m (Perera, 2006)
- Activities of Daily Living Scale of the Knee Outcome Survey
  - 10-30% reduction in the global score
  - MDIC = 7.1% (Piva, 2009)
- Berg Balance Scale
  - MDC=6.5 points (Romero, 2011)
- Bournemouth – Back Questionnaire
- A change of 26 points in acute conditions and 18 points in subacute/chronic conditions. (Newell, 2010). It is recommended that the Bournemouth be used at baseline and for every 2-4 weeks or 6-12 visits thereafter within the treatment program to measure progress.
- Bournemouth – Neck Questionnaire
- A change of 13 points or 36% is considered clinically significant improvement. (Bolton, 2004). It is recommended that the Bournemouth be used at baseline and for every 2-4 weeks or 6-12 visits thereafter within the treatment program to measure progress.
- Dizziness Handicap Inventory
  - MDC = 17.18 points (Yorke, 2013)
- Dynamic Gait Index
  - MDC=2.9 points (Romero, 2011)
- Functional Gait Assessment
• MCID=4 points

• Functional Rating Index
  - A 10% absolute change represents minimal clinically important change (Feise, 2010)
  - MCIC = 8.4%
  - It is recommended that for acute and subacute conditions the FRI be used at baseline and every 1 week or 3 visits thereafter. It is recommended that for chronic conditions the FRI be used at baseline and every 2 weeks or 6 visits thereafter. If the score does not improve by at least 10% (absolute change) in any two successive two-week periods, you should pursue a change in management.

• FOTO or Functional Status (FS) measure:
  - The MCII (Minimally Clinically Important Improvement) and MDC (Minimal Detectable Change) are stated on the assessment report. For significant, minimal improvement, the patient status should increase by the MDC value. FOTO summary report is available upon request.

• Gait Speed for Older Adults
  - Small meaningful change=.5m/sec (Perera, 2006)
  - Substantial meaningful change=.10m/sec (Perera, 2006)
  - Meaningful change for those with stroke undergoing rehab=.175 m/sec

• Headache Disability Inventory (HDI)
  - Authors of the index have determined that a decrease of 29 points or more is considered clinical significant (Jacobson, 1994).

• Keele STarT Back Screening Tool
  - No MDC or MCID established.
  - Low, Medium and High risk categories established for subscales and overall score

• LEFS
  - Minimal Detectable Change is 9 points.
  - Minimal Clinically Important Difference is 9 points. (Brinkley, 1999). It is recommended that the LEFS be used at baseline and for every 2-4 weeks or 6-12 visits thereafter within the treatment program to measure progress.

• Neck Disability Index
  - MDC=10 points. (Young, 2009). It is recommended that the Neck Disability Index be used at baseline and for every 2 weeks thereafter within the treatment program to measure progress. A score of 0%-20% represents a minimal disability. Usually no treatment is indicated, apart from advice on posture, physical fitness, and diet. Patients often do not score the Neck Disability items as zero, once they are in treatment. The practitioner should avoid the trap of "treating till zero", as this is not supportable based on current evidence.

• Numeric Pain Rating Scale
  - MCID=2 points. (Childs, 2005)

• Oswestry Disability Index
  - The Minimal Important Change is 10 points or a 30% improvement. (Smeets 2011). It is recommended that the Oswestry Disability Index be used at baseline and for every 2 weeks thereafter within the treatment program to measure progress. A score of 0%-20% represents a minimal disability. Usually no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness, and diet. Patients often do not score the Oswestry items as zero, once they are in treatment. The practitioner should avoid the trap of "treating till zero", as this is not supportable based on current evidence.

• Pain Disability Index
  - A decrease of 8.5-9.5 points is considered clinically important

• Patient Specific Functional Scale
  - Minimum detectable change (90%CI) for average score = 2 points
- Minimum detectable change (90%CI) for single activity score = 3 points (Stratford, 1995). It is recommended that the PSFS be used at baseline and for every 2-4 weeks or 6-12 visits thereafter within the treatment program to measure progress.

- Roland-Morris Disability Questionnaire
  - Minimal Detectable Change=7.6 points (Froud 2010) or a 30% improvement from baseline (Smeets, 2011). It is recommended that the RMDQ be used at baseline and for every 2-4 weeks or 6-12 visits thereafter within the treatment program to measure progress.

- Shoulder Pain and Disability Index
  - The smallest detectable change is 19.7 points and the minimal important change is 20 points (Thomes-de Graff, 2017). It is recommended that the SPADI be used at baseline and for every 2-4 weeks or 6-12 visits thereafter within the treatment program to measure progress.

- Timed Up and Go (TUG)
  - Cut-off score of 13.5 sec or longer is predictive of falls; however, the Timed Up and Go test has limited ability to predict falls in community dwelling elderly and should not be used in isolation to identify individuals at high risk of falls in this setting. (Barry, 2014).

- Tinetti (POMA)
  - MDC= 5 Points (Faber, 2006).

- VAS scores
  - Minimum of a 2 point change on a 0-10 pain scale

The records must compare baseline measures to updated measures and document progress toward measurable goals as defined in Clinical Guideline, Plan of Care.

**NOTE: Questionable Outcome tool: Global Rating of Change (GRoC)**

Further work is needed to determine the true value of the GRoC as an outcome measure and in turn as an anchor measure. Several key points have been identified:

1. There is fluctuant temporal stability of the GRoC from week to week.
2. There is poor correlation between the GRoC and functional measures.
3. The GRoC is only correlated to functional measures up to 3 weeks.
REFERENCES


Fritz JM, Childs JD, Flynn TW. Pragmatic application of a clinical prediction rule in primary care to identify patients with low back pain with a good prognosis following a brief spinal manipulation intervention. *BMC*. 2005; 6:29.


Policy Statement
Habilitative Physical and Occupational Therapy may or may not be covered by all clients of this organization. If the service is covered it may or may not require a prior authorization. Habilitative physical and occupational therapy should meet the definitions below, be provided in a clinic, an office, at home, or in an outpatient setting and be ordered by either a primary care practitioner or specialist.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose
To provide guidelines for the use of habilitative physical and occupational therapy.

Scope
Requirements for Habilitative Physical and Occupational Therapy services rendered by Physical Therapists, Physical Therapist Assistants, Occupational Therapists, and Occupational Therapist Assistants.

Definition
Habilitative Physical or Occupational Therapy
Treatment provided by a state-regulated physical therapist or occupational therapist for conditions that have significantly limited normal motor development of functional mobility and activity of daily living skills. There must be measurable improvement and progress towards functional goals within an anticipated timeframe toward a patient’s maximum potential. Treatment may also be appropriate in an individual with a progressive disorder when it has the potential to prevent the loss of a functional skill or enhance the adaptation to such functional loss. Ongoing treatment is not appropriate when a steady state of sensorimotor functioning has yielded no measurable functional progress.

Activities of Daily Living (ADLs)
Everyday activities such as eating, feeding, dressing, bathing, toileting, personal hygiene, and mobility necessary to perform these activities. The initial plan of care documents baseline impairments as they relate to ADLs with specific goals developed that are measurable, sustainable, and time-specific. Subsequent plans of care document progress toward attainment of these goals in perspective to the patients’ potential ability.

Functional Mobility Skills
They are considered necessary activities of daily life such as ambulation, transfers, and fine motor skills. The initial plan of care documents baseline impairments as they relate to functional skills with specific goals developed that are measurable, sustainable, and time-specific. Subsequent plans of care document progress toward attainment of these goals in perspective to the patients’ potential ability.

Sensory Integration Disorder
It is a neural system disorder that causes the sensory system to receive incoming information in a disorganized manner. Sensory Integration therapy is often used with individuals diagnosed with autism or other pervasive developmental disorder with the primary goal to promote the child’s ability to organize progressively and increasingly complex, successful adaptive responses.
Guidelines:

1. Must have written referral from primary care practitioner or other non-physician practitioner (NPP) as permitted by state guidelines.

2. Physical and Occupational Therapy initial evaluations and re-evaluations must include age-appropriate standardized tests documenting a developmental delay resulting in fine motor, gross motor, or ADL functionality that are:
   a. At or below the 10\textsuperscript{th} percentile of $\geq 1.5$ standard deviations below the normal for the patient’s age and
   b. Below the average functional ability for 12 year olds.

   \textit{Standard deviations and percentile rankings gathered from standardized testing are preferred. When a \textasciitilde 1.5 standard deviation or greater is not indicated by the test, a criterion referenced test along with informed clinical opinion must be included to support the medical necessity of services. Documentation of the reason a standardized test could not be used must be included in the evaluation.}

3. This organization advises that patients be evaluated by and/or be coordinating physical/occupational therapy services with other community service agencies and/or school system when available. The extent of these services must be indicated in the documentation. If services are not available then this should be indicated in the documentation.

4. Treatment goals must be realistic, measurable, and promote attainment of developmental milestones, functional mobility, and ADL skills appropriate to the patient’s age and circumstances, such as rolling, crawling, pull to stand, assisted or independent ambulation, dressing, bathing, grooming, and feeding skills.

5. Documentation should clearly reflect why the skills of a therapist are needed. There must be evidence as to whether the services are considered reasonable, effective treatments requiring the skills of a therapist or whether they can be safely and effectively carried out by non-skilled personnel without the supervision of qualified professionals.

6. Progress notes/updated plans of care that cover the patient’s specific progress towards their goals with review by the primary care practitioner (PCP) or other non-physician provider (NPP) will be required every 60-90 days or per state requirements. If the patient is not progressing, then documentation of a revised treatment plan is necessary.

7. It is expected that a discharge plan, with the expected treatment frequency and duration, must be included in the plan of care. The discharge plan must indicate the plan to wean services once the patient has attained their goals, if no measurable functional improvement has been demonstrated, or if the program can be carried out by caregivers or other non-skilled personnel.

8. It is expected that there be evidence of the development of age-appropriate home regimen to facilitate carry-over of target skills and strategies and education of patient, family, and caregiver in home exercises and self-monitoring.

9. For patients no longer showing functional improvement, a weaning process of one to two months should occur. If the patient shows signs of regression in function, the need for skilled physical or
occupational therapy can be re-evaluated at that time. Periodic episodes of care may be needed over a lifetime to address specific needs or changes in condition resulting in functional decline.

REFERENCES


Policy Statement
Habilitative Speech Therapy may or may not be covered by all clients. If the service is covered it may or may not require a prior authorization. Habilitative speech therapy should meet the definitions below, be provided in a clinic, an office, at home or in an outpatient setting and be ordered by either a primary care practitioner or specialist.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose
To provide guidelines for the use of habilitative speech therapy.

Scope
Physical medicine practitioners, including speech language pathologists, and speech therapist assistants.

Definition
Habilitative Speech Therapy
Treatment provided by a state-regulated speech therapist for conditions resulting in a delay in speech development including impaired articulation, fluency, resonance, receptive or expressive language. There must be measurable improvement and progress towards functional goals within an anticipated timeframe toward a patient’s maximum potential. Treatment may also be appropriate in a child with a progressive disorder when it has the potential to prevent the loss of a functional skill or enhance the adaptation to such functional loss. Ongoing treatment is not appropriate when a steady state of sensorimotor functioning has yielded no measurable functional progress.

Functional Skills
They are considered necessary communication activities of daily life. The initial plan of care documents baseline impairments as they relate to functional communication with specific goals developed that are measurable, sustainable and time-specific. Subsequent plans of care document progress toward attainment of these goals in perspective to the patients’ potential ability.

Guidelines
1. Must have written referral from primary care practitioner or other non-physician practitioner (NPP) as permitted by state guidelines.

2. Speech therapy initial evaluation and re-evaluations must include age appropriate standardized tests, documenting a developmental delay or condition that are:
   a. At or below the 10th percentile or ≥1.5 standard deviations below the mean in at least one subtest area or composite score
   b. Age equivalency scores will be accepted to meet this criterion. To constitute the basis for coverage of habilitative speech therapy, the age equivalency testing must show at least a 25% delay based upon the age of the member in months.
   When a <1.5 standard deviation or greater is not indicated by the test, a criterion-referenced test along with informed clinical opinion must be included to support the medical necessity of services. Documentation of the reason a standardized test could not be used must be included in the evaluation.
3. This organization advises that patients be evaluated by and/or be coordinating speech therapy services with other community service agencies and/or school system when available. The extent of these services must be indicated in the documentation. If services are not available then this should be indicated in the documentation.

4. Treatment goals must be realistic, measurable and promote attainment of developmental milestones and functional communication abilities appropriate to the patient’s age and circumstances.

5. Documentation should clearly reflect why the skills of a therapist are needed. There must be evidence as to whether the services are considered reasonable, effective treatments requiring the skills of a therapist or whether they can be safely and effectively carried out by non-skilled personnel without the supervision of qualified professionals.

6. Progress notes/updated plans of care that cover the patient’s specific progress towards their goals with review by the primary care practitioner or other NPP will be required every 60-90 days or per state guidelines. If the patient is not progressing then documentation of a revised treatment plan is necessary.

7. It is expected that a specific discharge plan, with the expected treatment frequency and duration, must be included in the plan of care. The discharge plan must indicate the plan to wean services once the patient has attained their goals, if no measurable functional improvement has been demonstrated, or if the program can be carried out by caregivers or other non-skilled personnel.

8. It is expected that there be evidence of the development of age-appropriate home regimen to facilitate carry-over of target skills and strategies and education of patient, family, and caregiver in home practice exercises and self-monitoring.

9. For patients no longer showing functional improvement, a weaning process of one to two months should occur. If the patient shows signs of regression in function, the need for skilled speech therapy can be re-evaluated at that time. Periodic episodes of care may be needed over a lifetime to address specific needs or changes in condition resulting in functional decline.

10. For bilingual patients whose primary language differs from the rendering therapist and in situations in which a clinician who has native or near-native proficiency in the target language is not available, use of an interpreter is appropriate and should be documented accordingly. If an interpreter is not present, rationale for this should be documented. Further, the assessment must contain appropriate tests and measures to clearly denote the presence of a communication disorder, as opposed to normal linguistic variations.
REFERENCES


Law J, Garrett Z, Nye C. *Speech and language therapy interventions for children with primary speech and language delay or disorder*. Cochrane Collaborative; 2006.


National Institute on Deafness and other Communication Disorders (NIDCD). *Speech-Language Developmental Milestones*. Bethesda, MD.
Policy Statement
This organization does not support the use of multiple passive treatments for the care of musculoskeletal pain within the scope of network practitioners. Most passive treatments have similar physiological effects related to pain control and reduction of inflammation. The use of modalities with duplicative physiological effects is unnecessary and inappropriate. Multiple passive treatments have not been shown to improve or accelerate patient health outcomes.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose
This policy will be used to provide medical necessity guidelines to support passive treatment services for musculoskeletal conditions in a clinical setting.

Scope
Physical medicine participating network practitioners, including rendering chiropractors, physical therapists, occupational therapists, speech therapists and therapist assistants as applicable. This policy also applies to out of network practitioners as dictated by the health plan.

Definition
Modality
Modality is defined as any group of agents that may include thermal, acoustic, radiant, mechanical, or electrical energy to produce physiologic changes in tissues of therapeutic purposes. Modalities affect tissue at the cellular level.

Multiple Passive Modalities
Multiple passive modalities are defined as the use of and/or billing of two or more physical medicine modalities each visit or during the same session to the same region.

Passive Modalities
Modality that is applied by the provider or in a clinical setting and does not involve active participation by the patient. The purpose of passive modalities use is to promote pain reduction, improve function, and quickly transition the patient to self-care engagement.

Procedure
Procedure is a service provided to increase the functional abilities in self-care, mobility, or safety.

I. The following is a list of procedures and modalities considered to be passive treatment:

A. Thermal and light therapy – Hot/cold (97010), diathermy (97024), microwave (97020) infrared (97026), ultraviolet (97028), ultrasound (US) (97035), paraffin bath (97018), and whirlpool (97022).

B. Electrical therapy – High volt, low volt, interferential current, transcutaneous electrical nerve stimulation (TENS) (97014 and 97032).
C. Mechanical – mechanically assisted and often a sustained pull of the spine or limb such as traction (97012). The use of traction for low back pain (LBP), with or without sciatica, is not supported by the literature, and is therefore not considered medically necessary.


II. Appropriate use of passive treatment

Passive treatment modalities may be utilized in the initial acute stage of a condition for pain control, reduction of inflammation, or reduction of muscle spasm. As a condition progresses, passive care should be replaced by active treatment modalities such as therapeutic exercise. Insufficient evidence exists to support the continued use of passive treatment as a means for improved clinical outcomes.

Passive modalities are considered to be clinically appropriate and/or necessary in the conservative management of neuromusculoskeletal conditions when:

- There are no contraindications to the intervention
- Self-administration is implausible or places the patient at risk of harm
- Used primarily during the initial period of an episode of treatment
- Used to support an active care approach (i.e., therapeutic exercise)
- Used for a particular condition for which there is an evidence-based of significant benefit

Passive modalities are considered NOT to be clinically appropriate and/or necessary when:

- Patient safety is jeopardized by the application of the modality
- The modality can be safely self-administered
- Used during a course of treatment, which continues beyond the initial period
- Used as the primary or sole therapy
- Greater than one passive modality is used involving the same body region(s)
- Used largely for the comfort and convenience of the patient
- Used as part of the routine office protocol

III. Exclusions

The use of chiropractic manipulation (98940-98943) is not considered a duplication of service or physiological effect when used in conjunction with passive treatment modalities, except for the following:

The National Correct Coding Initiative (NCCI) edits require that the manual therapy techniques be performed in a separate anatomic site than the chiropractic adjustments in order to be reimbursed separately.

Additional Information

The preponderance of evidence appears to support either a lack of efficacy or insufficient data to make a judgment on benefit for the modalities evaluated. When a positive outcome was described, the reported treatment effects were modest. Similarly, the duration of treatment effectiveness was typically reported as short (2 weeks to 2 months). Most international guidelines recommend these
interventions should only be used reservedly based upon individual circumstances, and not as a principle component of a treatment regime.

The use of passive modalities in the treatment of neuromusculoskeletal conditions presents the inherent risk of promoting passive dependence. It is the responsibility of the treating practitioner to judiciously apply passive modalities and encourage active patient participation in the treatment plan. Passive treatment is generally viewed as appropriate when used for a short period of time and in conjunction with an active care.

Surface electrical muscle stimulators (direct or alternating current, not high-voltage galvanic current) are considered experimental and investigational for the management of idiopathic scoliosis because there is inadequate evidence of its effectiveness and safety in the peer-reviewed published medical literature.

Resistive exercises, spinal manipulation, whole body vibration, manual therapy, and the Clear Protocol are considered experimental and investigational for the treatment of scoliosis because their effectiveness for this indication has not been established.

A review on non-pharmacological therapies for acute and chronic LBP by the American Pain Society and the American College of Physicians concluded that therapies with good evidence of moderate efficacy for chronic or sub-acute LBP are cognitive-behavioral therapy, exercise, spinal manipulation, and inter-disciplinary rehabilitation (Chou, 2007). For acute LBP, the only therapy with good evidence of efficacy is superficial heat.

No high quality evidence was found to support the use of ultrasound for improving pain or quality of life in patients with non-specific chronic LBP. There is some evidence that therapeutic ultrasound has a small effect on improving low-back function in the short term, but this benefit is unlikely to be clinically important. Evidence from comparisons between other treatments and therapeutic ultrasound for chronic LBP were indeterminate and generally of low quality. There was little evidence that active therapeutic ultrasound is more effective than placebo ultrasound for treating people with pain or a range of musculoskeletal injuries or for promoting soft tissue healing. Based on low to moderate level evidence, therapeutic US does not provide any benefit compared to a placebo or advice, to laser therapy or when combined to exercise for treatment of rotator cuff tendinopathy. Ultrasound provided no additional benefit in improving pain and function in addition to exercise training in the management of knee osteoarthritis.

No trials at low risk of bias support the use of traction, stretching, or ultrasound therapy for chronic neck pain.

Overall, there was limited high quality evidence for the effectiveness of manual therapy. Most reviewed evidence was of low to moderate quality and inconsistent due to substantial methodological and clinical diversity.

No high-quality evidence was found, indicating that there is great uncertainty about the effectiveness of exercise and manual therapy for treatment of temporomandibular joint dysfunction.

For adults with nonspecific shoulder pain of variable duration, cervicothoracic spinal manipulation and mobilization, in addition to usual care may improve self-perceived recovery compared to usual care alone. For adults with subacromial impingement syndrome of variable duration, neck mobilization in addition to a multimodal shoulder program of care, provides no added benefit.
Finally, for adults with grade I-II ankle sprains of variable duration, lower extremity mobilization, in addition to home exercise and advice, provides greater short-term improvements in activities and function over home exercise and advice alone (Southerst, 2015).

For patients with rotator cuff tendinopathy, based on low to moderate-quality evidence, manual therapy may decrease pain; however, it is unclear whether it can improve function. (Desjardins-Charbonneau, 2015).

The best available evidence indicates that exercise therapy (whether land-based or water-based) is more effective than minimal control in managing pain associated with hip osteoarthritis (OA) in the short term. Larger high-quality randomized controlled trials (RCT) are needed to establish the effectiveness of exercise and manual therapies in the medium and long term (Beumer, 2016).

Low quality evidence suggests clinically important long-term improvements in neck pain, function/disability, and global perceived effect, when manual therapy and exercise are compared to no treatment. High quality evidence suggests greater short-term pain relief than exercise alone, but no long-term differences across multiple outcomes for (sub) acute/chronic neck pain with or without cervicogenic headache. Moderate quality evidence supports this treatment combination for pain reduction and improved quality of life, over manual therapy alone for chronic neck pain and suggests greater short-term pain reduction when compared to traditional care for acute whiplash. Evidence regarding radiculopathy was sparse (Miller, 2010).

Both stretching exercise and manual therapy considerably decreased neck pain and disability in women with non-specific neck pain. The difference in effectiveness between the two treatments was minor. Low-cost stretching exercises can be recommended in the first instance, as an appropriate therapy intervention to relieve pain, at least in the short-term (Ylinen, 2007). Combining different forms of manual therapy with exercise is better than manual therapy or exercise alone (Hidalgo, 2017).

For the treatment of the diagnostic label Non-Specific Neck Pain, strong evidence of efficacy was only found for multimodal care (manipulation/mobilization and supervised exercises) (Tsakitzidis, 2013).

The Cochrane Back and Neck Group reported little confidence that massage is an effective treatment for LBP. Acute, sub-acute, and chronic LBP had improvements in pain outcomes with massage only in the short-term follow-up. Functional improvement was observed in participants with sub-acute and chronic LBP when compared with inactive controls, but only for the short-term follow-up (Furlan, 2015).

There are insufficient data to draw firm conclusion on the clinical effect of back schools, low-level laser therapy, patient education, massage, traction, superficial heat/cold, and lumbar supports for chronic LBP (Van Middelkoop, 2011).

A number of nonpharmacological, noninvasive treatments for low back pain are associated with small to moderate, primarily short-term effects on pain versus placebo, sham, wait list, or no treatment. Effects on function are generally smaller than effects on pain. More research is needed to understand optimal selection of treatments, effective combinations, and sequencing of treatments, and effectiveness of treatments for radicular low back pain (Chou, 2007; 2017).
Guidelines on treatment of LBP from the National Collaborating Centre for Primary Care found insufficient evidence for the use of interferential stimulation in LBP and recommended against its use for that indication (Savigny 2009).

In a systematic review and meta-analysis, Fuentes analyzed the available information regarding the efficacy of interferential therapy in the management of musculoskeletal pain. Interferential current alone was not significantly better than placebo or other therapy at discharge or follow-up (Fuentes, 2010).

The effectiveness of high-voltage, pulsed current treatments in humans as a means of controlling edema and post-traumatic pain has not yet been established.

Scientific evidence in peer review literature is lacking regarding the use, safety, improvement, or effectiveness on health outcomes for light emitting diode (infrared) therapy.

Documentation requirements:

The treatment plan or plan of care must include the clinical rationale for each service, a description of the service, the area of the body the service will be provided, goals for each service, and a time component, if indicated.

Contraindications: The use of ultrasound therapy is contraindicated for pregnant patients or patients with malignancy.
REFERENCES


Thoomes EJ. Effectiveness of manual therapy for cervical radiculopathy, a review. *Chiropr Man Therap*. 2016; 24:45.


**Policy Statement**
A properly documented plan of care is a required element of clinical documentation. It is based on the initial evaluation findings and patient’s functional status and establishes the medical necessity for treatment. The plan includes diagnoses, expected functional outcomes, specific interventions, and evaluation of progress toward outcomes based on follow up assessment. It is a framework to document critical thinking necessary for evidenced based outcomes.

**Purpose**
To provide network practitioners and therapy providers with current documentation requirements of a plan of care.

**Scope**
Physical medicine participating network practitioners, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

**Definition/Background**
- Plan of care must be included in the clinical documentation. Absence of this required information is considered failure to support the medical necessity of treatment.
- Plan of care must be individualized, goal-oriented, and aimed at restoring specific functional deficits.
- Plan of care elements:
  - Treatment diagnosis and specific contraindications to treatment
  - Baseline/current functional status/limitations as compared to pre-episode functional status
  - Patient-specific functional goals that are measurable, attainable, time-specific and sustainable. The initial plan of care for a musculoskeletal condition should not exceed 4 weeks.
  - Proposed frequency and duration of treatment within a reasonable and generally predictable time period
  - Specific therapeutic interventions to be provided
  - Predicted level of improvement in function (prognosis)
  - Specific discharge plan
- Plan of care should be reviewed at intervals appropriate to the patient and in accordance with state and third party requirements.
- Updated plan of care elements
  - Time frame for current treatment period
  - Total visits from start of care
  - Change in objective outcome measures and standardized testing compared to baseline and/or most recent re-assessment/updated plan of care
  - Measurable progress toward each goal including whether goal has been met or not met. Goals should be updated and modified as appropriate
  - Modification of treatment interventions in order to meet goals
  - Home program and self-management teaching
• Collaboration with other services/professionals

The plan of care should clearly support why the skills of a professional are needed, as opposed to discharge to self-management or non-skilled personnel without the supervision of qualified professionals.
REFERENCES


WPS Government Health Administrators. *Documentation Tips.* https://www.wpsgha.com/wps/portal/mac/site/claims/guides-and-resources/document-tips/?ut/p/z0/nY_LisIwFIZfRRddhhMVSredwaEzWBQXUrORmMZ4xjaJSerl7W1nIQxUQZf_7Rw-YFAA0_yEigcemletXrN4s8iyOBsldDYf55Sm-ddqMk1mH8lyBD_AHhe-07i7gL_HI0uBCaODvAQoztYP_oQOA6lVhX4f0WAsCiJaT7qI7qT0hOuSOIn1tnFe1m0SUdVgeU-8aZyQvt_tPo9d_pkrYJaHPUG9M1D0V3dp2wd_JtsoudY-0cspRFNx0oC2tg_i_tgW2vl-Q6qdTwBkHsYyY#!/. Published February 9, 2016. Updated March 1, 2018. Retrieved April 9, 2018.


Policy Statement
Recordkeeping is used to document the condition and care of the patient, avoid or defend against a malpractice claim, and support the concurrent and/or retrospective medical necessity requiring the provision of skilled services. The provider is responsible for documenting the evidence to clearly support the aforementioned indices and submitting the documentation for review in a timely manner.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose
Provide network practitioners with current medical record documentation criteria and requirements.

Scope
Physical medicine participating network practitioners, including rendering chiropractors, physical therapists, occupational therapists, speech therapists, and their assistants, as applicable. This policy also applies to out of network practitioners as dictated by the health plan.

Physical medicine participating network practitioners, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

Definition
Medical History: Applicable to all Network Providers
The Medical History includes all of the following:
- The history of Present Illness (HPI) includes the location, quality, severity, duration, timing, context, modifying factors that are associated with the signs and symptoms
- A Review of Systems (ROS) – 13 systems (musculoskeletal/neurological, etc.) and constitutional symptoms. Should also address communication/language ability, affect, cognition, orientation, consciousness
- Past Medical, Family and Social History (PFSH) that includes the patient’s diet, medications, allergies, hospitalizations, surgeries, illness or injury, the family health status, deaths, problem related diseases, and
- The patient’s social status that includes marital status, living conditions, education/occupation, alcohol/drug use, sexual history

Physical Examination (PE): Applicable to Chiropractors (CHIRO)
Examination of the body areas that includes the head, neck, chest, abdomen, back, and extremities, and the organ systems (11), constitutional, eyes, ENT, CV, GI, GU, musculoskeletal, skin, neurological, psychiatric, lymphatic, immunological, and hematological.

New Patient:
The patient has not been seen at any time by any practitioner within the same group practice, for any purpose, within the last 3 years.

GUIDELINES (CHIRO)
I. New patient Evaluation and Management (E/M) coding requirements – must have 3 of 3:
II. Established patient E/M coding requirements – must have 2 of 3:

<table>
<thead>
<tr>
<th>Code</th>
<th>99211</th>
<th>99212 (10m)</th>
<th>99213 (15m)</th>
<th>99214 (25m)</th>
<th>99215 (40m)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical History</strong></td>
<td>Problem focused CC</td>
<td>Problem focused CC</td>
<td>Expanded Problem focused CC</td>
<td>Detailed Problem focused CC</td>
<td>Comprehensive Problem focused CC</td>
</tr>
<tr>
<td></td>
<td>HPI: 1-3 ROS: none PFSH: None</td>
<td>HPI: 1-3 ROS: none PFSH: None</td>
<td>HPI: 1-3 ROS: related to CC PFSH: None</td>
<td>HPI: ≥ 4 ROS: ≥ 2.9 PFSH: 1 item any area</td>
<td>HPI: ≥ 4 ROS: ≥ 10.14 PFSH: 1 item each area</td>
</tr>
<tr>
<td><strong>Physical Exam</strong></td>
<td>Affected body area</td>
<td>Affected body area</td>
<td>Affected body areas/systematic/ and 5-7 related organ systems</td>
<td>Multi-system 8+ body systems</td>
<td>Multi-system 8+ body systems</td>
</tr>
<tr>
<td><strong>Medical Decision</strong></td>
<td>Straight forward</td>
<td>Straight forward</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
</tr>
</tbody>
</table>

PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY INITIAL EVALUATION

- Identified problems
- Treatment diagnosis and date of onset, as well as, contraindications
- Brief current and past medical history (see previous page)
- Summary of previous therapy
- Baseline evaluation including current and prior functional status (communication, cognition, vision, hearing, functional mobility, ADL, swallowing)
- Objective tests and measures appropriate to each discipline
- Functional outcome assessment and/or standardized test results with raw score, standardized scores, and interpretation
- School programs, including frequency and goals to ensure that there is not duplication (for habilitative)
- Information regarding home and community programs child is involved in (for habilitative)
- Treatment diagnosis, prognosis and rehab potential
# PHYSICAL THERAPY EVALUATION CODE REQUIREMENTS

<table>
<thead>
<tr>
<th>Complexity Level</th>
<th>Low – CPT 97161</th>
<th>Moderate – CPT 97162</th>
<th>High – 97163</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration</strong></td>
<td>Typically ≤ 20 minutes face-to-face with patient and/or family; and</td>
<td>Up to 30 minutes face-to-face with patient and/or family; and</td>
<td>Up to 45 minutes face-to-face with patient and/or family; and</td>
</tr>
<tr>
<td><strong>History</strong></td>
<td>No personal factors and/or comorbidities that impact the plan of care; and</td>
<td>1-2 personal factors and/or comorbidities that impact the plan of care; and</td>
<td>3 or more personal factors and/or comorbidities that impact the plan of care; and</td>
</tr>
<tr>
<td><strong>Examination</strong></td>
<td>An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations and/or participation restrictions; and</td>
<td>An examination of body system(s) using standardized tests and measures addressing 3 or more elements from any of the following: body structures and functions, activity limitations and/or participation restrictions; and</td>
<td>An examination of body system(s) using standardized tests and measures addressing 4 or more elements from any of the following: body structures and functions, activity limitations and/or participation restrictions; and</td>
</tr>
<tr>
<td><strong>Clinical Presentation</strong></td>
<td>Stable and/or uncomplicated characteristics; and</td>
<td>Evolving clinical presentation with changing characteristics; and</td>
<td>Unstable and unpredictable characteristics; and</td>
</tr>
<tr>
<td><strong>Decision Making</strong></td>
<td>Low complexity as determined by a standardized patient assessment instrument and/or measureable assessment of functional outcome</td>
<td>Moderate complexity as determined by a standardized patient assessment instrument and/or measureable assessment of functional outcome</td>
<td>High complexity as determined by a standardized patient assessment instrument and/or measureable assessment of functional outcome</td>
</tr>
</tbody>
</table>

*Complexity determination is based on least complex level for which all components are present.

97165 – Physical Therapy Reevaluation

Requires an examination including a review of history and use of standardized tests and measures; and Revised plan of care using a standardized patient assessment instrument and/or measureable assessment of functional outcome

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# OCCUPATIONAL THERAPY EVALUATION CODE REQUIREMENTS

<table>
<thead>
<tr>
<th>Low – CPT 97165</th>
<th>Occupational therapy evaluation, low complexity, requiring these components:</th>
</tr>
</thead>
</table>

© 2019 Magellan Healthcare Proprietary Page 895 of 927
• An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem;
• An assessment(s) that identifies 1-3 performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and
• Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.

Moderate – CPT 97166

Occupational therapy evaluation, moderate complexity, requiring these components:
• An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance;
• An assessment(s) that identifies 3-5 performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and
• Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
High – 97167

**Occupational therapy evaluation, high complexity, requiring these components:**
- An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance;
- An assessment(s) that identify 5 or more performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and
- A clinical decision-making is of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.

Re-evaluation – 97168

**Re-evaluation** of occupational therapy established plan of care, requiring these components:
- An assessment of changes in patient functional or medical status with revised plan of care;
- An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and
- A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required.

Typically, 30 minutes are spent face-to-face with the patient and/or family.

**SPEECH LANGUAGE PATHOLOGY EVALUATION CODES (ASHA)**

- 92521 Evaluation of speech fluency (e.g., stuttering, cluttering)
• 92522 Evaluation of speech sound production (e.g., articulation, phonological process, apraxia, dysarthria)
• 92523 Evaluation of speech sound production (e.g., articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (e.g., receptive and expressive language)
• 92524 Behavioral and qualitative analysis of voice and resonance
• 92610: Evaluation of oral and pharyngeal swallowing function
• 92597: Evaluation for use and/or fitting of voice prosthetic device to supplement oral speech. Under Medicare, applies to tracheoesophageal prostheses (e.g. Passy-Muir Valve), artificial larynges, as well as voice amplifiers. Use 92507 for training and modification of voice prostheses.
• 96105: Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, eg, by Boston Diagnostic Aphasia Examination) with interpretation and report, per hour
• 92626: Evaluation of auditory rehabilitation status, first hour
• 92627: Evaluation of auditory rehabilitation status, each additional 15 minutes
• 96125: Standardized cognitive performance testing (eg, Ross Information Processing Assessment) per hour of a qualified health care professional's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report.
• G0451: Developmental testing, with interpretation and report, per standardized instrument form; Medicare-specific code to be used instead of 96110
• 92607: Evaluation for prescription of speech-generating AAC device, first hour

MEDICAL RECORD CONTENT REQUIREMENTS FOR ALL PATIENTS:

• The reason for the encounter i.e., presenting complaint(s)
• The patient’s prior medical, familial, and social history, including, but not limited to accidents, surgeries, medications, illness, and co-morbidities and history of any past or current treatment for the same or similar presenting complaint
• Patient demographics must also include name, address, home and work telephone numbers, gender, date of birth, occupation, and marital status
• Systems review consistent with the nature of the complaint(s) and relevant historical information
• The working diagnosis(es) must be documented and consistent with the associated findings
• Treatment plan that includes all of the following: diagnosis and contraindications to treatment; description of functional status/limitations; treatment plan with frequency and duration and type of treatment interventions to be provided; educational plan, including home exercises, ADL modifications; treatment goals that are measurable, functional, time-specific, patient-oriented goals; and specific discharge plan. Specific treatment goals (functional/measurable/time-dependent) should be included in the records where care is likely to extend >2 weeks
• Contraindications to care must be listed with an explanation of their current management
• All chart entries must be dated with the month, day, and year.
• Treating practitioner and credentials must be identified on each date of service.
• Records must be in chronological order and written in permanent ink
• Each date of service must include the subjective complaint(s), objective findings, assessment, diagnosis, treatment/ancillary diagnostic studies performed, and any recommendations or instructions given to the patient
• Services must be documented in accordance with Current Procedural Terminology (CPT) coding criteria e.g., location (body region), time component, etc.
• Each patient record must identify the patient and each page in the record must contain the patient’s name
• Any corrections to the patient’s record must be made legibly in ink, dated, and authenticated by the person making the correction(s).
• The patient record must include periodic measures of treatment response
• Discharge status including the current functional status, degree of goal attainment, home program given, referral or follow up, equipment given, and reason for discharge
• Daily notes should be in a standard type format i.e. SOAP and contain the date for return visits or follow-up
• The patient record should include valid, reliable, and relevant outcome assessment tools, ensuring that a peer reviewer or other healthcare professionals can render a reasonable determination on the baseline status and treatment response
• Adverse events associated with treatment should be recorded in the patient chart
• All records must be legible, which is defined as the ability of at least two people to read and understand the documents.
• Progress toward measurable, functional goals, and updated treatment plan goals
• Copies of reports and correspondence with other caregivers: including, but not limited to: diagnostic studies, laboratory findings, and consultations
• Copies of reports and correspondence related to treating practitioner diagnostic studies, laboratory findings, and consultations, including rationale for the service or consult and findings, conclusions, and recommendations
• Appropriate consent forms when applicable
• A key or summary of terms when non-standard abbreviations are used. Another practitioner should be able to read the record and have a clear understanding of the patient’s condition and treatment rendered.

All services billed should be described in the patient chart in accordance with Current Procedural Terminology (CPT) coding criteria. Billed services which are not documented in the patient record are not eligible for reimbursement. The patient record should demonstrate the basis for clinical decision-making, document all services performed, and register the patient’s response to treatment.

Reevaluation should not be routine or recurring. While there is broad consensus on the general indications for formal reevaluation of patients, there is less agreement about proposed reasons for reporting patient re-evaluations i.e., discharge planning, on a routine/prescheduled basis, and/or in meeting regulatory requirements. An established patient evaluation is indicated if any of the following apply:
• The patient presents with a new condition
• There is a significant or unanticipated change in symptoms
• Assessment of response or non-response to treatment at a point in care when meaningful clinical change can reasonably be detected
• There is a basis for determining the need for change in the treatment plan/goals

The reevaluation exceeds the parameters of the typical office visit and includes the following:
• Updated history
• Subjective symptoms
• Physical examination findings
• Appropriate standardized outcome tool/measurements as compared to the previous evaluation/reevaluation
• Evidence to support the need for continued skilled care
• Identify appropriate services to achieve new or existing treatment goals
• Revision in Treatment Plan
• Correlation to meaningful change in function
• Evidence of the effectiveness of the interventions provided

Documentation should clearly reflect why the skills of a network practitioner are needed. The service is considered a skilled service if the inherent complexity of the service is such that it can be performed safely and/or effectively only by or under the supervision of a licensed chiropractor or rehabilitation therapist. The deciding factors are always whether the services are considered reasonable, effective treatments requiring the skills of a therapist or chiropractor or whether they can be safely and effectively carried out by non-skilled personnel without the supervision of qualified professionals.

Clinical Guidelines have been developed to support medically necessary treatment as part of the peer review process. Clinical documentation is evaluated when making utilization review determinations. The elements evaluated by a clinical reviewer include, but are not limited to:
• Whether treatment involves an initial trial of care or ongoing care
• Proposed services/procedures for initial trial or ongoing treatment
• Whether the reported condition was acute, sub-acute, or chronic at the onset of care
• Documentation of an exacerbation or significant flare-up
• Whether a condition is trauma-related, the result of activities of daily living, or insidious onset
• The date of onset and mechanism of onset is specified
• A history of the current condition is documented
• An interim history is provided for recurrent episodes
• The level, intensity, and frequency of pain is recorded
• Measurable treatment goals are recorded, appropriate, and monitored
• Outcome Assessment Tools are utilized at pre-determined intervals and treatment does not continue after further meaningful change would be minimal or difficult to measure
• Treatment demonstrates functional improvement that is sustained over time and meets minimum detectable change (MDC) and/or minimum clinically important change (MCIC) requirements
• All services billed meet CPT coding requirements; are supported by subjective complaints, objective findings, diagnoses, and treatment performed; and meet the requirements according to this organization’s Clinical Guidelines
• The record demonstrates the need for skilled services, as apposed to home management or unskilled services
• Patients with mild complaints and minimal functional limitations are released to a home exercise program
• Treatment has exceeded 2-3 months for the same or similar condition
• Treatment is provided on patient-directed PRN basis without a treatment plan, functional goals, or sustained improvement

CONFIDENTIALITY OF RECORDS

All contracted practitioners will treat patient identifiable health information according to HIPAA standards to ensure the confidentiality of the record and provide the minimum necessary information when requested to perform a review of services.
MEDICAL NECESSITY

All network practitioners will maintain clinical documentation that clearly supports the medical necessity of all health care services. In addition, all network practitioners are required to provide additional clinical documentation and/or explanation regarding medical necessity of services at the request of this organization.

Medically necessary care includes the following eight elements:
1. **Contractual** – all covered medically necessary health care services are determined by the practitioner's contract with the payer and individual health plan benefits.
2. **Scope of Practice** – medically necessary health care services are limited to the scope of practice under all applicable state and national health care boards.
3. **Standard of Practice** – all health care services must be within the practitioner’s generally accepted standard of practice and based on creditable, peer-reviewed, published medical literature recognized by the practitioner’s relevant medical community.
4. **Patient Safety** – all health care services must be delivered in the safest possible manner.
5. **Medical Service** – all health care services must be medical, not social or convenient for the purpose of evaluating, diagnosing, and treating an illness, injury, or disease and its related symptoms and functional deficit. These services must be appropriate and effective regarding type, frequency, level, duration, extent, and location of the enrollee's diagnosis or condition.
6. **Setting** – all health care services must be delivered in the least intensive setting.
7. **Cost** – the practitioner must deliver all health care services in the most cost-effective manner as determined by this organization, the health plan, and/or employer. No service should be more costly than an alternative diagnostic method or treatment that is at least as likely to provide the same diagnostic or treatment outcome.
8. **Clinical Guidelines** – health care services are considered medically necessary if they meet all of the Clinical Guidelines of this organization.
REFERENCES


**Policy Statement**
This policy will be used to define Durable Medical Equipment (DME), as well as, support the medical necessity of the billed DME.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

**Purpose**
To outline the medical necessity of Durable Medical Equipment.

**Scope**
This policy will apply to all physical medicine participating network practitioners, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

**Definition**
- DME is any equipment that provides therapeutic benefits to a patient for certain conditions and/or illnesses defined below.
- DME consist of items which:
  - Are used to treat a defined illness or injury
  - Are not useful to a person in the absence of illness or injury
  - Are reusable and durable enough for repeated use
  - Are appropriate for use outside of a medical setting such as home, at school, or a work
- DME includes but is not limited to: back supports/braces, cervical collars, foot orthotics, electrical stimulation units, traction devices, and wheelchairs and assistive devices for gait.
- The use of any DME must have evidence of efficacy in the peer reviewed guideline, systematic review, and/or randomized controlled trial medical literature. The use of these devices is not considered medically necessary in the absence of scientific evidence in peer reviewed medical literature.

"The “Original Date” above reflects the date the Policy was initiated by HSM Physical Health, Inc., (HSM). The “Adoption Date” above indicates the date that the Magellan Healthcare NIA Clinical Guideline Task Force reviewed and approved the Policy. HSM was acquired by National Imaging Associates, Inc., (NIA) in 2015 and is now a wholly owned subsidiary of NIA. National Imaging Associates, Inc., is a subsidiary of Magellan Healthcare, Inc.

**Medical Necessity**
Durable Medical Equipment and services are medically necessary when the following criteria are met:
1. The equipment is expected to provide improvement in specific, measurable functional deficits related to a documented illness or injury; and
2. The DME is provided by a health care professional; and
3. The equipment does not have significant non-medical uses; and
4. The clinical records clearly establish the medical need for the DME

Clinical documentation must include the following elements:
1. A diagnosis that justifies the equipment or supply being requested
2. A treatment plan (anticipated start and end date) for the use of the DME
3. Documented measurable functional deficit(s)
4. Expected outcomes and benefit related to a measurable functional deficit
5. Documentation of the healthcare providers training/education, supervision, and monitoring of the use of the DME, as evidenced by the identification of provider type and signature in the record.

6. Documentation of a trial of conservative services that failed to improve a measurable functional deficit unless contraindicated

7. When appropriate, documentation of a trial of in-office care, such as cervical traction, that provided improvement in a measurable functional deficit

8. If an insurance plan does not cover a DME, then any visit associated with instruction on the DME would not be covered

**DME**

DME may be subject to medical necessity review. This would include: Transcutaneous electrical nerve stimulation or other electrical stimulation units, traction devices, or chairs, etc. Additionally, any DME with a purchase or rental price of more than **$200** will be subject to review.

**Specific Durable Medical Equipment:**

**Electrical Stimulation for Pain**

Transcutaneous electrical nerve stimulation (TENS) uses electrical stimulation at a painful site via the application of electrodes from the device to the surface of the skin. TENS devices generate electrical output, usually by a portable, battery operated method.

TENS is considered a medically necessary DME when used as an adjunct or as an alternative to common conservative treatments for the initial 30 days of acute post-operative pain and for some forms of chronic musculoskeletal and neuropathic pain causing significant documented disruption of function unresponsive to at least a 1 month trial of conservative care including but not limited to manual therapy, active care, and pharmacotherapy. Please note that not all health plans reimburse for rental or purchase of home TENS units.

TENS is considered experimental and investigational for acute non-operative pain, acute and chronic headaches, deep abdominal pain, and chronic temporomandibular joint (TMJ) pain, adhesive capsulitis (frozen shoulder), chronic low back pain, neuropathic pain, pelvic pain, phantom pain, stump pain, and all other indications because there is inadequate scientific evidence to support its efficacy for these specific types of pain.

A trial of TENS use for at least 30 days, but not to exceed 90 days must be monitored by the healthcare provider. This trial period must include documentation of the effect on the patient’s pain and measurable function to determine the effectiveness of the TENS unit. Treatment for long-term use is considered medically necessary if the trial period produced significant improvement in the patient’s pain and measurable functional deficit(s). This documentation must include how the patient used the unit, the duration of use each time the unit was used, as well as, the results of use. Concurrent chiropractic and/or physical therapy services are not indicated for the treatment of the same condition during the trial period.

The use of form-fitting conductive garments is not considered medically necessary.

The following forms of electrical stimulation are not considered medically necessary. This list is not all-inclusive.

- Noninvasive neuron blockage devices
- Electroceutical therapy devices
- Bioelectric treatment systems
- Electro-Acuscope Therapy System
• Electrical stimulation of the sacral nerve roots or lumbosacral plexus for treatment of chronic pelvic or abdominal pain
• High-frequency pulsed electromagnetic stimulation
• Vagus nerve stimulation
• Bone growth stimulators

On June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) rendered a decision memo for TENS for chronic low back pain. It states that TENS is not reasonable and necessary for the treatment of chronic low back pain.

In an evidence-based review, the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology evaluated the effectiveness of TENS in the treatment of pain in neurological disorders (Dubinsky 2010). There are conflicting reports of TENS compared to sham TENS in the treatment of chronic low back pain (LBP), with two, Class II studies showing benefit, while two, Class I studies and another Class II study not showing benefit. Because the Class I studies are stronger evidence, TENS is established as ineffective for the treatment of chronic LBP. The authors concluded that TENS is not recommended for the treatment of chronic LBP.

Guidelines on treatment of LBP from the National Collaborating Centre for Primary Care (Savigny 2009) found insufficient evidence for the use of TENS in LBP and recommended against its use for that indication.

Evidence is insufficient to support the use of knee braces as a treatment for patellofemoral pain syndrome.

**Home Traction Devices**

Home traction therapy is unproven and not medically necessary for treating low back and neck disorders with or without radiculopathy. The majority of studies are office based with mixed results. The quality of peer reviewed studies for home traction are limited as well to conclude that it is effective in the management of neck or low back pain or that it improves health outcomes. The indications for clinical application, patient selection criteria, risks, and comparison to alternative technologies have not been established for home traction therapy.

There is insufficient evidence from peer-reviewed published studies to conclude that lumbar spinal traction devices are effective at improving specific, measurable and functional deficits related to low back pain and leg-related low back pain. Lumbar auto-traction devices are considered experimental and investigational. This would include, but is not limited to: the Spinalator, the Arthrotonic stabilizer, the Anatomotor, Saunders Lumbar Hometrac, etc. Axial spinal uploading (gravity-dependent traction) devices are considered experimental and investigation for the treatment of low back pain and leg-related low back pain. This would include, but is not limited to: the LTX 3000, VAX-D, and other decompression or traction devices, tables, weights or vests.

**Orthotics, Prosthetics, Bracing and Assistive Devices**

No definitive evidence as yet supports the use of orthoses in painful conditions of the cervical or lumbar spine. They should, therefore, be used only after individual consideration of the indications in each case.

Studies suggest that wearing a wrist splint can provide relief from carpal tunnel symptoms within a few weeks; however, the effect is only temporary.
The use of these devices must be necessary for the treatment of an illness or injury and to improve documented, measurable, and functional deficit(s). The documentation must include the reason the equipment is needed and the duration of its need.

A brace, orthotic, or prosthetic is a rigid or semi-rigid device. It is used to support and/or substitute a documented weak or deformed body part that is causing a documented measurable functional deficit.

The use of assistive devices is considered a standard of practice for general mobility needs and reduction in patients at risk of falling. Clinical documentation must support the use of these devices.

There is insufficient evidence to support the use of insoles or foot orthoses as either a treatment for LBP or in the prevention of LBP. Foot orthoses produce small short-term benefits in function and may also produce small reductions in pain for people with plantar fasciitis, but they do not have long-term beneficial effects compared with a sham device. Foot orthotics have no proven value for knee pain (other than medial osteoarthritis), pes planus (flat feet), pronation, corns and calluses, hip osteoarthritis, and lower leg injuries. Customized and prefabricated orthoses have similar effectiveness in the treatment of plantar fasciitis. Spinal Pelvic Stabilizers (Foot Levelers, Inc.) are specialized custom molded inserts designed to prevent foot injuries and improve foot alignment; these are considered experimental and investigational because their value in treatment of foot disease has not been proven. The available evidence does not reveal any clear advantage of foot orthoses over simple insoles or physiotherapy for patellofemoral pain. While foot orthoses may help relieve knee pain over the short term, the benefit may be marginal. There is moderate evidence to support the use of foot orthotics in the treatment of chronic ankle instability to help improve postural control.

Overall, the evidence appears to suggest that custom foot orthotics and prefabricated orthotics have similar effectiveness. Therefore, prefabricated orthotics should be prescribed when there is a clinical indication for foot orthotics.

HCPCS 2018 Code L0631: Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise. The clinical record must clearly document that this service involved customization of the lumbar orthosis in order for it to be reimbursable.

**Strapping**

The application of casts, splints, or straps is performed in an attempt to provide temporary immobilization or fixation to correct, protect, or stabilize a fracture, dislocation, or documented joint instability as a result of injury, disease or surgery.

The use of casting, splinting or strapping may be considered medically necessary for a patient who has experienced a fracture, dislocation or who has ligamentous instability following an acute injury, or as the result of a disease or surgery.

The application of casting, splinting or strapping should not be reported when any kind of treatment or restorative service aimed at correcting, protecting, or stabilizing the fracture, dislocation, or instability is concurrently done.

Strapping uses rigid material in order to restrict joint and/or muscular movement. Tape is typically worn for a relatively short duration (<18 hours). In contrast, kinesiology (kinesio) taping (KT) is a therapeutic
taping method that utilizes a latex-free elastic tape, which is purported to give support and stability to joints and muscles without affecting circulation, range of motion, and biomechanics. It is also used for preventive maintenance, edema, and to treat pain. KT methods use highly-specific designed tape, which may be pre-cut for certain joints, and reportedly can be used by patients of every age and condition for 1-5 days per application. The consensus findings of peer reviews did not support the application of KT in clinical settings.
REFERENCES


Cai C, Ming G, Ng LY. Development of a clinical prediction rule to identify patients with neck pain who are likely to benefit from home-based mechanical cervical traction. *Eur Spine J*. 2011; 20(6):912-922.


Policy Statement
While the evaluation, diagnosis, and management of infants falls within the scope of chiropractic practice, participating network providers should not engage in unsafe or unproven services as outlined in this policy. There is insufficient evidence that manual therapy (spinal manipulation, extra-spinal manipulation, and mobilization) results in improved health outcomes, particularly functional outcomes, related to the treatment of both musculoskeletal and non-musculoskeletal infant conditions.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose
This policy will be used to support medically necessary, appropriate, and acceptable treatment of infants defined as ages birth to 24 months.

Scope
Physical medicine participating network practitioners, including rendering chiropractors.

Procedure
All of the following apply:

I. A therapeutic trial of chiropractic care can be a reasonable approach to management of the infant patient in the absence of conclusive research evidence when clinical experience and patient/parent preferences are aligned. If the infant patient is not showing clinically significant improvement, as evidenced by progress toward measurable goals, after a two-week trial of chiropractic care, no additional chiropractic care is indicated and referral may be appropriate (Hawk, 2016).

II. Manual-based therapy (spinal manipulation, extra-spinal manipulation, and mobilization), active care and passive therapies have not been shown to improve the health outcomes of spine or extremity-based musculoskeletal conditions in infant populations.

III. The use of manual-based therapy (manipulation and mobilization), active care and passive therapies have not been shown to improve the health outcomes of non-musculoskeletal conditions in infant populations (Hawk, 2007).

IV. The use of manual-based therapy, active care and passive therapies have not been proven to be a substitutive treatment for childhood immunizations or the treatment of infectious diseases in infant populations.

V. The following are considered unsafe or unproven services:
   • The use of spinal and extra-spinal manipulation for non-musculoskeletal conditions is unproven. There is no contemporary chiropractic consensus demonstrating a general agreement among a significant portion of the chiropractic community to support the treatment of non-musculoskeletal conditions, such as the treatment of the common cold, sinus congestion, allergies, sleep disturbances, difficulty nursing, infantile colic, ADHD, asthma, autism, cancer, cerebral palsy, constipation, nocturnal enuresis, and otitis media. The data regarding the use of manual therapy interventions for the treatment of non-musculoskeletal conditions is sparse,
the level of evidence is generally low, and the data is generally inconsistent or conflicting. Wellness care, well-baby checks, and preventive care are not covered. Considerations are derived from peer reviewed scientific studies published in or accepted for publication by medical or chiropractic journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

• The use of maintenance or preventative (defined as prevention of any disease or condition, or the promotion and enhancement of health after maximum therapeutic benefit has occurred) spinal and extra-spinal manipulation.

• The use of the following services:

  o CPT code 97012 – Mechanical traction
  o CPT code 97014 – Unattended electrical stimulation
  o CPT code 97032 – Attended electrical stimulation
  o HCPCS code G0283 – Electrical stimulation
  o CPT code 97035 – Ultrasound
  o CPT code S9090 or any code used to bill low level laser

The following codes will require peer review of clinical documentation to determine medical necessity:

• CPT code 97110 – Therapeutic exercise
• CPT code 97112 – Neuromuscular reeducation
• CPT code 97530 – Activities of daily living
• CPT code 98942 – 5-region chiropractic manipulative therapy
• CPT code 98943 – Extra-spinal chiropractic manipulative therapy
• CPT code 97124 – Massage therapy
• CPT code 97140 – Manual therapy
• All X-rays

VI. This organization has the ultimate authority to determine if treatment is medically necessary and appropriate.
Literature Search

As of February 15, 2018, there is no first level evidence available in the literature in relation to the effectiveness of manual therapy/manipulation for spinal disorders in the young population. No guidelines, systematic reviews, or randomized controlled trials were discovered in a literature search regarding the treatment of infant musculoskeletal conditions with spinal or extra-spinal manipulation, mobilization, massage therapy, mechanical traction, electrical stimulation, ultrasound therapy, or low level laser therapy.

*The “Original Date” above reflects the date the Policy was initiated by HSM Physical Health, Inc., (HSM). The “Adoption Date” above indicates the date that the Magellan Healthcare NIA Clinical Guideline Task Force reviewed and approved the Policy. HSM was acquired by National Imaging Associates, Inc., (NIA) in 2015 and is now a wholly owned subsidiary of NIA. National Imaging Associates, Inc., is a subsidiary of Magellan Healthcare, Inc.
REFERENCES


Policy Statement
The use of plain films is medically necessary when clinical findings dictate their utilization. Films are not indicated to identify unsuspected contraindications to chiropractic manipulation, view postural changes and biomechanics, or identify subluxations. Insufficient scientific evidence exists to support the use of routine plain film radiographs as a means for improved clinical outcomes in spinal disorders. There is insufficient clinical research to support improved clinical outcomes when radiographs are a part of a routine component of the initial evaluation or ongoing treatment. This organization has adopted the Diagnostic Imaging Practice Guidelines for Musculoskeletal Complaints in Adults. These guidelines represent the official position of the Council on Chiropractic Guidelines and Practice Parameters in matters relating to the use of diagnostic imaging in the chiropractic profession.

The use of full spine radiographs, except for the clinical investigation and diagnosis of scoliosis, is not supported by clinical research.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose
This policy will be used to support the medical necessity of plain film radiographs by chiropractic providers within the first 30 days of care.

Scope
This policy will apply to all participating network chiropractic practitioners.

Definition
Plain films:
Spinal or extremity radiographs used as a diagnostic tool by chiropractors.

Guidelines:
I. An appropriate history and examination are required to identify if plain films are clinically indicated.

II. Utilization of radiographs by chiropractors will not be reimbursed unless sufficient medical record documentation is submitted with claims to support the medical necessity of the film. The clinical record must clearly document the rationale for the x-rays, any suspected pathology, or what condition the chiropractor hopes to rule out. The use of plain films to rule out an unsuspected pathology is not clinically indicated.

III. Routine use of radiographs as part of the initial evaluation or part of an ongoing treatment plan will not be reimbursed.

IV. The use of full spine radiographs for any diagnosis other than scoliosis is not considered medically necessary and will not be reimbursed.

V. Contraindications to plain film x-rays include:
   a. Infants (0-36 months)
   b. Pregnancy or possible pregnancy
c. Obesity, if size precludes good radiographic resolution
d. Patient has positioning difficulty due to mental status or physical restrictions, which precludes good radiographic resolution
e. Children 3 to 18 years of age, except for investigation of suspected acute fracture, dislocation, infection, scoliosis, developmental defects, or a suspected pathology.

VI. Requirements:
1. The clinical record must contain a written x-ray report within five (5) business days from the date of service.

2. The clinic must have all of the following:
   • A documented Quality Control Program inclusive of both imaging equipment and film processors
   • A documented Radiation Safety and As Low As Reasonably Achievable (ALARA) Program
   • Documented emergency policies, procedures, and equipment on site (i.e. automated external defibrillator (AED))
   • Documentation of current Basic Life Support (BLS) certification
   • Records of formal preventative maintenance program per original equipment specifications
   • A current (within three (3) years) letter of state inspection, calibration report, or physicist’s report
   • At a minimum, an automatic processor must be used to develop all analog plain films.

CLINICAL EXAMPLES of MEDICALLY NECESSARY X-RAYS:

• Investigation of suspected acute fracture
• Follow up radiographs to monitor a healing fracture
• Investigation of suspected bony dislocation
• Evaluation of prior surgical site where manual based treatment may be applied (where no previous films are available for review)
• Suspect (patient history, pain characteristics and/or physical examination) malignancy, infection, systemic disease, or inflammatory spondyloarthropathy
• Precise quantification of clinically suspected active child or juvenile scoliosis
• Persistent (same or worse pain) after first month of treatment
• Significant history of drug or alcohol abuse such as IV drugs or chronic alcoholism or chronic use of steroids
• Adult patient with thoracolumbar, lumbar, or thoracic spine blunt trauma or acute injuries (falls, motor vehicle accidents [MVAs], motorcycle, pedestrian, cyclists, etc)
• Adults with complicated (ie, “red flag”) LBP, thoracic pain, or neck pain & indicators of contraindication to SMT (relative/absolute)
• Suspected inflammatory spondyloarthropathies, neoplasia, or infection
• Adult patient: in the absence of expected treatment response or worsening after 4 weeks of conservative treatment
• Adult patient with acute neck injury and positive CCSR (Canadian Cervical Spine Rule for Radiography in Alert and Stable Trauma Patients.)
• Suspected lumbar degenerative spinal stenosis or spondylolisthesis if patient is greater than 50 years of age and/or has progressive neurological deficit – AP (or PA) and lateral lumbar views
• Adult with recent unimaged blunt trauma to pelvis and unable to bear weight – AP pelvis and lateral hip “frog leg” views
• Acute neck pain with recent unimaged dangerous trauma, paresthesia in extremities or age greater than 65 or non-traumatic neck pain with radicular symptoms – APOM, AP lower cervical and lateral neutral views

• Adult with painful or progressive scoliosis – Erect standing full spine (14x36) PA and lateral views in the absence of recent films. Plain film x-rays may be appropriate when red flags suggest further screening for cancer, infection, or fracture. They may also be sufficient for the initial evaluation of patients with the following red flags: age >70 years, a history of recent significant trauma, or risk of osteoporosis. Plain film x-rays may be appropriate, but are usually not sufficient for clinical decision making without advanced imaging, in the presence of other red flags. Radiographs are unreliable for assessment of bone mass changes before at least a 30%-50% loss. In healthy peri- and early postmenopausal women (45-64 yoa), consider using the OST score (Osteoporosis Self Assessment Tool.) OST score considers only 2 variables: (weight in kg − age)/5. The cut-off for a positive test is <2, indicating this woman should be referred for DXA.

• Current x-ray recommendations/guidelines for spinal and extremity disorders emphasize a focused history and physical examination, reassurance, initial pain management medications if necessary (acetaminophen or nonsteroidal anti-inflammatory drugs), and consideration of nonpharmacologic therapies (e.g., manipulation, exercise, etc.) without routine imaging in patients with nonspecific neck and/or low back pain (Bussières, 2007, 2008; Dagenais, 2010; Koes, 2010; Pillastrini, 2011). Imaging is considered for those without improvement after 6 weeks and for those with clinical indicators of serious pathologies (red flags) (Bach, 2009; Bussières, 2007, 2008; Chou, 2011, 2007).

Plain film x-rays of the extremities may be indicated in the following circumstances:

• Significant history of recent trauma sufficient to cause fracture
• Significant history of repetitive stress to cause stress fracture
• History or clinical findings of malignancy
• Previous surgery or fracture
• Suspicion of or confirmed inflammatory arthritis
• Evaluation of gross deformities
• Bruising, swelling, redness heat, indicating infection
• Lymphadenopathy
• Evaluation of developmental hip dysplasia in the pediatric population
• Evaluation of Leg-Calve-Perthes disease
• Evaluation of slipped capital femoral epiphysis in the pediatric population

Plain film radiographs may be appropriate but are usually not sufficient for clinical decision making without advanced imaging (MR and/or CT) in the presence of other red flags including [Davis, Dagenais (2012)]:

1. Age <20 years or >50 years
2. Failure to improve with care, no prior films
3. Personal history of intravenous drug abuse
4. History of malignancy
5. Immune suppression
6. Night pain
7. Night pain (unrelated to movement)
8. Pain at multiple sites
9. Pain at rest
10. Fever
11. Structural deformity
12. Systemic unwellness
13. Unexplained weight loss

Spinal radiographs also have a role in evaluation of scoliosis and in postoperative evaluation of instrumentation and fusion (Davis, 2011). For the evaluation of scoliosis in children, radiographic decision-making and examinations should be performed in accordance with guidance published by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR) (Faerber, 2009, 2012).
Radiographic examination is indicated for pediatric patients at high risk for cervical spine instability – especially those with Down syndrome (Faeber, 2012).

**INITIAL PLAIN FILM X-RAYS ARE NOT INDICATED in the FOLLOWING CASES:**

- Adult patient with acute uncomplicated LBP (<4 wks' duration). Uncomplicated definition: nontraumatic pain without neurologic deficits or indicators of potentially serious pathologies
- Adult patient with uncomplicated subacute (4-12 wks' duration) or persistent LBP (>12 wks' duration) AND no previous treatment trial
- Adult patient with nontraumatic acute LBP (<4 wks' duration) AND sciatica and no red flags
- Sciatica, unless patient is age >50 or has progressive neurological deficits
- Suspected lumbar disc herniation
- Suspected degenerative spondylolthesis/lateral stenosis, unless patient is age >50 or has progressive neurological deficits
- Suspected lumbar degenerative spinal stenosis, unless patient is age >50 or has progressive neurological deficits
- Adult patient with uncomplicated acute (<4 wk duration) thoracic spine pain
- Adult patient with uncomplicated subacute (4-12 wk duration) or persistent (>12 week duration) thoracic spine pain and no previous treatment trial
- Adult patient with nonpainful and nonprogressive scoliosis
- Adult patient with acute uncomplicated neck pain (<4 wks' duration)
- Adult patient with uncomplicated subacute neck pain (4-12 wks' duration) with or without arm pain
- Adult patient with persistent neck pain (>12 wk) with or without arm pain
- Adult patient with acute neck injury and negative CCSR (Canadian Cervical Spine Rule for Radiography in Alert and Stable Trauma Patients) (Stiell 2011)
- In headache complaints, vital signs (to R/O severe hypertension or fever) and testing of the cranial nerves (to R/O vascular events, space occupying lesions, etc) should be an integral part of initial examination. Significant positive findings mandate further evaluation. Without red flags or significant findings, no initial films are indicated.
- Coccyx trauma and coccydynia
- The routine use of spinal radiographs for structural and biomechanical analysis has not been substantiated to improve patient outcomes (Peterson 2005). The clinical evidence is insufficient to support an association between sagittal (lordosis, kyphosis) spinal curves and health outcomes including spine-related pain (Christensen 2008). The utility of plain film radiography for the detection of spinal 'subluxations', or to guide the specifics of spinal manipulative therapy, is controversial (Petersen 2005). “The validity of the various systems of roentgenometric analysis has not been proven and their underlying premise of bilateral symmetry within the body does not take into account natural structural anomalies” (Petersen 2005). Adding to this controversy is the fact that nonspecific spinal abnormalities are common in asymptomatic patients (Davis 2011).
- “Strong evidence shows that routine back imaging does not improve patient outcomes, exposes patients to unnecessary harms, and increases costs” (Chou 2012). “Available evidence indicates that immediate, routine lumbar spine imaging in patients with LBP and without features indicating a serious underlying condition, did not improve outcomes compared with usual clinical care without immediate imaging. Clinical care without immediate imaging seems to result in no increased odds of failure in identifying serious underlying conditions in patients without risk factors for these conditions. In addition to lacking clinical benefit, routine lumbar imaging is associated with radiation exposure (radiography and CT) and increased direct expenses for patients and may lead to unnecessary procedures. This evidence confirms that clinicians should
refrain from routine, immediate lumbar imaging in primary care patients with nonspecific, acute or subacute LBP and no indications of underlying serious conditions” (Andersen 2011).
REFERENCES


