2017 MAGELLAN\textsuperscript{1} CLINICAL GUIDELINES FOR MEDICAL NECESSITY REVIEW

Version: 3  
Effective: January 2017
Guidelines for Clinical Review Determination

Preamble
Magellen 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.

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All guidelines were reviewed between January 1, 2016 and September 1, 2016.

Prepared December 15, 2016
INTRODUCTION:

Temporomandibular joint (TMJ) dysfunction causes pain and dysfunction in the jaw joint and muscles controlling jaw movement. Symptoms may include: jaw pain, jaw 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 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:

- 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.

ADDITIONAL INFORMATION RELATED TO TEMPOROMANDIBULAR JOINT (TMJ) MRI:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

MRI Imaging of Temporomandibular Joint – Imaging of the temporomandibular joint has been difficult as the mandibular condyle is small and located close to dense and complex anatomic structures. MRI produces cross-sectional multiplanar images that document both soft and osseous tissue abnormalities of the joint and the surrounding structures and may help in determining the pathology around the joint.

REFERENCES:


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:
- For the evaluation of a single study related to 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:
- 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 cognitive assessment:
- Change in mental status with a mental status score of either MMSE or MoCA of less than 26 or other similar mental status exams 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:
- 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/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:
- 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.
- Patient with history of cancer, or significantly immunocompromised, with new onset headache.
- New headache in occipitonal region 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:**
- 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).
- For patient with history of cancer with suspected recurrence or metastasis [based on symptoms or examination findings (may include new or changing lymph nodes)].
- Evaluation of 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.
- Evaluation for a bone tumor or abnormality of the skull.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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
  - Cancer surveillance – Active monitoring for recurrence as clinically indicated.

**For evaluation of known or suspected stroke:**
- 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) and MRI is contraindicated or cannot be performed:**
- Patients with 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.
- 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):

- 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 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.
- Evaluation of craniosynostosis and other head deformities.
- 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.

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:

- Evaluation of 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 defect etc).
- Anosmia (loss of smell) (documented by objective testing).
- For 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.
- 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.

REDDUCING 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.

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

REFERENCES


CPT Codes: 70480, 70481, 70482

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

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:

- For assessment of proptosis (exophthalmos).
- For evaluation of progressive vision loss.
- For evaluation of decreased range of motion of the eyes.
- For screening and evaluation of ocular tumor, especially melanoma.
- For screening and assessment of suspected hyperthyroidism (such as Graves’ disease).
- For assessment of trauma.
- For screening and assessment of known or suspected optic neuritis if MRI is contraindicated or is unable to be performed.
- For evaluation of unilateral visual deficit.
- For screening and evaluation of suspected orbital Pseudotumor.
- Papilledema
- Orbital infection

COMBINATION OF STUDIES WITH ORBIT CT:

- **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.

ADDITIONAL INFORMATION RELATED TO ORBIT CT:

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.

Proptosis or exophthalmos – Proptosis is a bulging of one or two of the eyes. Bulging of the eyes may be caused by hyperthyroidism (Graves’ disease) or it may be caused by orbital tumors, cancer, infection, inflammation and arteriovenous malformations. The extent of proptosis, the abnormal bulging of one or two eyes, can be assessed by using a mid-orbital axial scan.
Orbital Pseudotumor – Pseudotumor may appear as a well-defined mass or it may mimic a malignancy. A sclerosing orbital Pseudotumor can mimic a lacrimal gland tumor.

Grave’s Disease – Enlargement of extraocular muscles and exophthalmos are features of Grave’s disease. CT may show unilateral or bilateral involvement of single or multiple muscles. It will show fusiform muscle enlargement with smooth muscle borders, especially posteriorly and pre-septal edema may be evident. Quantitative CT imaging of the orbit evaluates the size and density values of extraocular muscles and the globe position and helps in detecting opthalmopathy in Grave’s disease.

Orbital Trauma – CT is helpful in assessing trauma to the eye because it provides excellent visualization of soft tissues, bony structures and foreign bodies.

Ocular Tumor – In the early stages, a choroidal malignant melanoma appears as a localized thickening of sclero-uveal layer. It may be seen as a well defined mass if it is more than 3 mm thick.

REFERENCES:


CPT Codes: 70480, 70481, 70482

INTRODUCTION:
Temporal bone/mastoid 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 contrast for different tissue types.

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 TEMPORAL BONE, MASTOID CT:
- For evaluation of conductive hearing loss.
- For evaluation of chronic otitis media, ear infections or drainage.
- For evaluation of mastoiditis.
- For evaluation of cholesteatoma.
- For evaluation of congenital hearing loss or deformity.
- For evaluation of dehiscence of the jugular bulb or carotid canal.
- For evaluation of aberrant blood vessels or malformations.
- For evaluation of cochlear implants.

ADDITIONAL INFORMATION RELATED TO TEMPORAL BONE, MASTOID CT:

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.

Internal Auditory Canal (IAC) – The Internal Auditory Canal is the bony channel within the temporal bone that carries the VIIth and VIIIth cranial nerves (and blood vessels) from the inner ear to the brain stem. The IAC is approximately 1 cm in length. An acoustic neuroma is a benign tumor that arises from the nerve sheath and may cause sensorineural hearing loss, vertigo, or facial nerve weakness as it enlarges. Tumors or lipomas within the IAC have been reported.

Conductive Hearing Loss – Conductive hearing loss may be caused by fluid in the middle ear resulting from otitis media or from eustachian tube obstruction. CT scans may demonstrate underlying problems due to its aid in visualization of the middle ear space and the mastoid.

Chronic Otitis – When the eustachian tube is blocked for long periods of time, the middle ear may become infected with bacteria. The infection sometimes spreads into the mastoid bone behind the ear. Chronic otitis may be due to chronic mucosal disease or cholesteatoma and it may cause permanent damage to the ear. CT scans of the mastoids may show spreading of the infection beyond the middle ear.

Mastoiditis – CT is an effective diagnostic tool in determining the type of therapy for mastoiditis, a complication of acute otitis media leading to infection in the mastoid process.
**Cholesteatoma** – A cholesteatoma is a cyst-like mass occurring most commonly in the middle ear and mastoid region. CT scanning may help to determine the extent of the disease process. It can determine the extent of cholesteatoma by showing the combination of a soft tissue mass and bone erosion.

**Congenital Hearing Loss** – Genetic factors and factors present either in utero or at time of birth may cause congenital hearing loss in children. High-resolution CT provides the examination of choice furnishing anatomic detail for planning a surgical approach.

**Cochlear Implants** – Cochlear implants provide an opportunity to restore partial hearing. The electronic device, surgically implanted, converts sound to an electrical signal. CT allows the visualization of cochlear anatomy and provides 3D positional information. CT also offers contrast for different tissue types and may be used even when the implant is in place.

**REFERENCES:**


INTRODUCTION:

The sella turcica is a saddle-shaped depression in the sphenoid bone at the base of the human skull which holds the pituitary gland.

Computed tomography (CT) is useful in the delineation of the osseous margins of the sella. It is particularly helpful in evaluating the bony changes related to pathologic processes. The most frequent finding is a change in the size of the sella turcica such as an enlargement unaccompanied by bone erosion. The most common causes are the presence of interstellar adenomas and empty sella syndrome. The shape of the sella may also be affected by pathological conditions, such as Down syndrome, Williams’ syndrome, Sickle syndrome, and lumbosacral myelomenigocele.

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 SELLA CT:

- For assessment of proptosis (exophthalmos).
- For evaluation of progressive vision loss/visual field deficit.
- For evaluation of decreased range of motion of the eyes.
- For screening and evaluation of ocular tumor, pituitary adenoma and parasellar bony structures for the evaluation of certain sellar tumors.
- For screening and assessment of known or suspected optic neuritis if MRI is contraindicated or is unable to be performed.
- For screening and evaluation of suspected orbital Pseudotumor.

ADDITIONAL INFORMATION RELATED TO SELLA CT:

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.

Proptosis or exophthalmos – Proptosis is a bulging of one or two of the eyes. Bulging of the eyes may be caused by hyperthyroidism (Graves’ disease) or it may be caused by orbital tumors, cancer, infection, inflammation and arteriovenous malformations. The extent of proptosis, the abnormal bulging of one or two eyes, can be assessed by using a mid-orbital axial scan.

Orbital Pseudotumor – Pseudotumor may appear as a well-defined mass or it may mimic a malignancy. A sclerosing orbital Pseudotumor can mimic a lacrimal gland tumor.

Grave’s Disease – Enlargement of extraocular muscles and exophthalmos are features of Grave’s disease. CT may show unilateral or bilateral involvement of single or multiple muscles. It will show fusiform muscle enlargement with smooth muscle borders, especially posteriorly and pre-septal edema may be evident. Quantitative CT imaging of the orbit evaluates the size and density values of extraocular muscles and the globe position and helps in detecting opthalmopathy in Grave’s disease.
**Orbital Trauma** – CT is helpful in assessing trauma to the eye because it provides excellent visualization of soft tissues, bony structures and foreign bodies.

**Ocular Tumor** – In the early stages, a choroidal malignant melanoma appears as a localized thickening of sclero-uveal layer. It may be seen as a well defined mass if it is more than 3 mm thick.

**REFERENCES:**


CPT Codes: 70486, 70487, 70488

INTRODUCTION:
Computed tomography (CT) primarily provides information about bony structures, but may also be useful in evaluating some soft tissue masses. It helps document the extent of facial bone fractures secondary to facial abscesses and diagnosing parotid stones. Additionally, CT may be useful in identifying tumor invasion into surrounding bony structures of the face and may be used in the assessment of chronic osteomyelitis.

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 FACE CT:
- For the evaluation of sinonasal or facial tumor.
- For the assessment of osteomyelitis.
- For the diagnosis of parotid stones.
- For the assessment of trauma, (e.g. suspected facial bone fractures).
- For the diagnosis of facial abscesses.

ADDITIONAL INFORMATION RELATED TO FACE CT:

**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.

**Facial Bone Fractures** – Computed tomography (CT) of the facial bones following trauma provides high quality images of fracture sites and adjacent soft tissue injury. It is helpful in planning surgical intervention, if needed.

**Sinonasal and facial tumors** - Computed tomography (CT) of the face produces images depicting a patient’s paranasal sinus cavities, hollow and air-filled spaces located within the bones of the face and surrounding the nasal cavity. Face CT of this system of air channels connecting the nose with the back of the throat may be used to evaluate suspected nasopharyngeal tumors. Face CT may detect other tumors and usually provide information about the tumor invasion into surrounding bony structures.

**Chronic Osteomyelitis** – CT may be used in patients with chronic osteomyelitis to evaluate bone involvement and to identify soft tissue involvement (cellulitis, abscess and sinus tracts). It is used to detect intramedullary and soft tissue gas, sequestra, sinus tracts, and foreign bodies but is not sufficient for the assessment of the activity of the process.

**Parotid Stones** – The sensitivity of CT to minimal amounts of calcific salts makes it well suited for the imaging of small, semicalcified parotid stones. Early diagnosis and intervention are important because patients with parotid stones eventually develop sialadenitis. With early intervention, it may be possible to...
avoid further gland degeneration and parotidectomy. The CT scan identifies the exact location of a parotid stone expediting intraoral surgical removal.

REFERENCES:


INTRODUCTION:

CT scans can provide much 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 also be quite 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.

INDICATIONS FOR SINUS & MAXILLOFACIAL AREA 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.
- 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).
- Osteomyelitis of facial bone where imaging study, (such as plain films, or brain MRI, etc.) demonstrates an abnormality or is indeterminate.

For evaluation of known or suspected tumor:
- For known or suspected tumor with bony abnormality or opaque sinuses seen on imaging or for mucocele (unusual benign tumor).

For evaluation of trauma:
- Suspected fracture AND prior imaging was nondiagnostic or equivocal.
- For follow-up trauma with fracture or opaque sinuses visualized on x-ray.

Pre-operative evaluation:
- Planned maxillo-facial surgery.
- For use as adjunct to image guided sinus exploration or surgery.

Post-operative evaluation:
- Complications, e.g., suspected CSF leak, post-operative bleeding as evidenced by persistent opaqueness on imaging.
- Non-improvement two (2) or more weeks after surgery.

Other indications for Sinus CT:
- For poorly controlled asthma associated with upper respiratory tract infection. May be performed without failing 4 consecutive weeks of treatment with medication.
• For presence of polyposis on imaging or direct visualization that may be causing significant airway obstruction.
• For deviated nasal septum or structural abnormality seen on imaging or direct visualization that may be causing significant airway obstruction.
• For new onset of anosmia (lack of sense of smell) or significant hyposmia (diminished sense of smell).
• Other conditions such as Granulomatosis with polyangiitis (Wegener’s) may present as rhinosinusitis.
• 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.

**COMBINATION OF STUDIES WITH SINUS 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) disease (GPA).

**ADDITIONAL INFORMATION RELATED TO SINUS CT:**

**Sinusitis** - In acute sinusitis, routine imaging is not recommended except for patients with suspected complications (especially in the brain and in the orbit). In addition to CT scanning, magnetic resonance (MR) imaging of the sinuses, orbits, and brain should be performed whenever extensive or multiple complications of sinusitis are suspected. In chronic sinusitis, CT scanning is the gold standard for the diagnosis and the management, because it also provides an anatomic road map, when surgery is required.

**Allergic rhinitis** - Allergic rhinitis is rhinitis caused by allergens, which are substances that trigger an allergic response. Allergens involved in allergic rhinitis come from either outdoor or indoor substances. Outdoor allergens such as pollen or mold spores are usually the cause of seasonal allergic rhinitis (also called hay fever). Indoor allergens such as animal dander or dust mites are common causes of year-round allergic rhinitis.

**Multiple polyps** - These are soft tissues that develop off stalk-like structures on the mucus membrane. They impede mucus drainage and restrict airflow. Polyps usually develop from sinus infections that cause overgrowth of the mucus membrane in the nose. They do not regress on their own and may multiply and cause considerable obstruction.

**Deviated Septum** - A common structural abnormality of the nose that causes problems with air flow is a deviated septum. The septum is the inner wall of cartilage and bone that separates the two sides of the nose. When deviated, it is not straight but shifted to one side, usually the left.

**A coronal CT image** is the preferred initial procedure. Bone window views provide excellent resolution and a good definition of the complete osteomeatal complex and other anatomic details that play a role in sinusitis. The coronal view also correlates best with findings from sinus surgery. Approximately 30% of patients cannot lie in the needed position for coronal views and so axial views would be taken (and “reconstructed” afterwards).

**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:


Dykewicz, M.S. (2003). Rhinitis and Sinusitis. Journal of Allergy and Clinical Immunology, 111(2), 520-529. ISSN: 1080-0549.


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 two and three-dimensional images generated by CT. It 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:

For evaluation of known tumor, cancer or mass:
- Evaluation of neck tumor, mass or history of cancer with suspected recurrence or metastasis [based on symptoms or examination findings (may include new or changing lymph nodes)].
- Evaluation of skull base tumor, mass or cancer.
- Evaluation of tumors of the tongue, larynx, nasopharynx, pharynx, or salivary glands.
- Evaluation of parathyroid tumor when:
  - CA> normal and PTH > normal WITH
    - Previous nondiagnostic ultrasound or nuclear medicine scan AND
    - Surgery planned.

Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  - Cancer surveillance – Active monitoring for recurrence as clinically indicated.

For evaluation of suspected tumor, cancer or mass:
- Evaluation of neck tumor, mass or cancer with suspected recurrence or metastasis [based on symptoms or examination findings (may include new or changing lymph nodes)].
- Evaluation of palpable lesions in mouth or throat.
- Evaluation of non-thyroid masses in the neck when present greater than one month, noted to be ≥ 1 cm or associated with generalized lymphadenopathy.

For evaluation of known or suspected inflammatory disease or infections:
- For evaluation of abscesses of the pharynx and neck.
- Evaluation of lymphadenopathy in the neck when present greater than one month, noted to be ≥ 1 cm or associated with generalized lymphadenopathy.

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:
- For evaluation of vocal cord lesions or vocal cord paralysis.
- For evaluation of stones of the parotid and submandibular glands and ducts.
- For evaluation of tracheal stenosis.

Indications for combination studies:
- **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.

**ADDITIONAL INFORMATION RELATED TO NECK CT:**

**CT and Tumors of the Neck (non-thyroid)** – CT is a standard modality for imaging neck tumors. Pre-treatment imaging is important in the management of neck cancer. CT assists in pre-treatment planning by defining the extent of the primary tumor; the peripheral borders of the neoplasm must be determined as accurately as possible. In neck cancer, the identification of lymphatic tumor spread is crucial. Multislice-spiral CT improves the assessment of tumor spread and lymph node metastases and defines the critical relationship of tumor and lymph node metastasis. CT is also used in the follow-up after surgical, radiation or combined treatment for a neck neoplasm.

**CT and Tumoral and Non-Tumoral Trachea Stenoses** – Bronchoscopy is the “gold standard” for detecting and diagnosing tracheobronchial pathology because it can directly visualize the airway lumen, but it may be contraindicated in patients with some conditions, e.g., hypoxemia, tachycardia. Spiral CT provides a non-invasive evaluation of the trachea and may be used in most patients to assess airway patency distal to stenoses.

**CT and Parotid and Submandibular Gland and Duct Stones** – The sensitivity of CT to minimal amounts of calcific salts makes it well suited for the imaging of small, semi calcified parotid or submandibular gland stones. Early diagnosis and intervention are important because patients with salivary gland stones may eventually develop sialadenitis. With early intervention, it may be possible to avoid further gland degeneration requiring parotid or submandibular gland excision. The CT scan identifies the exact location of a ductal stone expediting intraoral surgical removal.

**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:
- To evaluate known intracranial aneurysm or arteriovenous malformation (AVM).
- To evaluate known vertebrobasilar insufficiency (VBI).
- To re-evaluate vascular abnormality visualized on previous brain imaging.
- For evaluation of known vasculitis.

For evaluation of suspected intracranial vascular disease:
- 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.
- To evaluate previously diagnosed subarachnoid hemorrhage (SAH).
- To evaluate suspected vertebrobasilar insufficiency (VBI) in patients with symptoms such as vision changes, vertigo, or abnormal speech.
- To evaluate suspected arteriovenous malformation (AVM) in patient with previous or indeterminate imaging study.
- For evaluation of suspected venous thrombosis (dural sinus thrombosis).
- Distinguishing benign intracranial hypertension (pseudotumor cerebri) from dural sinus thrombosis.
- For evaluation of pulsatile tinnitus for vascular etiology.
- For evaluation of suspected vasculitis with abnormal lab results suggesting acute inflammation or autoimmune antibodies.

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 Brain CTA/Neck CTA combination studies:
• For evaluation of patients who have had a stroke or transient ischemic attack (TIA) within the past 2 weeks.
• 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 trauma in a patient with closed head injury for suspected carotid or vertebral artery dissection.
• For evaluation of pulsatile tinnitus for 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:

For evaluation of vascular disease:
- For evaluation of patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 60%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries).
- For evaluation of head trauma in a patient with closed head injury for suspected carotid or vertebral artery dissection.

For evaluation of known or suspected tumor/mass:
- For evaluation of carotid body tumors, also called paragangliomas.
- For evaluation of pulsatile neck mass.

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:
- For evaluation of patients who have had a stroke or transient ischemic attack (TIA) within the past 2 weeks.
- 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 trauma in a patient with closed head injury for suspected carotid or vertebral artery dissection.
- For evaluation of pulsatile tinnitus for vascular etiology.
Neck CTA/Brain CT:
- Confirmed carotid stenosis of >60%, surgery or angioplasty candidate.

ADDITIONAL INFORMATION RELATED TO NECK CTA:

CTA 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. Computed tomography angiography of carotid arteries may be performed using a multislice spiral CT scanner. The 3D volume-rendering reconstructions provide a selective visualization of the anatomic relationships among carotid body tumors, vessels, and surrounding osseous structures with good detail.

Post-operative evaluation of carotid endarterectomy – Carotid endarterectomy is a vascular surgical procedure that removes plaque from the carotid artery. CTA, 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.

The Asymptomatic Carotid Atherosclerosis Study (ACAS): The ACAS clinical trial is an often quoted study that demonstrated a 5-year reduction in stroke risk of asymptomatic patients with ≥ 60% carotid diameter reduction that underwent carotid endarterectomy compared to those who received medical treatment.

REFERENCES


INTRODUCTION:
Magnetic resonance imaging (MRI) is a noninvasive and radiation free radiologic technique used in the diagnosis and management of ocular and orbital disorders. Common uses include the evaluation of suspected optic nerve involvement in patients suspected of having multiple sclerosis and assessment of tumor invasion of the orbit. MRI is used in the evaluation of hyperthyroid related exophthalmos as well as in identifying the structural causes of unilateral proptosis. It is a sensitive method for showing soft tissue abnormalities which makes it a useful technique in evaluating orbital disorders, e.g., orbital pseudotumor.

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 MRI:
- For assessment of proptosis (exophthalmos).
- For evaluation of progressive vision loss.
- For evaluation of decreased range of motion of the eyes.
- For screening and evaluation of ocular tumor, especially melanoma.
- For screening and assessment of suspected hyperthyroidism (such as Graves’ disease).
- For assessment of trauma.
- For screening and assessment of known or suspected optic neuritis.
- For evaluation of unilateral visual deficit.
- For screening and evaluation of suspected orbital Pseudotumor.
- Papilledema
- Orbital infection

COMBINATION OF STUDIES WITH ORBIT MRI:
- 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 ORBIT MRI:
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.
**MRI imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

**MRI and Optic Neuritis** – MRI is useful in the evaluation of patients who have signs and symptoms of optic neuritis. These signs and symptoms may be the first indications of demyelinating disease, e.g., multiple sclerosis (MS). MRI findings showing the presence of three or more bright spots in brain white matter on T₂-weighted images are indicative of MS and may be used as a criterion for initiating treatment.

**MRI and Exophthalmos (Proptosis)** – Proptosis is characterized by a bulging of one or two eyes and may be caused by hyperthyroidism (Grave’s disease) or it may be caused by other conditions, e.g., orbital tumors, infection and inflammation. The degree of exophthalmos in thyroid-associated ophthalmopatathy is related to the orbital fatty tissue volume. MRI is able to define orbital soft tissues and measure the volumetric change in orbital fatty tissues.

**MRI and Orbit Tumors** – The most common intraocular malignant tumor is choroidal melanoma. Most choroidal melanomas can be evaluated by ophthalmoscopy and ultrasonography. MRI may be used to differentiate the types of mass lesions and to define their extent.

"Retinoblastoma and intracranial tumors": Histologically similar tumors may occur in the pineal, suprasellar or parasellar regions of patients with ocular retinoblastoma, also known as “trilateral retinoblastoma”. The incidence of these intracranial tumors in either unilateral or bilateral retinoblastoma patients is 1.5%-5 %.

**Unilateral papilledema**: The most common causes of unilateral optic disc edema are nonarteritic anterior ischemic optic neuropathy (AION), optic neuritis (termed *papillitis* when disc swelling is present), and orbital compressive lesions. Idiopathic intracranial hypertension (pseudotumor cerebri) and central retinal vein occlusive lesions can also present with unilateral papilledema.

**Nonarteritic anterior ischemic optic neuropathy (NAION)** - Nonarteritic anterior ischemic optic neuropathy (NAION) is the most common form of ischemic optic neuropathy. It is an idiopathic, ischemic insult of the optic nerve head characterized by acute, monocular, painless visual loss with optic disc swelling. The pathophysiology for reduction in blood flow to the optic nerve is controversial.

**REFERENCES**


CPT Codes: 70540, 70542, 70543

INTRODUCTION:

Magnetic resonance imaging (MRI) is useful in the evaluation of the soft tissues of the face, facial tumors, and osteomyelitis. It is indicated for evaluating soft-tissue within the sinuses and is sensitive for differentiating between inflammatory disease and malignant 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 FACE MRI:

- For evaluation of sinonasal and/or facial soft tissue masses or tumors.
- For evaluation of osteomyelitis.
- For evaluation of parotid tumors.

ADDITIONAL INFORMATION RELATED TO FACE MRI:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

MRI and Sinonasal Tumors – Sinus tumors are rare, but the prognosis is often poor due to advanced disease at diagnosis. MRI can distinguish between tumor and retained secretions or inflammatory sinus disease. Squamous cell carcinoma is the most common malignant tumor of the sinonasal cavity. On MRI these tumors are hypointense on T2W images and heterogeneous with solid enhancement, unlike the uniform appearance of secretions.

MRI and Chronic Osteomyelitis – MRI may be used in patient with chronic osteomyelitis to identify soft tissue involvement. It may demonstrate edema in soft tissues beyond the usual sites of enhancement and the full extent of soft-tissue mass.

REFERENCES

CPT Codes: 70540, 70542, 70543

INTRODUCTION:
Magnetic resonance imaging (MRI) is used in the evaluation of head and neck region tumors. The soft-tissue contrast among normal and abnormal tissues provided by MRI permits the exact delineation of tumor margins in regions, e.g., the nasopharynx, oropharynx, and skull base regions. MRI is used for therapy planning and follow-up of head and neck neoplasms. It is also used for the evaluation of neck lymphadenopathy, tracheal stenosis, and vocal cord lesions.

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 MRI:

For evaluation of known tumor, cancer or mass:
- Evaluation of neck tumor, mass or cancer for patient with history of cancer with suspected recurrence or metastasis [based on symptoms or examination findings (may include new or changing lymph nodes)].
- Evaluation of skull base tumor, mass or cancer.
- Evaluation of tumors of the tongue, larynx, nasopharynx pharynx, or salivary glands.
- Evaluation of parathyroid tumor when:
  - CA> normal and PTH > normal WITH
  - Previous nondiagnostic ultrasound or nuclear medicine scan AND
  - Surgery planned.

Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  - Cancer surveillance – Active monitoring for recurrence as clinically indicated.

For evaluation of suspected tumor, cancer or mass:
- Evaluation of neck tumor, mass or with suspected recurrence or metastasis [based on symptoms or examination findings (may include new or changing lymph nodes)].
- Evaluation of palpable lesions in mouth or throat.
- Evaluation of non-thyroid masses in the neck when persistent, greater than one month, and ≥ to 1 cm or associated with generalized lymphadenopathy.

For evaluation of known or suspected inflammatory disease or infections:
- Evaluation of lymphadenopathy in the neck when greater than one month, and ≥ to 1 cm or associated with generalized lymphadenopathy.

Pre-operative evaluation.

Post-operative/procedural evaluation (e.g. post neck dissection/exploration):
• 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 MRI:
• For evaluation of vocal cord lesions or vocal cord paralysis.
• For evaluation of stones of the parotid and submandibular glands and ducts.
• Brachial plexus dysfunction (Brachial plexopathy/Thoracic Outlet Syndrome).

Indications for combination studies:
• 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.

ADDITIONAL INFORMATION RELATED TO NECK MRI:

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

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.

MRI and Neck Tumors – MRI plays a positive role in the therapeutic management of neck tumors, both benign and malignant. It is the method of choice for therapy planning as well as follow-up of neck tumors. For skull base tumors, CT is preferred but MRI provides valuable information to support diagnosis of the disease.

MRI and Vocal Cord Paralysis or Tumors – MRI helps in the discovery of tumors or in estimating the depth of invasion of a malignant process. It provides a visualization of pathological changes beneath the surface of the larynx. MRI scans may indicate the presence or absence of palsy and possible reasons for it. If one or both vocal cords show no movement during phonation, palsy may be assumed.

MRI and Cervical Lymphadenopathy – MRI can show a conglomerate nodal mass that was thought to be a solitary node. It can also help to visualize central nodal necrosis and identify nodes containing metastatic disease. Imaging of the neck is not done just to evaluate lymphadenopathy, but is performed to evaluate a swollen lymph node and an unknown primary tumor site. Sometimes it is necessary to require a second imaging study using another imaging modality, e.g., a CT study to provide additional information.

MRI and Submandibular Stones – Early diagnosis and intervention are important because patients with submandibular stones may eventually develop sialadenitis. MRI provides excellent image contrast and resolution of the submandibular gland and duct and helps in the evaluation of stones.
REFERENCES


CPT Codes: 70540, 70542, 70543

INTRODUCTION:

MRI of the sinus is useful for evaluating soft tissue involvement. It can help rule out fungal sinusitis and may differentiate between inflammatory disease and malignant tumors. MRI may also identify encephaloceles or a cerebrospinal fluid (CSF) leak.

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 SINUS MRI:

- Evidence of tumor from a physical exam, plain sinus x-ray or previous CT.
- Cerebrospinal Fluid (CSF) leak.
- Unresolved sinusitis after four (4) consecutive weeks of medication, e.g., antibiotics, steroids or antihistamines.
- Osteomyelitis (rare) of the facial bone.

ADDITIONAL INFORMATION RELATED TO SINUS MRI:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

Sinusitis - In addition to CT scanning, magnetic resonance (MR) imaging of the sinuses, orbits, and brain should be performed whenever extensive or multiple complications of sinusitis are suspected.

Limitations of sinus MRI - MRI has limitations in the definition of the bony anatomy, but is sensitive for differentiating between inflammatory disease and malignant tumors.

REFERENCES


CPT Codes: 70544, 70545, 70546

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:
- To evaluate known intracranial aneurysm or arteriovenous malformation (AVM).
- To evaluate known vertebrobasilar insufficiency (VBI).
- To re-evaluate vascular abnormality visualized on previous brain imaging.
- For evaluation of known vasculitis.

For evaluation of suspected intracranial vascular disease:
- 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.
- To evaluate previously diagnosed subarachnoid hemorrhage (SAH).
- To evaluate suspected vertebrobasilar insufficiency (VBI) in patients with symptoms such as vision changes, vertigo, or abnormal speech.
- To evaluate suspected arteriovenous malformation (AVM) in patient with previous or indeterminate imaging study.
- For evaluation of suspected venous thrombosis (dural sinus thrombosis).
- Distinguishing benign intracranial hypertension (pseudotumor cerebri) from dural sinus thrombosis.
- For evaluation of pulsatile tinnitus for vascular etiology.
- For evaluation of suspected vasculitis with abnormal lab results suggesting acute inflammation or autoimmune antibodies.
- For evaluation of stroke risk in sickle cell patients (2 - 16 years of age) with a transcranial doppler velocity >200.
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 Brain MRA/Neck MRA combination studies:
- For evaluation of patients who have had a stroke or transient ischemic attack (TIA) within the past 2 weeks.
- 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 trauma in a patient with closed head injury for suspected carotid or vertebral artery dissection.
- For evaluation of pulsatile tinnitus for vascular etiology.

INFORMATION RELATED TO BRAIN (HEAD) MRA

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindications. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindications.

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.

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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 patients with an abnormal ultrasound of the neck or carotid duplex imaging (e.g. carotid stenosis ≥ 60%, technically limited study, aberrant direction of flow in the carotid or vertebral arteries).
• For evaluation of head trauma in a patient with closed head injury for suspected carotid or vertebral artery dissection.

For evaluation of known or suspected tumor/mass:
• For evaluation of carotid body tumors, also called paragangliomas.
• For evaluation of pulsatile neck mass.

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:
• For evaluation of patients who have had a stroke or transient ischemic attack (TIA) within the past 2 weeks.
• 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 trauma in a patient with closed head injury for suspected carotid or vertebral artery dissection.
• For evaluation of pulsatile tinnitus for vascular etiology.

Neck MRA/Brain MRI:
• Confirmed carotid stenosis >60%, surgery or angioplasty candidate.
ADDITIONAL INFORMATION RELATED TO NECK MRA:

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

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.

The Asymptomatic Carotid Atherosclerosis Study (ACAS): The ACAS clinical trial is an often quoted study that demonstrated a 5-year reduction in stroke risk of asymptomatic patients with ≥ 60% carotid diameter reduction that underwent carotid endarterectomy compared to those who received medical treatment.

REFERENCES


CPT Codes:
70551, 70552, 70553 – Brain MRI
70540, 70542, 70543 - IAC

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):
- For evaluation of patient with neurologic symptoms or deficits within the last four (4) weeks.

For evaluation of known multiple sclerosis (MS):
- Stable condition with no prior imaging within the past ten (10) months.
- 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:
- New onset of a seizure.
- Medically refractory epilepsy.

For evaluation of suspected Parkinson’s disease:
- For evaluation of suspected Parkinson’s disease as a baseline study.

For evaluation of known Parkinson’s disease:
- For evaluation of new non-Parkinson symptoms complicating the evaluation of the current condition.

For evaluation of neurologic symptoms or deficits:
- 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 cognitive assessment:
- Change in mental status with a mental status score of either MMSE or MoCA of less than 26 or other similar mental status exams 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:
- 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:
- 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.
- Patient with history of cancer, or significantly immunocompromised, with new onset headache.
- New headache in occipitonal region 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:
- 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 ongoing tumor/cancer surveillance 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.
  - Cancer surveillance: Active monitoring for recurrence as clinically indicated.

For evaluation of known or suspected stroke:
• 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):
• 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):
• 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 head deformities
• 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.

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):
• 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:
• Evaluation of suspected acute subarachnoid hemorrhage (SAH).
• Follow up for known hemorrhage, hematoma or vascular abnormalities.
• 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).
• For 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** –
  o Confirmed carotid occlusion >60%, surgery or angioplasty candidate.
• **Brain MRI/Cervical MRI** –
  o For evaluation of Arnold Chiari Malformation.
  o For follow-up of known multiple sclerosis (MS).
• **Brain MRI/Orbit MRI** –
  o 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”)
  o 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.
**MRI imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindications. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindications.

**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 undergoing brain surgery for tumors. 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:

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.

ADDITIONAL INFORMATION RELATED TO BRAIN MRI:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O_{2} tanks may also be contraindicated.

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:**


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 55-80 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.

For evaluation of known tumor, cancer or mass:
- Initial evaluation of diagnosed cancer.
- Evaluation of known tumor or cancer for patient undergoing active treatment with most recent follow-up study
- 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.
- Cancer surveillance: 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).

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).

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:

- 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.

Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  - Cancer surveillance - Active monitoring for recurrence as clinically indicated.

Other indications for Chest CT:

- Pre-operative evaluation.
- For further evaluation after abnormal imaging within past 30 - 60 days and with no improvement on x-ray, (not indicated with known rib fractures).
- For evaluation of persistent unresolved cough with at least four weeks duration, unresponsive medical treatment and chest x-ray has been performed.
- For evaluation of other chest or thorax adenopathy.
- Evaluation of pneumothorax.
• For evaluation of vocal cord paralysis.
• For suspected thymoma with myasthenia gravis.

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 treatment with medication.
• Granulomatosis with polyangiitis (GPA) (Wegener's).

ADDITIONAL INFORMATION RELATED TO CHEST CT:

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 modules. 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.

CT and Pulmonary Embolism (PE) – Spiral CT is sometimes used as a substitute for pulmonary angiography in the evaluation of pulmonary embolism. It may be used in the initial test for patients with suspected PE when they have an abnormal baseline chest x-ray. It can differentiate between acute and chronic pulmonary embolism but it can not rule out PE and must be combined with other diagnostic tests to arrive at a diagnosis. CT chest is NOT indicated if the patient has none of the risks/factors AND the D-Dimer is negative. (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.)
REFERENCES


CPT Codes: 71275

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. 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*)

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).
- Congenital thoracic vascular anomaly, (e.g., coarctation of the aorta or evaluation of a vascular ring suggested by GI study).
- Signs or symptoms of vascular insufficiency of the neck or arms (e.g., subclavian steal syndrome with abnormal ultrasound).
- Follow-up evaluation of progressive vascular disease when new signs or symptoms are present.
- Pulmonary hypertension.

Preoperative evaluation
- Known vascular abnormalities and patient has not had a catheter angiogram within the last month.
- Proposed ablation procedure for atrial fibrillation.

Postoperative or post-procedural evaluation
- Known vascular abnormalities with physical evidence of post-operative bleeding complication or restenosis.
- 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.

Chest CTA and Abdomen CTA or Abdomen/Pelvis CTA or 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 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.
- For evaluation of myasthenia gravis with suspected thymoma.
- For evaluation of brachial plexus dysfunction (brachial plexopathy/thoracic outlet syndrome).
- For evaluation of a thoracic/thoracoabdominal aneurysm or dissection (documentation of clinical history may include hypertension and reported “tearing or ripping type” chest pain.
- 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)].
- For evaluating whether masses invade into specific thoracic structures (e.g. aorta, pulmonary artery, brachial plexus, subclavian vessels, or thoracic spine).
- To determine the consistency of thoracic masses (cystic vs. solid vs. mixed).

ADDITIONAL INFORMATION RELATED TO CHEST MRI:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

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**


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*).**

**For evaluation of suspected or known vascular abnormalities:**
- Thoracic/thoracoabdominal aneurysm or dissection (documentation of clinical history may include hypertension and reported “tearing or ripping type” chest pain).
- Congenital thoracic vascular anomaly, (e.g., coarctation of the aorta or evaluation of a vascular ring suggested by GI study).
- Signs or symptoms of vascular insufficiency of the neck or arms (e.g., subclavian steal syndrome with abnormal ultrasound).
- Follow-up evaluation of progressive vascular disease when new signs or symptoms are present.
- Pulmonary hypertension.

**Preoperative evaluation**
- Known vascular abnormalities
- Proposed ablation procedure for atrial fibrillation.

**Postoperative or post-procedural evaluation**
- Known vascular abnormalities with physical evidence of post-operative bleeding complication or re-stenosis.
- 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.

**ADDITIONAL INFORMATION RELATED TO CHEST MRA:**

**MRI imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.
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 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

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


CPT Codes: 72125, 72126, 72127

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:
- To assess union of a fracture when physical examination or plain radiographs suggest delayed or non-healing.
- To determine the position of fracture fragments.

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 exam.

For evaluation of suspected myelopathy when MRI is contraindicated:
- 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 back pain with any of the following when Cervical Spine MRI is contraindicated:
- 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.

For evaluation of new onset of neck pain when Cervical Spine MRI is contraindicated:
- Failure of conservative treatment*, for at least six (6) weeks.
- 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.

For evaluation of trauma or acute injury within past 72 hour:
• 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:**
• For staging of known tumor.
• For follow-up evaluation of patient undergoing active treatment.
• Presents with new signs or symptoms (e.g., 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.
• With no imaging/restaging within the past ten (10) months.

**For evaluation of suspected tumor:**
• Prior abnormal or indeterminate imaging that requires further clarification.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated.

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

**For post-operative / procedural evaluation for surgery or fracture occurring within the past six (6) months:**
• 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.
• Delayed or non-healing fracture 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.
• For evaluation of suspicious sacral dimples associated with lesions such as hairy patches or hemangiomas.
• Known arnold-chiari syndrome and Cervical Spine MRI is contraindicated.
• Syrinx or syringomyelia and Cervical Spine MRI is contraindicated.

FOR COMBINATION OF STUDIES WITH CERVICAL SPINE CT:
Cervical/Thoracic/Lumbar CTs:
• CT myelogram or discogram.
• Any combination of these for spinal survey in patient with metastases.
Cervical MRI/CT - unstable craniovertebral junction.
Brain CT/Cervical CT – for evaluation of Arnold Chiari Malformation.

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).

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, Hans-Ekkehard, Dalitz, Kristina

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 or plain radiographs suggest delayed or non-healing.
- To determine the position of fracture fragments.

For evaluation of neurologic deficits:
- 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 exam.

For evaluation of suspected myelopathy when MRI is contraindicated:
- 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:
- 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.

For evaluation of new onset of back pain when Thoracic Spine MRI is contraindicated:
- Failure of conservative treatment* for at least six (6) weeks.
- 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.

For evaluation of trauma or acute injury within past 72 hours:
• 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:
• For staging of known tumor.
• For follow-up evaluation of patient undergoing active treatment.
• Presents with new signs or symptoms (e.g., 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.
• With no imaging/restaging within the past ten (10) months.

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

Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated

For evaluation of known or suspected infection, abscess, or inflammatory disease when Thoracic MRI is contraindicated:
• 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, lymphoma when Thoracic MRI is contraindicated:
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

For post-operative / procedural evaluation of surgery or fracture occurring within past six (6) months:
• 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.
• Delayed or non-healing fracture 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.
• For evaluation of suspicious sacral dimples associated with lesions such as hairy patches or hemangiomas
• Syringom or syringomyelia and Thoracic Spine MRI is contraindicated.
• Known Arnold-Chiari syndrome.

COMBINATION OF STUDIES WITH THORACIC SPINE CT:

Cervical/Thoracic/Lumbar CTs:
• CT myelogram or discogram.
• Any combination of these for spinal survey in patient with metastases.

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:
  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 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.

MRI and Degenerative Disc Disease – Degenerative disc disease is very common and CT 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, and MRI is contraindicated.
REFERENCES


CPT Codes: 72131, 72132, 72133

INTRODUCTION:
Computed tomographic scans provide bone detail and define the bony anatomy in one or two planes. It demonstrates the lumbar subarachnoid space and provides 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 known fracture where physical or plain film findings suggest delayed or non-healing.
- To determine position of known fracture fragments.

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 when Lumbar Spine MRI is contraindicated:
- 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.

For evaluation of new onset of back pain when Lumbar Spine MRI is contraindicated:
- Failure of conservative treatment*, for at least six (6) weeks.
- 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.

For evaluation of trauma or acute injury within past 72 hours:
- 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:
- For staging of known tumor.
- For follow-up evaluation of patient undergoing active treatment.
- Presents with new signs or symptoms (e.g., 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.
• With no imaging/restaging within the past ten (10) months.

For evaluation of suspected tumor:
• Prior abnormal or indeterminate imaging that requires further clarification

Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated

For evaluation of known or suspected infection, abscess, or inflammatory disease when Lumbar Spine MRI is contraindicated:
• 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, lymphoma and Lumbar Spine MRI is contraindicated:
• As evidenced by signs/symptoms, laboratory or prior imaging findings.

For post-operative / procedural evaluation of surgery or fracture occurring within past six (6) months:
• 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.
• Delayed or non-healing fracture 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.
• For evaluation of suspicious sacral dimples associated with lesions such as hairy patches or hemangiomas.
• Tethered cord, known or suspected spinal dysraphism and Lumbar Spine MRI is contraindicated.
• Ankylosing Spondylitis - For diagnosis when suspected as a cause of back or sacroiliac pain and completion of the following initial evaluation and Lumbar Spine MRI is contraindicated:
  o History of back pain associated with morning stiffness
  o Sedimentation rate and/or C-reactive protein
  o HLA B27
  o Non-diagnostic or indeterminate x-ray
• Known arnold-chiari syndrome.
COMBINATION OF STUDIES WITH LUMBAR SPINE CT:

Cervical/Thoracic/Lumbar CTs:
- CT myelogram or discogram
- Any combination of these for spinal survey in patient with metastasis.
- For evaluation of spinal abnormalities associated with Chiari Malformation.

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:
- 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).

CT and Fracture of the Lumbar Spine – CT scans of the lumbar spine generate high-resolution spinal images; their contrast definition and the absence of superimposed structures allow accurate diagnosis of lumbar fractures.

CT and Radiculopathy – Lumbar radiculopathy is caused by compression of a dorsal 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 need medical attention. Multidetector CT may be performed to rule out or localize lumbar disk herniation before surgical intervention. Radiation dose should be kept as low as possible in young individuals undergoing CT of the lumbar 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 transient compression of the cauda equina. This is a surgical emergency and CT may be performed to help assess the problem. CT scans provide visualization of the vertebral canal and may demonstrate encroachment of the canal by osteophytes, facets, pedicles or hypertrophied lamina. The anatomy of the vertebral canal is demonstrated by three-dimensional CT.

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.
**Tethered spinal cord syndrome** - a neurological disorder caused by tissue attachments that limit the movement of the spinal cord with 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 (a delicate filament near the tailbone)
- History of spine trauma/surgery

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.

**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):
- Evidence of MS on recent baseline Brain MRI.
- Suspected MS with new or changing symptoms consistent with cervical spinal cord disease.
- Follow up to known Multiple Sclerosis.
- Follow up to the initiation or change in medication for patient with known Multiple Sclerosis.

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 exam.

For evaluation of suspected myelopathy:
- 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 back pain with any of the following:
- 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.

For evaluation of new onset of neck pain:
- Failure of conservative treatment*, for at least six (6) weeks.
- 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.

For evaluation of trauma or acute injury within past 72 hours:
- 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:
• For staging of known tumor.
• For follow-up evaluation of patient undergoing active treatment.
• Presents with new signs or symptoms (e.g., 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.
• With no imaging/restaging within the past ten (10) months.

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

Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated.

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

For post-operative / procedural evaluation for surgery or fracture occurring within the past six (6) months:
• 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.
• Delayed or non-healing fracture 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.
• For evaluation of suspicious sacral dimples associated with lesions such as hairy patches or hemangiomas.
• Known arnold-chiari syndrome.
• Syrinx or syringomyelia.

COMBINATION OF STUDIES WITH CERVICAL SPINE MRI:

Cervical/Thoracic/Lumbar MRIs:
• Any combination of these for scoliosis survey in infant/child.
• Any combination of these for spinal survey in patient with metastases.
• For evaluation of spinal abnormalities associated with Chiari Malformation.

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).

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, Hans-Ekkehart, Dalitz, Kristina

MRI for Evaluation of Discitis – Discitis is a known complication of cervical discography. Postoperative discitis in the cervical spine does not occur frequently but 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 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 RE et al.). 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 et al.). 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: 72146, 72147, 72157

INTRODUCTION:

Magnetic resonance imaging 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:

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 exam.

For evaluation of suspected myelopathy:
- 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:
- 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.

For evaluation of new onset of back pain:
- Failure of conservative treatment* for at least six (6) weeks.
- 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.

For evaluation of trauma or acute injury within past 72 hours:
- 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:
- For staging of known tumor.
- For follow-up evaluation of patient undergoing active treatment.
• Presents with new signs or symptoms (e.g., 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.
• With no imaging/restaging within the past ten (10) months.

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

Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated.

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

For post-operative / procedural evaluation of surgery or fracture occurring within past six (6) months:
• 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.
• Delayed or non-healing fracture 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.
• For evaluation of suspicious sacral dimples associated with lesions such as hairy patches or hemangiomas.
• Known arnold-chiari syndrome.
• Syrinx or syringomyelia.

COMBINATION OF STUDIES WITH THORACIC SPINE MRI:

Cervical/Thoracic/Lumbar MRIs:
• Any combination of these for scoliosis survey in infant/child.
• Any combination of these for spinal survey in patient with metastases.
• For evaluation of spinal abnormalities associated with Chiari Malformation.

ADDITIONAL INFORMATION RELATED TO THORACIC SPINE MRI

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

*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).

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 neurology 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 conductions 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 RE et al). 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 et al). 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: 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:
- 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

For evaluation of new onset of back pain:
- Failure of conservative treatment*, for at least six (6) weeks
- 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

For evaluation of trauma or acute injury within past 72 hours:
- 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:
- For staging of known tumor.
- For follow-up evaluation of patient undergoing active treatment.
- Presents with new signs or symptoms (e.g., 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.
• With no imaging/restaging within the past ten (10) months.

**For evaluation of suspected tumor:**
• Prior abnormal or indeterminate imaging that requires further clarification.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated.

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

**For post-operative / procedural evaluation of surgery or fracture occurring within past six (6) months:**
• 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.
• Delayed or non-healing fracture 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, known or suspected spinal dysraphism.
• For evaluation of suspicious sacral dimples associated with lesions such as hairy patches or hemangiomas.
• Ankylosing Spondylitis · For diagnosis when suspected as a cause of back or sacroiliac pain and completion of the following initial evaluation:
  o History of back pain associated with morning stiffness
  o Sedimentation rate and/or C-reactive protein
  o HLA B27
  o Non-diagnostic or indeterminate x-ray
• Known arnold-chiari syndrome.

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

**Cervical/Thoracic/Lumbar MRIs:**
• Any combination of these for scoliosis survey in infant/child.
• Any combination of these for spinal survey in patient with metastasis.
• For evaluation of spinal abnormalities associated with Chiari Malformation.
ADDITIONAL INFORMATION RELATED TO LUMBAR SPINE MRI:

**MRI imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

*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 preformed to evaluate Cauda equina syndrome, severe spinal compression.

**Tethered spinal cord syndrome** - a neurological disorder caused by tissue attachments that limit the movement of the spinal cord with 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 (a delicate filament near the tailbone)
- 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 et al). 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 et al). 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


ACR-AIUM-SPR-SRU Practice Parameter For The Performance of AN Ultrasound Examination Of The Neonatal And Infant Spine (2016)
http://www.acr.org/~media/222a9d4cc654409ba108b8929a56d1d9.pdf


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 is used for the evaluation of spinal arteriovenous malformations, cervical spine fractures and vertebral artery injuries.

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 SPINAL CANAL MRA:

- For the evaluation of spinal arteriovenous malformation (AVM).
- For the evaluation of a cervical spine fracture.
- For the evaluation of known or suspected vertebral artery injury.

ADDITIONAL INFORMATION RELATED TO SPINAL CANAL MRA:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

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.

Cervical Spine Fracture – The American College of Radiology (ACR) appropriateness criteria scale indicates that MRA of the neck is most appropriate for suspected acute cervical spine trauma and where clinical or imaging findings suggest arterial injury.

Vertebral Artery Injury – Two-dimensional time-of-flight (2D TOF) magnetic resonance angiography (MRA) is used for detecting vertebral artery injury in cervical spine trauma patients.
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 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 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 >3.5 cm, < six month follow up (and consider intervention)
- Suspected retroperitoneal hematoma or hemorrhage.
- Venous thrombosis if previous studies have not resulted in a clear diagnosis.
- Vascular invasion or displacement by tumor.
- Pelvic vein thrombosis or thrombophlebitis.
- For evaluation of suspected pelvic vascular disease when findings on ultrasound are indeterminate.

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 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 peritoneal cavity.
• Follow-up for post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA). Routine, baseline study (post-op/intervention) is warranted within 1-3 months.
  ▪ Asymptomatic at six (6) month intervals, for two (2) years.
  ▪ 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.

**Follow-up of asymptomatic incidentally-detected iliac artery aneurysms:**
• <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

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 symphsis. 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. Clinician should exercise increased caution with CT imaging in children, pregnant women and young adults. 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:

For known or suspected prostate cancer and for recurrence workup:
- 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.
- In patients without confirmed diagnosis of prostate cancer (with persistently elevated or rising PSA, prior negative prostate biopsy and MRI is contraindicated.
- Prostatic cancer with:
  - PSA greater than twenty (20).
  - Gleason score of seven (7) or greater.

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 pelvis by physical exam or imaging study, such as Ultrasound (US).
- 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 last follow-up.

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,
    - Melanoma without symptoms or signs of metastasis.
• Three (3) month follow-up of known pelvic cancer undergoing active treatment within the past year.
• Six (6) month follow-up of known pelvic cancer undergoing active treatment within the past year.
• Follow-up of known cancer of patient undergoing active treatment within the past year.
• Known cancer with suspected pelvis metastasis based on a sign, symptom or an abnormal lab value.
• Cancer surveillance: Active monitoring for recurrence as clinically indicated

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

**For evaluation of suspected infection or inflammatory disease:**
• Suspected acute appendicitis (or severe acute diverticulitis) 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 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 in the pelvis

**For evaluation of known infection or inflammatory disease follow up:**
• 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)**:
• 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
  o Suspected or known iliac artery aneurysm >2.5 cm AND equivocal or indeterminate ultrasound results OR
  o Prior imaging (e.g. ultrasound) demonstrating iliac artery aneurysm >2.5cm in diameter OR
  o Suspected complications of known aneurysm as evidenced by clinical findings such as new onset of pelvic pain.
  o 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/iliaal endograft or stent.
  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:**
• 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.
• 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 ongoing tumor/cancer surveillance 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.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated.

**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.
• Ischemic bowel.
• Known or suspected aseptic/avascular necrosis of hip(s) and MRI is contraindicated after completion initial x-ray.
• Scoliosis (infectious or inflammatory) after completion of initial x-ray and MRI is contraindicated.
• Sacroiliac joint dysfunction and MRI contraindicated:
  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).

**Combination of studies with Pelvis 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 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 urothelia 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:**
- <3.0 cm: rarely rupture, 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

**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. Helical CT of the prostate may be a useful alternative to MRI in patients with an increasing PSA level and negative findings on biopsy.

**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 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 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 addition 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.

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.

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:

For known or suspected prostate cancer and for recurrence workup:
- 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.
- In patients without confirmed diagnosis of prostate cancer (with persistently elevated or rising PSA and prior negative biopsy).
- Prostatic cancer with:
  - PSA greater than twenty
  - Gleason score of seven or greater.

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 or imaging study, such as Ultrasound (US).
- 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 last follow-up.

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,
    - Melanoma without symptoms or signs of metastasis.
- Three (3) month follow-up of known pelvic cancer undergoing active treatment within the past year.
- Six (6) month follow-up of known pelvic cancer undergoing active treatment within the past year.
- 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.
- Cancer surveillance: Active monitoring for recurrence as clinically indicated.
For evaluation of suspected infection or inflammatory disease:
• Suspected acute appendicitis (or severe acute diverticulitis) 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 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 in the pelvis.

For evaluation of known infection or inflammatory disease follow up:
• 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.
• 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.

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.
• 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).
• Sacroiliitis (infectious or inflammatory)
• Sacroiliac Joint Dysfunction:
  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:
  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:
  - For evaluation of persistent groin or symphysis pubis pain related to a suspected diagnosis of athletic pubalgia (sports hernia), when ordered by a general surgeon, orthopedic surgeon or sports medicine specialist, when xrays are unrevealing.

**Indication for combination studies for the initial pre-therapy staging of cancer, OR ongoing tumor/cancer surveillance 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
  - Cancer surveillance – Active monitoring for recurrence as clinically indicated.

**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.
- 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.
- For evaluation of uterus prior to embolization.
- For evaluation of endometriosis.
- 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.

**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 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 imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

MRI and Undescended Testes – The most common genital malformation in boys is undescended testis. The timely management of undescended testis is important to potentially minimize the risk of infertility
and less 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 in pregnancy. It can identify and characterize different neoplastic and nonneoplastic abnormalities, e.g., exophytic leiomyoma, endometrioma, dermoid cyst, and ovarian edema. It is a useful adjunct when sonography is inconclusive in the evaluation of adnexal masses in pregnancy.

**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** – 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 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.

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 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 is 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 trasrectal 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.

**REFERENCES**


TOC

72198 – MR Angiography, Pelvis

CPT Codes: 72198

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 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 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 >2.5cm 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)
- Suspected retroperitoneal hematoma or hemorrhage.
- For evaluation of suspected pelvic vascular disease when findings on ultrasound are indeterminate.
- Venous thrombosis if previous studies have not resulted in a clear diagnosis.
- Vascular invasion or displacement by tumor.
- Pelvic vein thrombosis or thrombophlebitis.

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 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 peritoneal cavity.
Follow-up for post-endovascular repair (EVAR) or open repair of abdominal aortic aneurysm (AAA). Routine, baseline study (post-op/intervention) is warranted within 1-3 months.
- Asymptomatic at six (6) month intervals, for two (2) years.
- 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:

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

Abdomen/Pelvis MRA & Lower Extremity MRA Runoff Requests: Two auth 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.

Bruitis: 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.

REFERENCES


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):
- 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.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study or abnormal lab value.
- Surveillance: One follow-up exam if initial evaluation is indeterminant 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:
- Initial staging of known cancer in the upper extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Known cancer with suspected upper extremity metastasis based on a sign, symptom, imaging study or abnormal lab value.
- Cancer surveillance: Active monitoring for recurrence as clinically indicated

For evaluation of known or suspected infection or inflammatory disease: (e.g. osteomyelitis) 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.

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.

For evaluation of suspected or known auto immune disease, (e.g. rheumatoid arthritis) and MRI is contraindicated or cannot be performed:
- Known or suspected auto immune disease and non-diagnostic findings on prior imaging.

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 include medical therapy (may include physical therapy or 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 evaluation

Post-operative/procedural evaluation:
• When imaging, physical, or laboratory findings indicate joint infection, delayed or non-healing, or other surgical/procedural complications.
• 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 an Upper Extremity (Hand, Wrist, Arm, Elbow, or Shoulder) CT:
• Abnormal bone scan and x-ray is non-diagnostic or requires further evaluation.
• CT arthrogram and MRI is contraindicated or cannot be performed.
• To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, treated osteochondral defects where physical or imaging findings suggest its presence and MRI is contraindicated or cannot be performed.

Additional indications for Shoulder CT:
• 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.
• Evaluation of recurrent dislocation and MRI is contraindicated or cannot be performed.
• 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 impingement, rotator cuff tear, or labral tear (SLAP lesion, Bankart lesion) when ordered by orthopedic specialist and MRI is contraindicated or cannot be performed.
• Known or suspected impingement or when impingement test is positive and is ordered by orthopedic surgeon and MRI is contraindicated or cannot be performed.
• Impingement or rotator cuff tear indicated by positive Neer’s sign, Hawkin’s sign or drop sign and MRI is contraindicated or cannot be performed.
• 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.

When additional indications for Wrist CT and MRI are contraindicated or cannot be performed:
• 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 when ordered by orthopedic specialist or primary care physician on behalf of the specialist.

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. NOTE: for joint and extremity injuries, part of this combination may include the physician instructing patient to rest the area or stay off the injured part.

**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 can not 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.

**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.

**Occult Scaphoid Fractures** – 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 proved to be superior to MRI in the detection of cortical involvement of occult scaphoid fractures.

**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 of 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.
REFERENCES:


CPT Codes: 73206

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.
- For evaluation of Raynaud's syndrome.
- For evaluation of vascular invasion or displacement by tumor.
- For evaluation of complications of interventional vascular procedures, e.g., pseudoaneurysms related to surgical bypass grafts, vascular stents, or stent-grafts.
- For evaluation of suspected upper extremity embolism or thrombosis.

Preoperative evaluations:
- For preoperative evaluation from known vascular disease/condition.

Post-operative/procedural evaluations:
- 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.

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, and abnormalities in ligaments, tendons/cartilages, 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):
- 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.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study or abnormal lab value.
- 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:
- Initial staging of known cancer in the upper extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Known cancer with suspected upper extremity metastasis based on a sign, symptom, imaging study or abnormal lab value.
- Cancer surveillance: Active monitoring for recurrence as clinically indicated.

For evaluation of known or suspected infection or inflammatory disease (e.g. osteomyelitis):
- 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 x-ray) of septic arthritis or osteomyelitis.

For evaluation of suspected (AVN) avascular necrosis (i.e. aseptic necrosis):
- Further evaluation of an abnormality or non-diagnostic findings on prior imaging.

For evaluation of suspected or known auto immune disease, (e.g. rheumatoid arthritis):
- Known or suspected auto immune disease and non-diagnostic findings on prior imaging.

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 include - medical therapy (may include physical therapy or 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 evaluation**

**Post-operative/procedural evaluation:**
• When imaging, physical or laboratory findings indicate joint infection, delayed or non-healing or other surgical/procedural complications.
• 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 an Upper Extremity (Hand, Wrist, Arm, Elbow, or Shoulder) MRI:**
• Abnormal bone scan and x-ray is non-diagnostic or requires further evaluation.
• MR arthrogram.
• To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, treated osteochondral defects where physical or imaging findings suggest its presence.

**Additional indications for Shoulder MRI:**
• For evaluation of known or suspected impingement, rotator cuff tear, or labral tear (SLAP lesion, Bankart lesion).
• Known or suspected impingement or when impingement test is positive.
• Impingement or rotator cuff tear indicated by positive Neer’s sign, Hawkins’s sign or drop sign.
• Status post prior rotator cuff repair with suspected re-tear and findings on prior imaging are indeterminate.
• For evaluation of brachial plexus dysfunction (brachial plexopathy/thoracic outlet syndrome).
• For evaluation of recurrent dislocation.

**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.

**ADDITIONAL INFORMATION RELATED TO UPPER EXTREMITY MRI:**

**MRI imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

*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. NOTE: for joint and extremity injuries, part of this combination may include the physician instructing patient to rest the area or stay off the injured part.

**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 under-estimation 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 arthroscopic

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.

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.
- For evaluation of Raynaud's syndrome.
- For evaluation of vascular invasion or displacement by tumor.
- For evaluation of complications of interventional vascular procedures, e.g., pseudoaneurysms related to surgical bypass grafts, vascular stents, or stent-grafts.
- For evaluation of suspected upper extremity embolism or thrombosis.

Preoperative evaluations:
- For preoperative evaluation from known vascular disease/condition.

Postoperative/procedural evaluations:
- 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:

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

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, Coarctation of aorta.

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. CTA 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.

**REFERENCES**


CPT Codes: 73700, 73701, 73702

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):

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.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study or abnormal lab value.
- Surveillance: One follow-up exam if initial evaluation is indeterminant 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:
- Initial staging of known cancer in the lower extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Known cancer with suspected lower extremity metastasis based on a sign, symptom, imaging study or abnormal lab value.
- Cancer surveillance: Active monitoring for recurrence as clinically indicated.

For evaluation of known or suspected infection or inflammatory disease (e.g. osteomyelitis) 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.

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.

For evaluation of suspected or known auto immune disease, (e.g. Rheumatoid arthritis) and MRI is contraindicated or cannot be performed:
- Known or suspected auto immune disease and non-diagnostic findings on prior imaging.

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 (e.g. x-ray) 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 include - medical therapy (may include physical therapy or 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 evaluation.

Post-operative/procedural evaluation:
• When imaging, physical, or laboratory findings indicate joint infection, delayed or non-healing, or other surgical/procedural complications.
• 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 Lower Extremity (Foot, Ankle, Knee, Leg, or Hip) CT:
• Abnormal bone scan and 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).
• CT arthrogram and MRI is contraindicated or cannot be performed.
• To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, treated osteochondral defects where physical or imaging findings suggest its presence and MRI is contraindicated or cannot be performed.

Additional indication specific 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 on clinician’s decision to evaluate for known or suspected tarsal coalition.
• Accompanied by 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 specific for KNEE CT and MRI is contraindicated or cannot be performed:
• Accompanied by blood in the joint (hemarthrosis) demonstrated by aspiration.
• Presence of a joint effusion.
• Accompanied by physical findings of a meniscal injury determined by physical examination tests (McMurray’s, Apley’s) or significant laxity on varus or valgus stress tests.
• Accompanied by physical findings of anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) ligamental injury determined by the drawer test or the Lachman test.

Additional indications specific for HIP CT:
• For any evaluation of patient with hip prosthesis or other implanted metallic hardware where prosthetic loosening or dysfunction is suspected on physical examination or imaging.
• For evaluation of total hip arthroplasty patients with suspected loosening and/or wear or osteolysis or assessment of bone stock is needed.
• For evaluation of suspected slipped capital femoral epiphysis with non-diagnostic or equivocal imaging and MRI is contraindicated or cannot be performed.
• Suspected labral tear of the hip with signs of clicking and pain with hip motion especially with hip flexion, internal rotation and adduction which can also be associated with locking and giving way sensations of the hip on ambulation 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. NOTE: for joint and extremity injuries, part of this combination may include the physician instructing patient to rest the area or stay off the injured part.

**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 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 early 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 is 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.

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.
- Large vessel diseases, e.g. aneurysm, dissection, arteriovenous malformations (AVMs), and fistulas, intramural hematoma, and vasculitis.
- Arterial entrapment syndrome, e.g. peripheral artery disease (PAD).
- Venous thrombosis if previous studies have not resulted in a clear diagnosis.
- Vascular invasion or displacement by tumor.
- Pelvic vein thrombosis or thrombophlebitis
- Abnormal preliminary testing (ankle/brachial index, ultrasound/doppler arterial evaluation) associated with significant symptoms of claudication with exercise.

Pre-operative evaluation:
- Evaluation of known peripheral vascular disease of the leg and ultrasound indicates significant disease and an indeterminate conclusion about whether the condition would be amenable to surgery.

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.
- 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:

Abd/Pelvis CTA & Lower Extremity CTA Runoff Requests: 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

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 aneurismal changes. It can reveal both vascular and extravascular complications.

**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, and abnormalities in ligaments, tendons/cartilages, 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):
- 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.
- Suspected tumor size increase or recurrence based on a sign, symptom, imaging study or abnormal lab value.
- Surveillance: One follow-up exam if initial evaluation is indeterminant 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:
- Initial staging of known cancer in the lower extremity.
- Follow-up of known cancer of patient undergoing active treatment within the past year.
- Known cancer with suspected lower extremity metastasis based on a sign, symptom, imaging study or abnormal lab value.
- Cancer surveillance: Active monitoring for recurrence as clinically indicated.

For evaluation of known or suspected infection or inflammatory disease (e.g. osteomyelitis):
- 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 x-ray) of septic arthritis or osteomyelitis.

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.

For evaluation of suspected or known auto immune disease, (e.g. rheumatoid arthritis):
- Known or suspected auto immune disease and non-diagnostic findings on prior imaging.

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 include · medical therapy (may include physical therapy or 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 evaluation.

Post-operative/procedural evaluation:
• When imaging, physical or laboratory findings indicate joint infection, delayed or non-healing or other surgical/procedural complications.
• 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 Lower Extremity (Foot, Ankle, Knee, Leg or Hip) MRI:
• Abnormal bone scan and x-ray is non-diagnostic or requires further evaluation.
• MR arthrogram.
• To assess status of osteochondral abnormalities including osteochondral fractures, osteochondritis dissecans, treated osteochondral defects where physical or imaging findings suggest its presence.

Additional indication specific 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 on clinician’s decision to evaluate for known or suspected tarsal coalition. Do not add 6 mnts to this; don’t mention conservative care here.
• Accompanied by 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.

Additional indications specific for KNEE MRI:
• Accompanied by blood in the joint (hemarthrosis) demonstrated by aspiration.
• Presence of a joint effusion.
• For evaluation of suspected Baker’s cyst or posterior knee swelling with ultrasound requiring further evaluation.
• Accompanied by physical findings of a meniscal injury determined by physical examination tests (McMurray’s, Apley’s) or significant laxity on varus or valgus stress tests.
• Accompanied by physical findings of anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) ligamental injury determined by the drawer test or the Lachman test.

Additional indications specific for HIP MRI:
• For evaluation of suspected slipped capital femoral epiphysis with non-diagnostic imaging.
• For any evaluation of patient with hip prosthesis or other implanted metallic hardware where prosthetic loosening or dysfunction is suspected on physical examination or imaging.
• Suspected labral tear of the hip with signs of clicking and pain with hip motion especially with hip flexion, internal rotation and adduction which can also be associated with locking and giving way sensations of the hip on ambulation.

ADDITIONAL INFORMATION RELATED TO A LOWER EXTREMITY MRI:

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

*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. NOTE: for joint and extremity injuries, part of this combination may include the physician instructing patient to rest the area or stay off the injured part.

**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 normal 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 is 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 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. MRI is normally not used in the initial imaging of suspected ankle fractures: MRI is more specific for ligamentous injuries. MRI may identify ankle ligament injuries associated with problematic subsets of ankle fracture.

**REFERENCES**


**CPT Code:** 73725

**INTRODUCTION:**

MRA is used for imaging arterial obstructive disease in the lower extremity. It is noninvasive and has little risk. It can image tibia and pedal arteries and can evaluate symptoms that occur after 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 LOWER EXTREMITY MRA/MRV:**

For assessment/evaluation of suspected or known vascular disease/condition:
- Significant ischemia in the presence of ulcers/gangrene.
- Large vessel diseases, e.g., aneurysm, dissection, arteriovenous malformations (AVMs), and fistulas, intramural hematoma, and vasculitis.
- Arterial entrapment syndrome e.g. peripheral artery disease (PAD).
- Venous thrombosis if previous studies have not resulted in a clear diagnosis.
- Vascular invasion or displacement by tumor.
- Pelvic vein thrombosis or thrombophlebitis
- Abnormal preliminary testing (ankle/brachial index, ultrasound/doppler arterial evaluation) associated with significant symptoms of claudication with exercise.

Pre-operative evaluation:
- Evaluation of known peripheral vascular disease of the leg and ultrasound indicates significant disease and an indeterminate conclusion about whether the condition would be amenable to surgery.

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
- 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:**

**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.

**MRI imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.
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.

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, Coarctation of aorta.

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 disease involving the abdomen and pelvis. Abdominal imaging begins at the diaphragm and extends to the umbilicus or iliac crests. 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. Clinician should exercise increased caution with CT imaging in children, pregnant women and young adults. 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).
- 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.

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,
    - Melanoma without symptoms or signs of metastasis.
- Three (3) month follow-up of known abdominal cancer undergoing active treatment within the past year.
- Six (6) month follow-up of known abdominal cancer undergoing active treatment within the past year.
- 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 an organ enlargement:
- 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:
- Suspected acute appendicitis (or severe acute diverticulitis) if abdominal pain and tenderness to palpation is present, with at LEAST one of the following:
  - WBC elevated
  - Fever
  - Anorexia or
  - Nausea and vomiting.
- 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.
- Suspected inflammatory bowel disease (Crohn’s or ulcerative colitis) with abdominal pain, and persistent diarrhea, or bloody diarrhea.
- Follow up for 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 cholecystitis or retained gallstones with recent equivocal ultrasound.
- Suspected infection in the abdomen.

For evaluation of known infection or inflammatory disease follow up:
- 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.
- Hepatitis C/hepatoma evaluation with elevated alpha-fetoprotein (AFP) and equivocal ultrasound results
- Known infection in the abdomen.

For evaluation of known or suspected vascular disease (e.g., aneurysms or hematomas)**:
- 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 >2.5cm 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.
  - 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:
- For evaluation of trauma with lab or physical findings of intra-abdominal bleeding limited to 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 ongoing tumor/cancer surveillance 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.
  - Cancer surveillance – Active monitoring for recurrence as clinically indicated

Other Indications for an Abdomen CT:
- Suspected adrenal mass based on diagnostic testing/imaging results, and/or a suspicious clinical presentation
- 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
  - 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.
- Hernia with suspected complications.
- 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.

**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 urothelia tumors.

**CT Imaging for Abdominal Aortic Aneurysms** – The normal diameter of the suprarenal abdominal aorta is 3.0 cm and that of the infrarenal is 2.0cm. Aneurysmal dilatation of the infrarenal aorta is defined as diameter $\geq 3.0$ cm or dilatation of the aorta $\geq 1.5$ the normal diameter$.^1$ Abdominal aortic aneurysms are usually asymptomatic and most are discovered during imaging studies ordered for other indications or on physical examination as a pulsatile abdominal 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.

**Recommended intervals for initial follow-up imaging of ectatic aortas and Aabdominal 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

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 below 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% 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.

**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 suspected or known 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 and OR
  - Suspected complications of known aneurysm as evidenced by sign/symptoms such as new onset of abdominal or pelvic pain.
- Suspected retroperitoneal hematoma or hemorrhage.
- Venous thrombosis (for CT Venogram) if previous studies have not resulted in a clear diagnosis.
- Vascular invasion or displacement by tumor.

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). Routine, baseline study (post-op/intervention) is warranted within 1-3 months.
  - Asymptomatic at six (6) month intervals, for two (2) years.
  - 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.

*Bruits* - 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 2.0cm. Aneurysmal dilatation of the infrarenal aorta is defined as diameter >/= 3.0 cm or dilatation of the aorta >/= 1.5 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):**

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

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.

REFERENCES


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 suspected or known 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 signs/symptoms such as new onset of abdominal or pelvic pain.
- Suspected retroperitoneal hematoma or hemorrhage.
- Suspected renal vein thrombosis in patient with known renal mass.
- For evaluation of suspected chronic mesenteric ischemia.
- Venous thrombosis if studies have not resulted in a clear diagnosis.
- Vascular invasion or displacement by tumor.
- For evaluation of portal venous system (hepatic portal system).
- For evaluation of known or suspected renal artery stenosis or resistant hypertension demonstrated by any of the following:
  - Unsuccessful control after treatment with 3 or more 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.
  - New onset of hypertension after age 55 (>160/100).
  - Acute rise in blood pressure in a person with previously stable blood pressures.
  - Flash pulmonary edema without identifiable causes.
Malignant 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). Routine, baseline study (post-op/intervention) is warranted within 1-3 months.
  - Asymptomatic at six (6) month intervals, for two (2) years.
  - 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:**
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 >/= 3.0 cm or dilatation of the aorta >/= 1.5 the normal diameter¹. 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 contrast¹. The limitations are that overlying bowel gas can obscure findings and the technique is operator dependent.¹

**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):**
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

**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. 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. Clinician should exercise increased caution with CT imaging in children, pregnant women and young adults. 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:
- Hematuria

For evaluation of known or suspected kidney or ureteral stones:
- Delineation of known or suspected renal calculi or ureteral calculi.

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.
- 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,
    - Melanoma without symptoms or signs of metastasis.
    - Prostate cancer unless Gleason score seven plus (7+) or PSA over twenty (20)
- Three (3) month follow-up of known abdomen/pelvic cancer undergoing active treatment within the past year.
- Six (6) month follow-up of known abdomen/pelvic cancer undergoing active treatment within the past year.
- 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.
• Cancer surveillance: 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:**
• Suspected acute appendicitis (or severe acute diverticulitis) if abdominal 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 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.
• 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.

**For evaluation of known infection or inflammatory disease follow up:**
• 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.
  o 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.
• Known infection in the abdomen/pelvis region.

**For evaluation of known or suspected vascular disease (e.g., aneurysms or hematomas)** **:**
• Evidence of vascular abnormality seen on imaging studies.
• Evaluation of suspected or known aneurysm: > 2.5cm or in evaluating abdominal/pelvic extent of aortic aneurysm of suspected or known aorta aneurysm or in evaluating abdominal /pelvic extent of aortic aneurysm:
  o 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 or pelvic 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:
• 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 ongoing tumor/cancer surveillance 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.
  • Cancer surveillance – Active monitoring for recurrence as clinically indicated.

Other indications for Abdomen/Pelvic CT Combo:
• Suspected adrenal mass or pheochromocytoma based on diagnostic testing/imaging results, and/or a suspicious clinical presentation.
• 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
  • 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.
• Suspected Spigelian hernia (ventral hernia) or incisional hernia (evidenced by a surgical abdominal scar) when ordered as a pre-operative study.
• Hernia with suspected complications.
• Ischemic bowel.

ADDITIONAL INFORMATION RELATED TO ABDOMEN/PELVIS CT:

Ultrasound should be considered prior to a request for Abdomen or Pelvis 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 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 urothelia tumors.

**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 2.0cm. Aneurysmal dilatation of the infrarenal aorta is defined as diameter >/= 3.0 cm or dilatation of the aorta >/= 1.5 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

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


CPT Codes: 74181, 74182, 74183

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).
- 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 last follow-up.

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,
    - Melanoma without symptoms or signs of metastasis.
- Three (3) month follow-up of known abdominal cancer undergoing active treatment within the past year.
- Six (6) month follow-up of known abdominal cancer undergoing active treatment within the past year.
- 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:

- Suspected acute appendicitis (or severe acute diverticulitis) if abdominal pain and tenderness to palpation is present, with at LEAST one of the following:
  - WBC elevated
  - Fever
  - Anorexia or
• Nausea and vomiting.
• 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.
• 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.

For evaluation of known infection or inflammatory disease follow up:
• 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.
• Hepatitis C/hepatoma evaluation with elevated alpha-fetoprotein (AFP) and equivocal ultrasound results.
• Known infection in the abdomen.

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

Post-operative/procedural evaluation:
• Follow-up of suspected or known 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 ongoing tumor/cancer surveillance 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.
  o Cancer surveillance – Active monitoring for recurrence as clinically indicated.

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.

ADDITIONAL INFORMATION RELATED TO ABDOMINAL MRI:
**MRI imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

**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.

**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 clear suppression of the signals.

**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, a more recent development, 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.

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. 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 suspected or known aortic aneurysm**:
  - Suspected or known aneurysm > 2.5 cm AND equivocal or indeterminate ultrasound results OR
  - Prior imaging (e.g. ultrasound) demonstrating aneurysm >2.5cm 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.
- Suspected renal vein thrombosis in patient with known renal mass.
- For evaluation of mesenteric ischemia/ischemic colitis.
- 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).
- 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 demonstrated by any of the following:
  - Unsuccessful control after treatment with three (3) or more 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.
New onset of hypertension after age 55 (>160/100).
- Acute rise in blood pressure in a person with previously stable blood pressures.
- Flash pulmonary edema without identifiable causes.
- Malignant hypertension.

**Pre-operative evaluation:**
- Evaluation of 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).
  - Routine, baseline study (post-op/intervention) is warranted within 1-3 months.
  - Asymptomatic at six (6) month intervals, for two (2) years.
  - 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 imaging** – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

**MRI Follow-up for post-endovascular repair (EVAR)** - CT is generally the study of choice in this evaluation due to improved spatial resolution and less artifact from components of the stent graft.

**Abd/Pelvis MRA & Lower Extremity MRA Runoff Requests** - Two (2) auth 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 ≥ 1.5 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\(^1\). The limitations are that overlying bowel gas can obscure findings and the technique is operator dependent.\(^1\)

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)\(^1\):

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

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.

REFERENCES


INTRODUCTION:

Computed tomographic (CT) colonography, also referred to as 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 (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):

For diagnostic evaluation when conventional colonoscopy is contraindicated:
- 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 CTC 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.

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 screening is considered medically appropriate for an “average risk” member, every 5 (five) years, who is:

- 50 – 75 years of age
- 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 or familial adenomatous polyposis,
  - a personal history of inflammatory bowel disease,
  - a previous adenomatous polyp, or
  - a previous history of colorectal cancer.

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.

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 evaluation of known or suspected abnormality of the fetus.

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 maternal 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

ACR-SPR Practice Parameter for the Safe and Optimal Performance of Fetal Magnetic Resonance Imaging (MRI)  
http://www.acr.org/~/media/CB384A65345F402083639E6756CE513F.pdf


Society for Pediatric Radiology. Fetal MRI – General Information.  
http://www.pedrad.org/Specialties/Fetal-Imaging/Fetal-MRI-General-Information

TOC

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

INTRODUCTION:

Cardiac magnetic resonance imaging (MRI) is an imaging modality utilized in the assessment and monitoring of cardiovascular disease. It has a role in the diagnosis and evaluation of both acquired and congenital cardiac disease. MRI is a noninvasive technique using no ionizing radiation resulting in high quality images of the body in any plane, unlimited anatomic visualization and potential for tissue characterization.

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/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2010 APPROPRIATE USE CRITERIA for Heart MRI:

<table>
<thead>
<tr>
<th>Heart MRI (Appropriate ACCF et al. Criteria # with Use Score)</th>
<th>INDICATIONS (*Refer to Additional Information section)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A= Appropriate (7-9) U=Uncertain (4-6)</td>
<td>Detection of CAD: Symptomatic</td>
</tr>
<tr>
<td>Evaluation of Chest Pain Syndrome, Including Low Risk Unstable Angina (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)</td>
<td></td>
</tr>
<tr>
<td>2 U(4)</td>
<td>• Intermediate pre-test probability of CAD*</td>
</tr>
<tr>
<td></td>
<td>• ECG interpretable AND able to exercise</td>
</tr>
<tr>
<td>3 A(7)</td>
<td>• Intermediate pre-test probability of CAD*</td>
</tr>
<tr>
<td></td>
<td>• ECG uninterpretable OR unable to exercise</td>
</tr>
<tr>
<td>4 A(7-9)</td>
<td>• High pre-test probability of CAD*</td>
</tr>
</tbody>
</table>
### Followup of Known Ischemic CAD

#### Asymptomatic or Stable Symptoms

**A(7-9)**

- ROUTINE FOLLOW-UP when last invasive or non-invasive assessment of coronary artery disease showed HEMODYNAMICALLY SIGNIFICANT CAD (ischemia on stress test or FFR <= 0.80 for a major vessel or stenosis >=70% of a major vessel) over two years ago, without supervening coronary revascularization, is an appropriate indication for stress CMR in patients with high risk clinical scenarios, such as left ventricular dysfunction (ejection fraction less than 50%) or severe un-revascularized multivessel CAD (if it will alter management), OR in patients with HIGH RISK OCCUPATIONS (e.g. associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters) or a HIGH PERSONAL RISK (e.g. scuba divers, etc.).

#### New, recurrent, or worsening (progressive) symptoms in patients with known ischemic CAD

**A(7-9)**

- PRIOR LOW RISK CORONARY EVALUATION AT LEAST TWO YEARS EARLIER (e.g. limited extent of CORONARY ARTERY DISEASE, <5% myocardium at risk), AND NOW WITH NEW STABLE (or low risk unstable), RECURRENT, OR SLOWLY WORSENING (PROGRESSIVE) SYMPTOMS of coronary ischemia, is an appropriate indication for stress CMR in this patient group. However, regardless of timing of prior non-invasive assessment, clinical documentation of continued problematic symptoms or moderate to highly likely acute coronary syndrome (Table 6) of even low mortality risk (Table7) is often better assessed with invasive coronary arteriography, particularly when stress testing in the last 2 years and current clinical findings are at odds. This category is very documentation-sensitive and requires judgment.

**Note:** INVASIVE CORONARY ARTERIOGRAPHY IS GENERALLY PREFERABLE in those patients, who have a PRIOR MODERATE OR HIGH RISK STRESS TEST RESULT (especially if NOT previously evaluated by invasive coronary arteriography) or a current diagnosis of moderate to high risk UNSTABLE ANGINA, and inappropriate for repeat stress CMR unless supervening reasons to prefer a non-invasive approach are documented in the record (e.g. very unclear symptoms, CKD, dye allergy, etc.), and it could alter management.

#### New or Worsening Symptoms without Known CAD

**A(7—9)**

- One of the following, when invasive coronary arteriography is not clearly indicated or appropriate (e.g. data are equivocal, symptoms not clear, CKI, dye allergy, other etiologies suspect, etc.):
  - Normal exercise EKG
  - CCTA, invasive coronary arteriography, or stress imaging did not show obstructive CAD
| U(4-6) | • Abnormal prior stress imaging study, when invasive coronary arteriography is not clearly indicated or appropriate (e.g. data are equivocal, symptoms not clear, CKD, dye allergy, other etiologies suspect, etc.):
  o Post Coronary Revascularization |

| A(7-9) | • Symptomatic or ischemic equivalent that is well documented |

| A(7-9) | • Asymptomatic
  Minimum of 2 YEARS post coronary artery bypass grafting or 2 YEARS post percutaneous coronary intervention (whichever was the latter) is appropriate only for patients with high direct CORONARY-related risk, such as incomplete coronary revascularization with feasible additional revascularization of residual severe multivessel disease, need for otherwise unevaluated follow up of stenting of unprotected left main coronary artery (LM) disease or left ventricular dysfunction (ejection fraction less than 50%), OR for patients with HIGH OCCUPATIONAL RISK (e.g. associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters) or HIGH PERSONAL RISK (e.g. scuba divers, etc.).
  • Evaluation of Asymptomatic Patient |

| U(4-6) | • High Global Risk CAD
  • Regardless of EKG interpretability or ability to exercise >2 years from last assessment |

| **Evaluation of Intra-Cardiac Structures (Use of MR Coronary Angiography)** |

<p>| 8 A(8) | • Evaluation of suspected coronary anomalies or coronary aneurysms |</p>
<table>
<thead>
<tr>
<th></th>
<th>Acute Chest Pain (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td><strong>U(6)</strong>&lt;br&gt;• With history of intermediate pre-test probability of CAD&lt;br&gt;• No ECG changes and serial cardiac enzymes negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Risk Assessment With Prior Test Results (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td><strong>U(6)</strong>&lt;br&gt;• Intermediate Global risk&lt;br&gt;• Equivocal stress imaging test (exercise, stress SPECT, or stress echo)</td>
</tr>
<tr>
<td>13</td>
<td><strong>A(7)</strong>&lt;br&gt;• Coronary angiography (catheterization or CCTA)&lt;br&gt;• Stenosis of unclear significance</td>
</tr>
<tr>
<td>A(7-9)</td>
<td>• Prior Exercise EKG stress test or CCTA&lt;br&gt;• Equivocal result</td>
</tr>
<tr>
<td>A(7-9)</td>
<td>• One of the following:&lt;br&gt;  o High concern for ischemic EKG with intermediate to high global risk EKG, and indication for invasive coronary arteriography is not clear&lt;br&gt;  o Abnormal prior exercise EKG with preference to avoid invasive evaluation (e.g. unclear symptoms, mildly abnormal stress EKG, dye allergy, CKD, etc.)&lt;br&gt;  o Obstructive CAD on prior CCTA, and either physiologic evaluation for ischemia is required, or there are new or worsening symptoms.&lt;br&gt;  o Obstructive CAD on invasive coronary angiography, and physiologic evaluation for ischemia is required&lt;br&gt;  o LEFT BUNDLE BRANCH BLOCK, when the history (intermediate to high global risk), physical examination, and/or noninvasive ejection fraction together support further evaluation, and invasive coronary arteriography is not already indicated, is an indication for stress CMR</td>
</tr>
</tbody>
</table>

| U(4-6) | • One of the following:<br>  o High concern for ischemic EKG, but only low global risk CORONARY ARTERY DISEASE, and indication for invasive coronary arteriography is not clear<br>  o Abnormal prior stress imaging study, and indication for invasive coronary arteriography is not clear<br>  o LEFT BUNDLE BRANCH BLOCK, when the history (low global risk), physical examination, and/or noninvasive ejection fraction together support further evaluation, and invasive coronary arteriography is not already indicated, is an indication for stress CMR |
### Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery – Intermediate or High Risk Surgery (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 15 A(7-9) | • If all the following apply:
  o Coronary evaluation before thoracoabdominal aortic surgery
  o Patient has less than a 4 MET functional capacity
  o Patient has one peri-operative risk factor
  o No coronary evaluation (invasive or non-invasive) within the past year
  o If invasive coronary arteriography is preferable, then stress CMR is not appropriate
  o Alternatively, without the need for the above criteria, patient would be a candidate for stress CMR at the time of a preoperative evaluation if indications unrelated to the surgery were well documented in the clinical record. |

### Other Cardiovascular Conditions

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| A(7-9) | • One of the following:
  o Newly diagnosed systolic heart failure
  o Newly diagnosed diastolic heart failure
  o Sustained VT
  o VF
  o Exercise Induced VT or nonsustained VT
  o Prior to initiation of antiarrhythmic therapy in high CAD global risk patients |

| U(4-6) | • One of the following
  o Frequent PVCs (>30/min)
  o Intermediate or high Global Risk CAD |

### Structure and Function

#### Evaluation of Ventricular and Valvular Function

Procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and delayed contrast enhancement, when echocardiogram is inadequate.

| 18 A(9) | • Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves
  • Procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and contrast enhancement |

| 19 U(6) | • Evaluation of LV function following myocardial infarction OR in heart failure patients |

| 20 A(8) | • Evaluation of LV function following myocardial infarction OR in heart failure patients
  • Patients with technically limited images from echocardiogram |

| 21 A(8) | • Quantification of LV function
  • Discordant information that is clinically significant from prior tests |

| 22 A(8) | • Evaluation of specific cardiomyopathies (infiltrative [amyloidosis, sarcoidosis, hemochromatosis,], noncompaction, HCM, acute viral myocarditis or due to cardiotoxic therapies), if echocardiography is inadequate and the information might alter management
  • Use of delayed enhancement |
### Evaluation of Characterization of native and prosthetic cardiac valves
- Including morphology of a bicuspid aortic valve’s ascending aorta, hemodynamics, planimetry of stenotic disease, quantification of regurgitant disease, preoperative/preinterventional evaluation of septal defects, and valve/inflow/outflow/conduit dimensions, necessary evaluation of congenital heart disease (e.g. anomalous pulmonary venous return, tetralogy of Fallot, etc.)
- Patients with technically limited images from echocardiogram, transesophageal echocardiogram, or cardiac CT

### Evaluation of Intra- and Extra-Cardiac Structures

<table>
<thead>
<tr>
<th>Indication</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 (A9)</td>
<td>Evaluation for arrhythmogenic right ventricular cardiomyopathy (ARVC)</td>
</tr>
<tr>
<td></td>
<td>Patients presenting with syncope or ventricular arrhythmia</td>
</tr>
<tr>
<td>25 (A8)</td>
<td>Evaluation of myocarditis or myocardial infarction with normal coronary arteries</td>
</tr>
<tr>
<td></td>
<td>Positive cardiac enzymes without obstructive atherosclerosis on angiography</td>
</tr>
</tbody>
</table>

### Evaluation of Myocardial Scar and Viability

<table>
<thead>
<tr>
<th>Indication</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 A(7)</td>
<td>To determine the location, and extent of myocardial necrosis including ‘no reflow’ regions</td>
</tr>
<tr>
<td></td>
<td>Post acute myocardial infarction</td>
</tr>
<tr>
<td>31 U(4)</td>
<td>To detect post PCI myocardial necrosis</td>
</tr>
<tr>
<td>32 A(9)</td>
<td>To determine viability prior to revascularization</td>
</tr>
<tr>
<td></td>
<td>Establish likelihood of recovery of function with revascularization (PCI or CABG) or medical therapy</td>
</tr>
<tr>
<td>33 A(9)</td>
<td>To determine viability prior to revascularization</td>
</tr>
<tr>
<td></td>
<td>Viability assessment by SPECT or dobutamine echo has provided &quot;equivocal or indeterminate&quot; results</td>
</tr>
</tbody>
</table>

### INDICATIONS FOR HEART MRI:
- Where Stress Echocardiography (SE) is noted as an appropriate substitute for a Cardiac MRI indication (#’s 2, 3, 4, 12, and 13) then at least one of the following contraindications to SE must be demonstrated:
  - Stress echocardiography is not indicated; OR
  - Stress echocardiography has been performed however findings were inadequate, there were technical difficulties with interpretation, or results were discordant with previous clinical data; OR
Heart MRI is preferential to stress echocardiography including but not limited to following conditions:

- Ventricular paced rhythm
- Evidence of ventricular tachycardia
- Severe aortic valve dysfunction
- Severe Chronic Obstructive Pulmonary Disease, (COPD) as defined as FEV1 < 30% predicted or FEV1 < 50% predicted plus respiratory failure or clinical signs of right heart failure. (GOLD classification of COPD access http://www.pulmonaryreviews.com/jul01/pr_jul01_copd.html)
- Congestive Heart Failure (CHF) with current Ejection Fraction (EF) < 40%
- Inability to get an echo window for imaging
- Prior thoracotomy, (CABG, other surgery)
- Obesity BMI>40
- Poorly controlled hypertension [generally above 180 mm Hg systolic (both physical stress and dobutamine stress may exacerbate hypertension during stress echo)]
- Poorly controlled atrial fibrillation (Resting heart rate > 100 bpm on medication)
- Inability to exercise requiring pharmacological stress test
- Segmental wall motion abnormalities at rest (e.g. due to cardiomyopathy, recent MI, or pulmonary hypertension)

OR

- Arrhythmias with Stress Echocardiography - any patient on a type 1C anti-arrhythmic drug (i.e. Flecainide or Propafenone) or considered for treatment with a type 1C anti-arrhythmic drug.

For all other requests, the patient must meet ACCF/ASNC Appropriateness criteria for indications (score 4-9) above.

INDICATIONS IN ACC GUIDELINES WITH “INAPPROPRIATE” DESIGNATION:

Patient meets ACCF/ASNC Appropriateness criteria for indications (score 1-3) noted below OR meets any one of the following:

- For any combination imaging study
- For same imaging tests less than six weeks part unless specific guideline criteria states otherwise.
- For different imaging tests, such as CTA and MRA, 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
ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2006 APPROPRIATE USE CRITERIA for Heart MRI:

<table>
<thead>
<tr>
<th>Heart MRI (Appropriate ACCF et al. Criteria # with Use Score)</th>
<th>INDICATIONS (*Refer to Additional Information section)</th>
<th>APPROPRIATE USE SCORE (1-3): I= Inappropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection of CAD: Symptomatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation of Chest Pain Syndrome (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>• Low pre-test probability of CAD</td>
<td>I(2)</td>
</tr>
<tr>
<td></td>
<td>• ECG interpretable AND able to exercise</td>
<td></td>
</tr>
<tr>
<td>Evaluation of Chest Pain Syndrome (Use of MR Coronary Angiography)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>• Intermediate pre-test probability of CAD</td>
<td>I(2)</td>
</tr>
<tr>
<td></td>
<td>• ECG interpretable AND able to exercise</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>• Intermediate pre-test probability of CAD</td>
<td>I(2)</td>
</tr>
<tr>
<td></td>
<td>• ECG uninterpretable OR unable to exercise</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>• High pre-test probability of CAD</td>
<td>I(1)</td>
</tr>
<tr>
<td>Acute Chest Pain (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>• With history of high pre-test probability of CAD</td>
<td>I(1)</td>
</tr>
<tr>
<td></td>
<td>• ECG - ST segment elevation and/or positive cardiac enzymes</td>
<td></td>
</tr>
<tr>
<td>Risk Assessment With Prior Test Results (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>• Normal prior stress test (exercise, nuclear, echo, MRI)</td>
<td>I(2)</td>
</tr>
<tr>
<td></td>
<td>• High CHD risk (Framingham)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Within 1 year of prior stress test</td>
<td></td>
</tr>
<tr>
<td>Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery – Low Risk Surgery (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>• Intermediate perioperative risk predictor</td>
<td>I(2)</td>
</tr>
<tr>
<td>Detection of CAD: Post-Revascularization (PCI or CABG)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation of Chest Pain Syndrome (Use of MR Coronary Angiography)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>• Evaluation of bypass grafts</td>
<td>I(2)</td>
</tr>
<tr>
<td>17</td>
<td>• History of percutaneous revascularization with stents</td>
<td>I(1)</td>
</tr>
</tbody>
</table>

ADDITIONAL INFORMATION RELATED TO HEART MRI:

Abbreviations
ACCS = acute coronary syndrome
CABG = coronary artery bypass grafting surgery
CAD = coronary artery disease
CCTA = coronary CT angiography
CHD = coronary heart disease
CHF = congestive heart failure
CT = computed tomography
CTA = computed tomographic angiography
ECG = electrocardiogram
ERNA = equilibrium radionuclide angiography
FP = First Pass
HF = heart failure
LBBB = left bundle-branch block
LV = left ventricular
MET = estimated metabolic equivalent of exercise
MI = myocardial infarction
MPI = myocardial perfusion imaging
MRI = magnetic resonance imaging
PCI = percutaneous coronary intervention
PET = positron emission tomography
RNA = radionuclide angiography
SE = stress echocardiography
SPECT = single positron emission CT (see MPI)

What is a valid anginal or ischemic 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 by itself is generally not considered an anginal equivalent, and is handled under a separate category in this guideline.

Exercise Treadmill Testing - Exercise Treadmill Testing (ETT) is the appropriate first line test in most patients with suspected CAD. In appropriately selected patients the test provides adequate sensitivity and specificity with regard to diagnosis and prognostication. There are patients in whom the test is not the best choice, for example those with resting ECG abnormalities, inability to exercise and perhaps diabetes. Also of note from an operational standpoint the test does not require pre-authorization.

An uninterpretable baseline EKG includes:

- 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)
- EKG 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)
- Prior false positive stress EKG

*Pretest Probability of CAD for Symptomatic (Ischemic Equivalent) Patients:

Typical Angina (Definite): Defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.
Atypical Angina (Probable): Chest pain or discomfort that lacks 1 of the characteristics of definite or typical angina.
Nonanginal Chest Pain: Chest pain or discomfort that meets 1 or none of the typical angina characteristics.

Once the presence of symptoms (Typical Angina/Atypical Angina/Non angina chest pain/Asymptomatic) is determined, the probabilities of CAD can be calculated from the risk algorithms as follows:

<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>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</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>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>50-59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>&gt;60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
</tbody>
</table>

Very low: Less than 5% pretest probability of CAD
Low: Less than 10% pretest probability of CAD
Intermediate: Between 10% and 90% pretest probability of CAD
High: Greater than 90% pretest probability of CAD

**Coronary Heart Disease (CHD) Risk**

- **CHD Risk—Low**
  - Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CHD risk less than 10%.
- **CHD Risk—Moderate**
  - Defined by the age-specific risk level that is average or above average. In general, moderate risk will correlate with a 10-year absolute CHD risk between 10% and 20%.
- **CHD Risk—High**
  - Defined as the presence of diabetes mellitus or the 10-year absolute CHD risk of greater than 20%.

**Definition of Peripheral Arterial Disease/Cerebrovascular Disease:**
Non-coronary arterial narrowing causing symptoms (claudication, related tissue demise, threatened limb loss), asymptomatic 70% or more narrowing by non-invasive or invasive evaluation, atherosclerotic arterial aneurysm by non-invasive or invasive evaluation, or aortic atheroma of at least 4 mm thickness. As a subset of peripheral arterial disease, cerebrovascular disease is also defined as a history of stroke or TIA.

**Global CAD Risk:**
It is assumed that clinicians will use current standard methods of global risk assessment in the asymptomatic patient for primary prevention, based upon Framingham-ATP IV, Reynolds, Pooled Cohort Equation (includes cerebrovascular risk), ACC/AHA Risk Calculator, MESA Risk Calculator (includes
**calcium score), or very similar risk calculator** CAD risk refers to 10-year risk for any hard cardiac event (e.g., myocardial infarction or CAD death).

- **Low global CAD risk**
  Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CAD risk <10%. However, in women and younger men, low risk may correlate with 10-year absolute CAD risk <6%.

- **Intermediate global CAD risk**
  Defined by the age-specific risk level that is average. In general, moderate risk will correlate with a 10-year absolute CAD risk range of 10% to 20%. Among women and younger age men, an expanded intermediate risk range of 6% to 20% may be appropriate.

- **High global CAD risk**
  Defined by the age-specific risk level that is above average. In general, high risk will correlate with a 10-year absolute CAD risk of >20%. CAD equivalents (e.g., peripheral arterial disease (defined in additional information), cerebrovascular disease (history of stroke or TIA), or multiple simultaneous anti-rejection medications (e.g. cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine, long term supraphysiologic doses of glucocorticoids, but not everolimus or sirolimus/rapamycin), peripheral arterial disease) can also define high risk. High global risk can be further defined by **COMPELLING NON-INVASIVE DATA**, such as clearly pathologic Q waves on the EKG, marked ST-segment and/or T wave abnormalities of myocardial ischemia without symptoms, clear regional wall motion abnormalities of the left ventricle, or reduced ejection fraction below 50%.

**Peri-Operative Cardiac Risk Factors**

These are specifically: ischemic coronary artery disease (by study more than two years ago with lesions, which are: >=70% or ischemia producing on prior stress testing or with FFR <=0.80), cerebrovascular disease, insulin-requiring diabetes mellitus, history of congestive heart failure or ejection fraction less than 40%, or CKD with creatinine >= 2 mg/dl.

***Duke Treadmill Score***
The equation for calculating the Duke treadmill score (DTS) is,
\[
DTS = \text{exercise time} - (5 \times \text{ST deviation}) - (4 \times \text{exercise angina}),
\]
with 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.
The Duke Score provides an annual mortality estimate: <1% for low risk, 1-3% for intermediate risk, and >3% for high risk.

**Determinants of a 4 MET functional capacity:**
Examples of activities:

<4 METs: Slow ballroom dancing, golfing with a cart, playing a musical instrument, and walking at approximately 2 mph to 3 mph

>4 METs: Climbing a flight of stairs or walking up a hill, walking on level ground at 4 mph, and performing heavy work around the house

**Tools for Characterization of Unstable Angina:**
## Risk Stratification in Acute Coronary Syndrome from 2007 ACC/AHA Guidelines

### Three Principal Presentations of Unstable Angina (as defined within a two week time frame) (Braunwald)

<table>
<thead>
<tr>
<th>Class</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest angina*</td>
<td>Angina occurring at rest and prolonged, usually greater than 20 min</td>
</tr>
<tr>
<td>New-onset angina</td>
<td>New-onset angina of at least CCS class III severity</td>
</tr>
<tr>
<td>Increasing angina</td>
<td>Previously diagnosed angina that has become distinctly more frequent, longer in duration, or lower in threshold (i.e., increased by 1 or more CCS class to at least CCS class III severity)</td>
</tr>
</tbody>
</table>

### Table 6: Likelihood that Symptoms Represent an Acute Coronary Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>High Likelihood (Any of the following)</th>
<th>Intermediate Likelihood (Absence of high-likelihood features and presence of any of the following)</th>
<th>Low Likelihood (Absence of high- or intermediate-likelihood features but may have:</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Chest or left arm pain or discomfort as chief symptom reproducing prior documented angina; Known history of CAD, including MI</td>
<td>Chest or left arm pain or discomfort as chief symptom; Male sex; Age greater than 70 years; Diabetes mellitus</td>
<td>Probable ischemic symptoms in absence of any of the intermediate likelihood characteristics; Recent cocaine use</td>
</tr>
<tr>
<td>Examination</td>
<td>Transient MR murmur, hypotension, diaphoresis, pulmonary edema, or rales</td>
<td>Extracardiac vascular disease; T-wave flattening or inversion less than 1 mm in leads with dominant R waves</td>
<td>Chest discomfort reproduced by palpation</td>
</tr>
<tr>
<td>ECG</td>
<td>New, or presumably new, transient ST-segment deviation (5 mm or greater) or T-wave inversion in multiple precordial leads</td>
<td>ST depression 0.5 to 1 mm or T-wave inversion greater than 1 mm</td>
<td>Normal ECG</td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>Elevated cardiac Tnl, TnT, or CK-MB</td>
<td>Normal</td>
<td>Normal</td>
</tr>
</tbody>
</table>


ACS = acute coronary syndrome; CAD = coronary artery disease; CK-MB = MB fraction of creatine kinase; ECG = electrocardiogram; MI = myocardial Infarction; MR = mitral regurgitation; Tnl = troponin 1; TnT = troponin T.
Table 7: Short Term Risk of Death or Nonfatal MI in Acute Coronary Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>High Risk</th>
<th>Intermediate Risk</th>
<th>Low Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Accelerating tempo of ischemic symptoms in preceding 48 h</td>
<td>Prior MI, peripheral or cerebrovascular disease, or CVA, prior aspirin use</td>
<td>Increased angina frequency, severity, or duration</td>
</tr>
<tr>
<td>Character of pain</td>
<td>Prolonged angina (greater than 20 min) rest pain</td>
<td>Prolonged (greater than 20 min) rest angina, now relieved, with moderate or high likelihood of CAD</td>
<td>Angina provoked at a lower threshold</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rest angina (greater than 20 min) or relieved with rest or sublingual NTG</td>
<td>New onset angina with onset 2 weeks to 2 months prior to presentation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical findings</td>
<td>Pulmonary edema, most likely due to ischemia</td>
<td>Age greater than 70 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New or worsening MR murmur</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Systolic or new/worsening MI ECG</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hypotension, head/leg, tachycardia</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age greater than 75 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG</td>
<td>Angina at rest with transient ST-segment changes greater than 0.5 mm</td>
<td>T-wave changes</td>
<td>Normal or unchanged ECG</td>
</tr>
<tr>
<td></td>
<td>Bundle-branch block, new or presumed normal</td>
<td>Pathological Q waves or resting ST-depression less than 1 mm in multiple lead groups (anterior, inferior, lateral)</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>Elevated cardiac Troponin T, TnI, or CK-MB (e.g., TnT or TnI greater than 0.1 ng per ml)</td>
<td>Slightly elevated cardiac Troponin T, TnI, or CK-MB (e.g., TnT greater than 0.01 but less than 0.1 ng per ml)</td>
<td>Normal</td>
</tr>
</tbody>
</table>

The **TIMI Risk Score** is determined by the sum of the presence of 7 variables at admission: 1 point is given for each of the following variables: age ≥65 years, at least 3 risk factors for CAD, prior coronary stenosis of ≥50%, ST-segment deviation on ECG presentation, at least 2 anginal events in prior 24 hours, use of aspirin prior to 7 days, and elevated serum cardiac biomarkers. **Low-Risk TIMI Score**: TIMI score <2; **High-Risk TIMI Score**: TIMI score ≥2. A low risk TIMI score might still warrant invasive coronary arteriography, when other features, such as symptoms, are compelling.

**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.

**Metal devices or foreign body fragments** within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

**Cardiomyopathy** – Cardiac MRI is used to diagnose and differentiate cardiomyopathies in the same study. Very small morphological and functional changes in different types of cardiomyopathy may be detected and may be used to evaluate the chance of functional recovery after surgical revascularization.

**Cardiac Tumors** – 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 extracardiac 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.

**Pericardial abnormalities**—Complicated pericardial diseases may cause significant morbidity and mortality without therapeutic interventions. MRI imaging has an important role in the evaluation of pericardial abnormalities: the pericardium is well visualized on MRI due to its superb contrast resolution and multiplanar capability.

**REFERENCES**


CPT Codes: 75571, S8092

INTRODUCTION:

Advanced obstructive coronary heart disease (CHD) can exist with minimal or no symptoms and can progress rapidly. The first clinical manifestation is often catastrophic: acute myocardial infarction (MI), unstable angina, or sudden cardiac death. The rationale for early detection of CHD is that detection during the subclinical stages of disease might permit the reliable identification of subjects at increased risk of an adverse cardiac event and that appropriate therapy (e.g., lipid lowering) might improve the prognosis of those at high risk.

Coronary artery calcification screening, especially for intermediate-risk patients, can enhance the prediction of risk in asymptomatic individuals and increase the predictive value of the Framingham Risk Score.

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 EBCT:

For use as a risk stratification tool, based upon Framingham-ATP IV, Reynolds (includes family history), Pooled Cohort Equation (includes cerebrovascular risk), ACC/AHA Risk Calculator, or similar risk score:

- For the detection of coronary artery calcification in asymptomatic adults without known coronary artery disease (CAD) at intermediate global risk 10 to 20%, or 6-20% in women and younger men (when the result is expected to lead to a change in the management/treatment based upon reclassification to a lower or higher risk group.
- It is not to be used as a diagnostic test for CAD in a symptomatic patient.

Risk Calculators - Links to Cardiac/Vascular Risk Online Calculators:

Framingham-ATP IV:  
http://cvdrisk.nhlbi.nih.gov/

Reynolds Risk Score (Adds in family history):  
http://www.reynoldsriskscore.org/

Pooled Cohort Equation (includes cardiac and cerebrovascular risk):  
http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example

ACC/AHA Risk Calculator (includes cardiac and cerebrovascular risk):  
http://tools.acc.org/ASCVD-Risk-Estimator/

MESA Risk Calculator with addition of Coronary Artery Calcium Score:  
https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx
REFERENCES


Calcium Scoring Updated References:


CPT Codes: 75572, 75573

INTRODUCTION:

Cardiac computed tomography (Heart CT) can be used to image the cardiac chambers, valves, myocardium and pericardium to assess cardiac structure and function. Applications of Heart CT listed and discussed in this guideline include: characterization of congenital heart disease, characterization of cardiac masses, diagnosis of pericardial diseases, and pre-operative coronary vein mapping.

The table below correlates and matches the clinical indications with the Appropriate Use Score based on a scale of 4 to 9, where the upper range (7 to 9) implies that the test is generally acceptable and is a reasonable approach. The mid-range (4 to 6) indicates uncertainty in the appropriateness of the test for the clinical scenario. In all cases, additional factors should be taken into account including but not limited to cost of test, impact of the image on clinical decision making when combined with clinical judgment and risks, such as radiation exposure and contrast adverse effects, should be considered.

Where the Heart CT is the preferred test based upon the indication the Appropriate Use Score will be in the upper range such as noted with indication #51 assessment of right ventricular morphology or suspected arrhythmogenic right ventricular dysplasia.

For indications in which there are one or more alternative tests with an appropriate use score rating (appropriate, uncertain) noted, for example indication #52 (Assessment of myocardial viability, prior to myocardial revascularization for ischemic left ventricular systolic dysfunction and other imaging modalities are inadequate or contraindicated), additional factors should be considered when determining the preferred test (Stress Echocardiogram if there are no contraindications).

Where indicated as alternative tests, TTE (transthoracic echocardiography) and SE (Stress echocardiography) are a better choice, where possible, because of avoidance of radiation exposure. Heart MRI can be considered as an alternative, especially in young patients, where recurrent examinations may be 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.
INDICATIONS FOR HEART CT:

- To qualify for cardiac computed tomography, the patient must meet ACCF/ASNC Appropriateness Use Score (Appropriate Use Score 7–9 or Uncertain Appropriate Use Score 4–6).

ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 Appropriate Use Criteria for Cardiac (Heart) Computed Tomography:

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>Heart CT (Indication and Appropriate Use Score)</th>
<th>A= Appropriate; U=Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INDICATIONS</strong> (<em>Refer to Additional Information section</em>)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Evaluation of Cardiac Structure and Function

**Adult Congenital Heart Disease**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>46 A (9)</td>
<td>• Assessment of anomalies of coronary arterial and other thoracic arteriovenous vessels (*for “anomalies of coronary arterial vessels” CCTA preferred and for “other thoracic arteriovenous vessels” Heart CT preferred)</td>
<td></td>
</tr>
<tr>
<td>47 A (8)</td>
<td>• Further assessment of complex adult congenital heart disease after confirmation by TTE echocardiogram</td>
<td></td>
</tr>
</tbody>
</table>

**Evaluation of Ventricular Morphology and Systolic Function**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 48 A (7) | • Evaluation of left ventricular function  
• Following acute MI or in HF patients  
• Inadequate images from other noninvasive methods |
| 50 A (7) | • Quantitative evaluation of right ventricular function |
| 51 A (7) | • Assessment of right ventricular morphology  
• Suspected arrhythmogenic right ventricular dysplasia |
| 52 U (5) | • Assessment of myocardial viability  
• Prior to myocardial revascularization for ischemic left ventricular systolic dysfunction  
• Other imaging modalities are inadequate or contraindicated |

**Evaluation of Intra- and Extracardiac Structures**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 53 A (8) | • Characterization of native cardiac valves  
• Suspected clinically significant valvular dysfunction  
• Inadequate images from other noninvasive methods |
| 54 A (8) | • Characterization of prosthetic cardiac valves  
• Suspected clinically significant valvular dysfunction  
• Inadequate images from other noninvasive methods |
| 56 A (8) | • Evaluation of cardiac mass (suspected tumor or thrombus)  
• Inadequate images from other noninvasive methods |
| 57 A (8) | • Evaluation of pericardial anatomy |
ACCF et al. Criteria #
Heart CT
(Indication and
Appropriate Use
Score) A=
Appropriate; U=Uncertain

<table>
<thead>
<tr>
<th></th>
<th>INDICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(*Refer to Additional Information section)</td>
</tr>
</tbody>
</table>

58 A (8) • Evaluation of pulmonary vein anatomy  
• Prior to radiofrequency ablation for atrial fibrillation

59 A (8) • Noninvasive coronary vein mapping  
• Prior to placement of biventricular pacemaker

60 A (8) • Localization of coronary bypass grafts and other retrosternal anatomy*  
• Prior to preoperative chest or cardiac surgery  
(*for “localization of coronary bypass grafts” CCTA preferred and for “other retrosternal anatomy” Heart CT preferred)

Preoperative or Pre-Procedural Evaluation
• Pre-op evaluation prior to structural heart interventions, such as Transcatheter Aortic Valve Replacement (TAVR).

For indications in which there are one or more alternative tests with an appropriate use score rating (appropriate, uncertain) noted, (for example indication #52) then additional factors should be considered when determining the preferred test (Stress Echocardiogram if there are no contraindications).

Indication #52 of Heart CT:
• Assessment of myocardial viability  
• Prior to myocardial revascularization for ischemic left ventricular systolic dysfunction  
• Other imaging modalities are inadequate or contraindicated

INDICATIONS IN ACC GUIDELINES WITH “INAPPROPRIATE” DESIGNATION:

• Patient meets ACCF/ASNC Appropriateness Use Score for inappropriate indications (median score 1-3) noted below OR one or more of the following:
  o For same imaging tests less than six weeks apart unless specific guideline criteria states otherwise.  
  o 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.  
  o For re-imaging of repeat or poor quality studies.  
  o For imaging of pediatric patients twelve years old and younger under prospective authorizations.
• Contraindications - There is insufficient data to support the routine use of Heart CT for the following:  
  o As the first test in evaluating symptomatic patients (e.g. chest pain)  
  o To evaluate chest pain in an intermediate or high risk patient when a stress test (exercise treadmill, stress echo, MPI, cardiac MRI, cardiac PET) is clearly positive or negative.  
  o Preoperative assessment for non-cardiac, nonvascular surgery  
  o Preoperative imaging prior to robotic surgery (e.g. to visualize the entire aorta)
o Evaluation of left ventricular function following myocardial infarction or in chronic heart failure.
o Myocardial perfusion and viability studies.
o Evaluation of patients with postoperative native or prosthetic cardiac valves who have technically limited echocardiograms, MRI or TEE.

ADDITIONAL INFORMATION RELATED TO HEART CT:

Abbreviations
ACS = acute coronary syndrome
ARVC = arrhythmogenic cardiomyopathy
ARVD = arrhythmogenic right ventricular dysplasia
CABG = coronary artery bypass grafting surgery
CAD = coronary artery disease
CCS = coronary calcium score
CHD = coronary heart disease
CT = computed tomography
CTA = computed tomography angiography
ECG = electrocardiogram
EF = ejection fraction
HF = heart failure
MET = estimated metabolic equivalent of exercise
MI = myocardial infarction
MPI = Myocardial Perfusion Imaging or Nuclear Cardiac Imaging
PCI = percutaneous coronary intervention
SE = Stress Echocardiogram
TTE = Transthoracic Echocardiography

ECG–Uninterpretable
Refers to ECGs with resting ST-segment depression (≥0.10 mV), complete LBBB, preexcitation (Wolff-Parkinson-White Syndrome), or paced rhythm.

Acute Coronary Syndrome (ACS):
Patients with an ACS include those whose clinical presentations cover the following range of diagnoses: unstable angina, myocardial infarction without ST-segment elevation (NSTEMI), and myocardial infarction with ST-segment elevation (STEMI)

*Pretest Probability of CAD for Symptomatic (Ischemic Equivalent) Patients:

- **Typical Angina (Definite):** Defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.
- **Atypical Angina (Probable):** Chest pain or discomfort that lacks 1 of the characteristics of definite or typical angina.
- **Nonanginal Chest Pain:** Chest pain or discomfort that meets 1 or none of the typical angina characteristics.

Once the presence of symptoms (Typical Angina/Atypical Angina/Non angina chest pain/Asymptomatic) is determined, the pretest probabilities of CAD can be calculated from the risk algorithms as follows:
### Global CAD Risk:

It is assumed that clinicians will use current standard methods of global risk assessment such as those presented in the National Heart, Lung, and Blood Institute report on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III [ATP III]) (18) or similar national guidelines. CAD risk refers to 10-year risk for any hard cardiac event (e.g., myocardial infarction or CAD death).

<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>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>40–49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>&gt;60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

- **Very low**: Less than 5% pretest probability of CAD
- **Low**: Less than 10% pretest probability of CAD
- **Intermediate**: Between 10% and 90% pretest probability of CAD
- **High**: Greater than 90% pretest probability of CAD

#### Perioperative Clinical Risk Predictors:

- History of ischemic heart disease
- History of compensated or prior heart failure
- An ejection fraction of <40%
- History if cerebrovascular disease
- Diabetes mellitus (requiring insulin)
- Renal insufficiency (creatinine >2.0)

**Surgical Risk Categories (As defined by the ACC/AHA Guideline Update for Perioperative Cardiovascular Evaluation of Non-Cardiac Surgery)**
- **High-Risk Surgery**—cardiac death or MI greater than 5%
  - Emergent major operations (particularly in the elderly), aortic and peripheral vascular surgery, prolonged surgical procedures associated with large fluid shifts and/or blood loss.
- **Intermediate-Risk Surgery**—cardiac death or MI = 1% to 5%
  - Carotid endarterectomy, head and neck surgery, surgery of the chest or abdomen, orthopedic surgery, prostate surgery.
- **Low-Risk Surgery**—cardiac death or MI less than 1%
  - Endoscopic procedures, superficial procedures, cataract surgery, breast surgery.

**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.

**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, CT is useful and can often be performed with only mild sedation because of the short acquisition time.

**CT and 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 provides 3D anatomic relationship of the blood vessels and chest wall, and depicts cardiovascular anatomic structures. It is used in the evaluation of congenital heart disease in adults, e.g., ventricular septal defect and anomalies of the aortic valve. CT is also used increasingly in the evaluation of patients with chest pain, resulting in detection of unsuspected congenital heart disease. CT is useful in the evaluation of children with CHD when findings from echocardiography are unclear or need confirmation.

**CT and Cardiac Masses** – CT is used to evaluate cardiac masses, describing their size, density 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. Characteristic features of myxomas that can be assessed accurately on CT include location in the left atrium, lobulated margin, inhomogeneous content, and a CT attenuation value lower that that of blood. Echocardiography is the method of choice for the diagnosis of cardiac myxoma; CT is used to evaluate a patient with suspected myxoma before surgery. Cardiac tumors generally vary in their morphology and CT assessment may be limited. MRI may be needed for further evaluation.

**CT and Pericardial Disease** – CT is used in the evaluation of pericardial conditions. Echocardiography is most often used in the initial examination of pericardial disease, but has disadvantages when compared with CT which provides a larger field of view than echocardiography. CT also has superior soft-tissue contrast and provides anatomic delineations enabling localization of pericardial masses. Contrast-enhanced CT is sensitive in differentiating restrictive cardiomyopathy from constrictive pericarditis which is caused most often by cardiac surgery and radiation therapy. CT can depict thickening and calcification of the pericardium, which along with symptoms of physiologic constriction or restriction, may indicate constrictive pericarditis. CT is also used in the evaluation of pericardial masses which are often detected initially with echocardiography. CT can accurately define the site and extent of masses, e.g., cysts, hematomas and neoplasms.

**CT and Radiofrequency Ablation for Atrial Fibrillation** – Atrial fibrillation, an abnormal heart rhythm originating in the atria, is the most common supraventricular arrhythmia in the United States and can be a cause of morbidity. In patients with atrial fibrillation, radiofrequency ablation is used to electrically...
disconnect the pulmonary veins from the left atrium. Prior to this procedure, CT may be used to define
the pulmonary venous anatomy which is commonly variable. Determination of how many pulmonary
veins are present and their ostial locations is important to make sure that all the ostia are ablated.

REFERENCES

ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 Appropriate Use Criteria for Cardiac
Computed Tomography: A Report of the American College of Cardiology Foundation Appropriate Use
Criteria Task Force, the Society of Cardiovascular Computed Tomography, the American College of
Radiology, the American Heart Association, the American Society of Echocardiography, the American
Society of Nuclear Cardiology, the North American Society for Cardiovascular Imaging, the Society for
Cardiovascular Angiography and Interventions, and the Society for Cardiovascular Magnetic
Resonance, J. Am. Coll. Cardiol. 56, 1864-1894 Retrieved from
http://content.onlinejacc.org/cgi/content/short/56/22/1864

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Echocardiography. A Report of the American College of Cardiology Foundation Appropriate Use
Criteria Task Force, American Society of Echocardiography, American Heart Association, American
Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for
Cardiovascular Angiography and Interventions, Society of Critical Care Medicine, Society of
http://www.asecho.org/files/EchoAUC.pdf

ACCF/AHA/AATS/PCNA/SCAI/STS 2014 Focused Update of the Guideline for the Diagnosis and
Management of Patients With Stable Ischemic Heart Disease A Report of the American College of
Cardiology/American Heart Association Task Force on Practice Guidelines, and the American
Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for
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Criteria for the Detection and Risk Assessment of Stable Ischemic Heart Disease A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart
Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart
Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and
Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic
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September). MDCT of the left atrium and pulmonary veins in planning radiofrequency ablation for
http://www.ajronline.org/content/183/3/767.full


Van de Veire, N. R., Schuijff, J. D., De Sutter, J., Devos, D., Bleeker, G. B., de Roos, A., ... Bax, J. J. (2006, Nov). Non-invasive visualization of the cardiac venous system in coronary artery disease...


INTRODUCTION:

Coronary computed tomographic angiography (CCTA) is a noninvasive imaging study that uses intravenously administered contrast material and high-resolution, rapid imaging CT equipment to obtain detailed volumetric images of blood vessels. CTA can image blood vessels throughout the body. However, imaging of the coronary vasculature requires shorter image acquisition times to avoid blurring from the motion of the beating heart. The advanced spatial and temporal resolution features of these CT scanning systems offer a unique method for imaging the coronary arteries and the heart in motion, and for detecting arterial calcification that contributes to coronary artery 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.

The table below correlates and matches the clinical indications with the Appropriate Use Score based on a scale of 4 to 9, where the upper range (7 to 9) implies that the test is generally acceptable and is a reasonable approach. The mid-range (4 to 6) indicates uncertainty in the appropriateness of the test for the clinical scenario. In all cases, additional factors should be taken into account including but not limited to cost of test, impact of the image on clinical decision making when combined with clinical judgment and risks, such as radiation exposure and contrast adverse effects, should be considered.

Where the CCTA is the preferred test based upon the indication, the Appropriate Use Score will be in the upper range such as noted with indication # 46, Assessment of anomalies of coronary arterial and other thoracic arteriovenous vessels.

AN IMPORTANT COMMENT ON THE CONCEPT OF RISK:

It is important to adhere to the concept of risk in making appropriateness determinations. However, the terminology for risk assessment must be clarified here.

An asymptomatic patient should be assessed for GLOBAL RISK, using an accepted calculator, as listed in the references section, with available links to those calculators. Asymptomatic patients with known calcium scores should have their GLOBAL RISK assessed with the MESA calculator.

Symptomatic patients are assessed based upon whether their presentation is acute/subacute or stable/nonacute. The assessment of the stable/nonacute patient is referred to as the PRETEST PROBABILITY of coronary artery disease (CAD). Once tested, the patient has a POST-TEST PROBABILITY of coronary artery disease. The POST-TEST PROBABILITY becomes the PRETEST PROBABILITY for any subsequent test for coronary artery disease. For example, a DUKE score of negative 10 to positive 4 represents intermediate risk.

When the presentation is acute/subacute, the means of assessment for such potential acute coronary syndromes typically involves conventional history and physical, EKG, biomarkers, etc., and if no actionable diagnosis has been established at that point, the patient is generally considered to be at an
equivocal or low-to-intermediate risk for an acute coronary syndrome, for which further imaging, such as CCTA, might be appropriate.

When there has been an actionable diagnosis of an acute coronary syndrome, separate risk categorizations for that scenario apply.

**ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2010 APPROPRIATE USE SCORE CRITERIA for CCTA, with clarifications added, along with incorporation of the 2015 ACR/ACC/AHA/AATS/ACEP/ASNC/NASCI/SAEM/SCCT/SCMR/SCPC/SNMMI/STR/STS Appropriate Utilization of Cardiovascular Imaging in Emergency Department Patients With Chest Pain**

<table>
<thead>
<tr>
<th>ACCF et al. Criteria # CCTA (Indication and Appropriate Use Score)</th>
<th>INDICATIONS</th>
<th>(*Refer to Additional Information section)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Detection of CAD in Symptomatic Patients Without Known Heart Disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable/Nonacute Symptoms Possibly Representing an Ischemic Equivalent</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 1 I(1-3) | • Low pretest probability of CAD* AND  
• ECG interpretable and able to exercise | |
| 1 U(4-6) | • Intermediate pretest probability of CAD* AND  
• ECG interpretable AND able to exercise | |
| 2 U(4-6) | • Low pretest probability of CAD* AND  
• ECG uninterpretable or unable to exercise | |
| 2 A(8) | • Intermediate pretest probability of CAD* AND  
• ECG uninterpretable or unable to exercise | |
| 2 U(4-6) | • High pretest probability of CAD* AND  
• Regardless of ECG interpretability and ability to exercise | |
| **Acute Symptoms With Suspicion of ACS (Urgent Presentation) after Standard Evaluation Has Not Resulted in an Actionable Diagnosis** | | |
| 4 U(6) | • Persistent ECG ST-segment elevation following exclusion of MI by invasive coronary arteriography. | |
| 5 A(7-9) | If one of the following apply:  
• Acute chest pain of uncertain cause (differential diagnosis includes pulmonary embolism, aortic dissection, and ACS ["triple rule out"])  
• Equivocal diagnosis due to single troponin elevation without additional evidence of ACS  
• Equivocal diagnosis with ischemic symptoms resolved hours before testing  
• Low-to-intermediate likelihood of ACS based upon TIMI RISK Score = 0, with early high sensitivity troponin negative  
• Low-to-intermediate likelihood of ACS based upon normal/nonischemic initial EKG and normal initial troponin  
• SERIAL EKGs and troponins negative or if either is borderline for NSTEMI/ACS | |
### ACCF et al. Criteria #

to Appropriately Use Score

<table>
<thead>
<tr>
<th>Score</th>
<th>5 U(4-6)</th>
<th>6 Low/Int Pretest Probability* A(7) High Pretest Probability* U(4)</th>
<th>7 Low/Int Pretest Probability* A(7) High Pretest Probability* U(4)</th>
<th>8 Low/Int Pretest Probability* A(7) High Pretest Probability* U(4)</th>
<th>10 Intermediate Global Risk (10-20%, or 6-20% in women and younger men)** U(4-6)</th>
<th>12 U(6)</th>
<th>13</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INDICATIONS</strong></td>
<td>Diagnosis unequivocally positive for ACS, but this category should be reserved for patients in whom invasive coronary arteriography would be considered at least relatively contraindicated</td>
<td>Acute symptoms, possibly representing an ischemic equivalent AND Normal ECG and cardiac biomarkers (troponin and CPK/CPK-MB)</td>
<td>Acute symptoms, possibly representing an ischemic equivalent AND ECG uninterpretable</td>
<td>Acute symptoms, possibly representing an ischemic equivalent AND Nondiagnostic ECG or equivocal cardiac biomarkers</td>
<td>If all the following apply: Risk assessment in asymptomatic patients (not for diagnosis in symptomatic patients) No known CAD Result could change management of coronary risk</td>
<td>Routine evaluation of coronary arteries for transplant vasculopathy</td>
<td>Reduced left ventricular ejection fraction (&lt;40% EF), when invasive</td>
</tr>
</tbody>
</table>

**Note:** Refer to Additional Information section

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**Acute Symptoms with Suspicion of ACSx (Urgent Presentation), when the History Reveals a Particular Pretest Probability**

<table>
<thead>
<tr>
<th>Score</th>
<th>5 U(4-6)</th>
<th>6 Low/Int Pretest Probability* A(7) High Pretest Probability* U(4)</th>
<th>7 Low/Int Pretest Probability* A(7) High Pretest Probability* U(4)</th>
<th>8 Low/Int Pretest Probability* A(7) High Pretest Probability* U(4)</th>
<th>10 Intermediate Global Risk (10-20%, or 6-20% in women and younger men)** U(4-6)</th>
<th>12 U(6)</th>
<th>13</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INDICATIONS</strong></td>
<td>Diagnosis unequivocally positive for ACS, but this category should be reserved for patients in whom invasive coronary arteriography would be considered at least relatively contraindicated</td>
<td>Acute symptoms, possibly representing an ischemic equivalent AND Normal ECG and cardiac biomarkers (troponin and CPK/CPK-MB)</td>
<td>Acute symptoms, possibly representing an ischemic equivalent AND ECG uninterpretable</td>
<td>Acute symptoms, possibly representing an ischemic equivalent AND Nondiagnostic ECG or equivocal cardiac biomarkers</td>
<td>If all the following apply: Risk assessment in asymptomatic patients (not for diagnosis in symptomatic patients) No known CAD Result could change management of coronary risk</td>
<td>Routine evaluation of coronary arteries for transplant vasculopathy</td>
<td>Reduced left ventricular ejection fraction (&lt;40% EF), when invasive</td>
</tr>
</tbody>
</table>

**Note:** Refer to Additional Information section
<table>
<thead>
<tr>
<th>ACCF et al. Criteria # CCTA (Indication and Appropriate Use Score)</th>
<th>INDICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly Diagnosed Heart Failure A(7-9)</td>
<td>coronary arteriography is not the preferred method of evaluation</td>
</tr>
<tr>
<td>14 Newly Diagnosed Heart Failure U(4-6)</td>
<td>• Normal left ventricular ejection fraction</td>
</tr>
</tbody>
</table>

**Preoperative Coronary Assessment Prior to Noncoronary Cardiac Surgery**

<table>
<thead>
<tr>
<th>15 A(7-9)</th>
<th>If all the following apply:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Coronary evaluation before thoracoabdominal aortic surgery</td>
<td>• Patient has less than a 4 MET functional capacity</td>
</tr>
<tr>
<td>• Patient has one peri-operative risk factor</td>
<td>• No coronary evaluation (invasive or non-invasive) within the past year</td>
</tr>
<tr>
<td>• If invasive coronary arteriography is preferable, then CCTA is not</td>
<td>• Alternatively, without the need for the above criteria, patient would be</td>
</tr>
<tr>
<td>appropriate</td>
<td>a candidate for CCTA at the time of a preoperative evaluation if</td>
</tr>
<tr>
<td>• Alternatively, without the need for the above criteria, patient would be</td>
<td>indications unrelated to the surgery were well documented in the</td>
</tr>
<tr>
<td>a candidate for CCTA at the time of a preoperative evaluation if</td>
<td>clinical record</td>
</tr>
<tr>
<td>indications unrelated to the surgery were well documented in the</td>
<td></td>
</tr>
<tr>
<td>clinical record</td>
<td></td>
</tr>
</tbody>
</table>

**Arrhythmias—Etiology Unclear After Initial Evaluation**

<table>
<thead>
<tr>
<th>17 (1-3)</th>
<th>Any one of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Infrequent PVCs</td>
<td>• New Onset atrial fibrillation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17 U(4-6)</th>
<th>Any one of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Exercise induced or nonsustained ventricular tachycardia</td>
<td>• Ventricular fibrillation</td>
</tr>
<tr>
<td>• Sustained VT</td>
<td>• Prior to initiation of antiarrhythmic therapy in high global risk (CAD)patients</td>
</tr>
<tr>
<td>• Frequent PVCs (&gt;30/hr)</td>
<td></td>
</tr>
</tbody>
</table>

| 18 I(1-3)                                                               | Syncope |
|--------------------------------------------------------------------------|         |
| • Low Global CAD risk                                                    |         |

| 18 U(4-6)                                                               | Syncope |
|--------------------------------------------------------------------------|         |
| • Intermediate and High global CAD risk** initial evaluation includes    |         |
|   echocardiogram                                                         |         |

**Elevated Troponin of Uncertain Clinical Significance**

| 19 U(6)                                                                 | Elevated troponin without additional evidence of ACS or symptoms suggestive of CAD |

**Use of CTA in the Setting of Prior Test Results**

<table>
<thead>
<tr>
<th>20 A(7)</th>
<th>Prior ECG exercise AND</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Normal ECG exercise test AND</td>
<td>• Continued symptoms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>21 A(7)</th>
<th>Prior ECG exercise AND</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prior ECG exercise AND</td>
<td>• Intermediate mortality risk***based upon Duke Treadmill Score</td>
</tr>
<tr>
<td>ACCF et al. Criteria # CCTA (Indication and Appropriate Use Score)</td>
<td>INDICATIONS</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>U(4-6)</td>
<td>• Abnormal rest ECG (highly concerning for ischemia, without clear indication for invasive coronary arteriography)</td>
</tr>
<tr>
<td></td>
<td>• LEFT BUNDLE BRANCH BLOCK, when the history, physical examination, and/or noninvasive ejection fraction together support further evaluation, and invasive coronary arteriography is not already indicated, is an indication for stress imaging (MPI or echo).</td>
</tr>
</tbody>
</table>

### Sequential Testing After Stress Imaging Procedures

| 22 A(8) | • Discordant ECG exercise and imaging results |
| 23 Equivocal for Ischemia A(8) Mild Ischemia U(6) | • Prior stress ECG or stress imaging results: |

### Prior CCS

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ No longer applicable.</td>
</tr>
<tr>
<td>♦ Use MESA Global Risk Calculator and base decision on Global Risk</td>
</tr>
</tbody>
</table>

### Evaluation of New or Worsening Symptoms in the Setting of Past Stress Imaging Study

| 29 A(7-9) | • Previous stress ECG or stress imaging study abnormal when a noninvasive approach is preferable to proceeding to invasive coronary arteriography (unclear nature of symptoms, mildly abnormal or borderline EKG stress test or stress with echocardiogram/MPI, CKD, dye allergy, etc.) |
|                                                     | • Previous stress ECG study normal when a noninvasive approach is preferable to proceeding to invasive coronary arteriography (unclear nature of symptoms, mildly abnormal or borderline EKG stress test or stress with echocardiogram/MPI, CKD, dye allergy, etc.) |
|                                                     | • Previous stress imaging study normal within the past 2 years and currently compelling coronary history or symptoms should be considered appropriate indication for a CCTA, particularly if there are reasons to avoid cardiac catheterization (CKD, dye allergy, etc.), unless invasive coronary arteriography is strongly indicated (e.g. compelling presentation of moderate or high risk unstable angina). |

### Risk Assessment Preoperative Evaluation of Noncardiac Surgery Without Active Cardiac Conditions

<table>
<thead>
<tr>
<th>Intermediate-Risk Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>• See indication #15.</td>
</tr>
</tbody>
</table>

### Vascular Surgery

| • See indication #15. |

### Risk Assessment Post revascularization (PCI or CABG)
### ACCF et al. Criteria #

#### CCTA (Indication and Appropriate Use Score)

<table>
<thead>
<tr>
<th>Score</th>
<th>Indications</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>39 U(4-6)</td>
<td>Evaluation of graft patency after CABG or evaluation post percutaneous coronary intervention, with good documentation of symptomatic presentation, are indications for CCTA if it could affect management</td>
<td>(*Refer to Additional Information section)</td>
</tr>
<tr>
<td>42 U(4-6)</td>
<td>Prior left main coronary stent</td>
<td></td>
</tr>
</tbody>
</table>

#### Symptomatic (Ischemic Equivalent) Post Coronary Revascularization

- Prior left main coronary stent

#### Asymptomatic—Post Coronary Revascularization

- Prior left main coronary stent

#### Evaluation of Cardiac Structure and Function

#### Adult Congenital Heart Disease

- Assessment of anomalies of coronary arterial and other thoracic arteriovenous vessels. This includes long term follow-up of Kawasaki disease for aneurysm formation.

  (*for “anomalies of coronary arterial vessels” CCTA preferred and for “other thoracic arteriovenous vessels” Heart CT preferred)

#### Evaluation of Intra- and Extracardiac Structures

- Localization of coronary bypass grafts and other retrosternal anatomy
- Prior to preoperative chest or cardiac surgery

  (*for “localization of coronary bypass grafts” CCTA preferred and for “other retrosternal anatomy” Heart CT preferred)

### INDICATIONS FOR CORONARY CT ANGIOGRAPHY (CCTA):

- CCTA may be appropriately used when evaluating chest pain syndromes with low to intermediate risk CAD profiles such as in emergency room or observation unit situations.
- CCTA maybe an appropriate substitution exam for a left heart catheterization.

### INDICATIONS IN ACC GUIDELINES WITH “INAPPROPRIATE” DESIGNATION:

The patient must meet ACCF/ASNC Appropriateness criteria for inappropriate indications (median score 1 – 3) below OR meets any one of the following:

- Contra-indications to beta blockers used to slow heart rate during procedure.
- Acute chest pain/angina (*Patients with acute angina/chest pain may need to go directly to catheterization. Refer for MD Review*).
- Pre-op request for non-cardiac surgery
- Significant premature ventricular contractions, significant frequent atrial fibrillation, or relative contra-indication to CCTA
### ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2010 APPROPRIATE USE SCORE CRITERIA:

<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
<th>INDICATIONS</th>
<th>APPROPRIATE USE SCORE (1-3); I= Inappropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTA</td>
<td>Detection of CAD in Symptomatic Patients Without Known Heart Disease Symptomatic</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Nonacute Symptoms Possibly Representing an Ischemic Equivalent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• High pretest probability of CAD*</td>
<td>I(3)</td>
</tr>
<tr>
<td></td>
<td>• ECG interpretable and able to exercise</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Acute Symptoms With Suspicion of ACS (Urgent Presentation)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Definite MI</td>
<td>I(1)</td>
</tr>
<tr>
<td>10</td>
<td>Noncontrast CT for CCS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Low global CHD risk estimate**</td>
<td>I(2)</td>
</tr>
<tr>
<td>11</td>
<td>Coronary CTA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Low or Intermediate global CHD risk estimate**</td>
<td>I(2)</td>
</tr>
<tr>
<td>15</td>
<td>Detection of CAD in Other Clinical Scenarios</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Preoperative Coronary Assessment Prior to Noncoronary Cardiac Surgery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• High pretest probability of CAD*</td>
<td>I(3)</td>
</tr>
<tr>
<td></td>
<td>• Coronary evaluation before noncoronary cardiac surgery</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Arrhythmias—Etiology Unclear After Initial Evaluation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• New-onset atrial fibrillation (atrial fibrillation is underlying rhythm during imaging</td>
<td>I(2)</td>
</tr>
<tr>
<td>21</td>
<td>Use of CTA in the Setting of Prior Test Results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ECG Exercise Testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prior ECG exercise testing</td>
<td>I(2)</td>
</tr>
<tr>
<td></td>
<td>• Duke Treadmill Score***—low risk findings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>21</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prior ECG exercise testing</td>
<td>I(3)</td>
</tr>
<tr>
<td></td>
<td>• Duke Treadmill Score***—high risk findings</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Sequential Testing After Stress Imaging Procedures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Stress imaging results: moderate or severe ischemia</td>
<td>I(2)</td>
</tr>
<tr>
<td>ACCF et al. Criteria #</td>
<td>INDICATIONS</td>
<td>PROPRIETE USE SCORE (1-3); I=Inappropriate</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>✓ Refer to Additional Information section</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior CCS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Positive Coronary Calcium Score &gt;2 y ago</td>
<td>I(2)</td>
</tr>
<tr>
<td>Periodic Repeat Testing in Asymptomatic OR Stable Symptoms With Prior Stress Imaging or Coronary Angiography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>No known CAD</td>
<td>I(2)</td>
</tr>
<tr>
<td></td>
<td>Last study done &lt;2 y ago</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>No known CAD</td>
<td>I(3)</td>
</tr>
<tr>
<td></td>
<td>Last study done ≥2 y ago</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>Known CAD</td>
<td>I(2)</td>
</tr>
<tr>
<td></td>
<td>Last study done &lt;2 y ago</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>Known CAD</td>
<td>I(3)</td>
</tr>
<tr>
<td></td>
<td>Last study done ≥2 y ago</td>
<td></td>
</tr>
<tr>
<td>Risk Assessment Preoperative Evaluation of Noncardiac Surgery Without Active Cardiac Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low-Risk Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Preoperative evaluation for noncardiac surgery risk assessment, irrespective of functional capacity</td>
<td>I(1)</td>
</tr>
<tr>
<td>Intermediate-Risk Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>No clinical risk predictors</td>
<td>I(2)</td>
</tr>
<tr>
<td>32</td>
<td>Functional capacity ≥4 METs</td>
<td>I(2)</td>
</tr>
<tr>
<td>34</td>
<td>Asymptomatic &lt;1 y following a normal coronary angiogram, stress test, or a coronary revascularization procedure</td>
<td>I(1)</td>
</tr>
<tr>
<td>Vascular Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>No clinical risk predictors</td>
<td>I(2)</td>
</tr>
<tr>
<td>36</td>
<td>Functional capacity ≥4 METs</td>
<td>I(2)</td>
</tr>
<tr>
<td>38</td>
<td>Asymptomatic &lt;1 y following a normal coronary angiogram, stress test, or a coronary revascularization procedure</td>
<td>I(2)</td>
</tr>
<tr>
<td>Risk Assessment Post revascularization (PCI or CABG)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic (Ischemic Equivalent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>Prior coronary stent with stent diameter &lt;3 mm or not known</td>
<td>I(3)</td>
</tr>
<tr>
<td>Asymptomatic—CABG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACCF et al. Criteria #</td>
<td>INICATIONS (*Refer to Additional Information section)</td>
<td>APPROPRIATE USE SCORE (1-3); I=Inappropriate</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>42</td>
<td>Prior coronary bypass surgery &lt;5 y ago</td>
<td>I(2)</td>
</tr>
<tr>
<td><strong>Asymptomatic—Prior Coronary Stenting</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>44</td>
<td>Prior coronary stent with stent diameter &lt;3 mm or not known</td>
<td>I(2)</td>
</tr>
<tr>
<td>45</td>
<td>Prior coronary stent with stent diameter ≥3 mm</td>
<td>I(3)</td>
</tr>
<tr>
<td></td>
<td>Less than 2 y after PCI</td>
<td></td>
</tr>
<tr>
<td><strong>Evaluation of Cardiac Structure and Function</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Evaluation of Ventricular Morphology and Systolic Function</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>48</td>
<td>Initial evaluation of left ventricular function</td>
<td>I(2)</td>
</tr>
<tr>
<td></td>
<td>Following acute MI or in HF patients</td>
<td></td>
</tr>
<tr>
<td><strong>Evaluation of Intra- and Extracardiac Structures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>55</td>
<td>Initial evaluation of cardiac mass (suspected tumor or thrombus)</td>
<td>I(3)</td>
</tr>
</tbody>
</table>

**ADDITIONAL INFORMATION RELATED TO CORONARY CT ANGIOGRAPHY:**

**Abbreviations**
- ACS = acute coronary syndrome
- CABG = coronary artery bypass grafting surgery
- CAD = coronary artery disease
- CCS = coronary calcium score
- CHD = coronary heart disease
- CT = computed tomography
- CTA = computed tomography angiography
- ECG = electrocardiogram
- HF = heart failure
- MET = estimated metabolic equivalent of exercise
- MI = myocardial infarction
- MPI = Myocardial Perfusion Imaging
- PCI = percutaneous coronary intervention
- SE = Stress Echocardiogram
- TTE = Transthoracic Echocardiography

**What is a valid anginal or ischemic 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
Exercise Treadmill Testing - Exercise Treadmill Testing (ETT) is the appropriate first line test in most patients with suspected CAD. In appropriately selected patients the test provides adequate sensitivity and specificity with regard to diagnosis and prognostication. There are patients in whom the test is not the best choice, for example those with resting ECG abnormalities, inability to exercise and perhaps diabetes. Also of note from an operational standpoint the test does not require pre-authorization.

An uninterpretable baseline EKG includes:

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)
EKG 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\(\cdot\)25K)
Prior false positive stress EKG

*Pretest Probability of CAD for Symptomatic (Ischemic Equivalent) Patients:*

- **Typical Angina (Definite):** Defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.
- **Atypical Angina (Probable):** Chest pain or discomfort that lacks 1 of the characteristics of definite or typical angina.
- **Nonanginal Chest Pain:** Chest pain or discomfort that meets 1 or none of the typical angina characteristics.

Once the presence of symptoms (Typical Angina/Atypical Angina/Non angina chest pain/Asymptomatic) is determined, the pretest probabilities of CAD can be calculated from the risk algorithms as follows:

<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>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</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>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Low</td>
</tr>
<tr>
<td>&gt;60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
</tbody>
</table>

- **Very low:** Less than 5% pretest probability of CAD
- **Low:** Less than 10% pretest probability of CAD
- **Intermediate:** Between 10% and 90% pretest probability of CAD
- **High**: Greater than 90% pretest probability of coronary artery disease

**Definition of Peripheral Arterial Disease/Cerebrovascular Disease:**

Non-coronary arterial narrowing causing symptoms (claudication, related tissue demise, threatened limb loss), asymptomatic 70% or more narrowing by non-invasive or invasive evaluation, atherosclerotic arterial aneurysm by non-invasive or invasive evaluation, or aortic atheroma of at least 4 mm thickness. As a subset of peripheral arterial disease, cerebrovascular disease is also defined as a history of stroke or TIA.

**Global CAD Risk:**

It is assumed that clinicians will use current standard methods of global risk assessment in the asymptomatic patient for primary prevention, based upon Framingham-ATP IV, Reynolds, Pooled Cohort Equation (includes cerebrovascular risk), ACC/AHA Risk Calculator, MESA Risk Calculator (includes calcium score), or very similar risk calculator. CAD risk refers to 10-year risk for any hard cardiac event (e.g., myocardial infarction or CAD death).

- **Low global CAD risk**
  Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CAD risk <10%. However, in women and younger men, low risk may correlate with 10-year absolute CAD risk <6%.

- **Intermediate global CAD risk**
  Defined by the age-specific risk level that is average. In general, moderate risk will correlate with a 10-year absolute CAD risk range of 10% to 20%. Among women and younger age men, an expanded intermediate risk range of 6% to 20% may be appropriate.

- **High global CAD risk**
  Defined by the age-specific risk level that is above average. In general, high risk will correlate with a 10-year absolute CAD risk of >20%. CAD equivalents (e.g., peripheral arterial disease (defined in additional information), cerebrovascular disease (history of stroke or TIA), or multiple simultaneous anti-rejection medications (e.g. cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine, long term supraphysiologic doses of glucocorticoids, but not everolimus or sirolimus/rapamycin), peripheral arterial disease) can also define high risk. High global risk can be further defined by **COMPELLING NON-INVASIVE DATA, such as clearly pathologic Q waves on the EKG, marked ST-segment and/or T wave abnormalities of myocardial ischemia without symptoms, clear regional wall motion abnormalities of the left ventricle, or reduced ejection fraction below 50%**.

**Peri-Operative Cardiac Risk Factors**

These are specifically: ischemic coronary artery disease (by study more than two years ago with lesions, which are: >=70% or ischemia producing on prior stress testing or with FFR <=0.80), cerebrovascular disease, insulin-requiring diabetes mellitus, history of congestive heart failure or ejection fraction less than 40%, or CKD with creatinine >= 2 mg/dl.

**Duke Treadmill Score**

The equation for calculating the Duke treadmill score (DTS) is:

\[
\text{DTS} = \text{exercise time} \cdot (5 \cdot \text{ST deviation}) \cdot (4 \cdot \text{exercise angina}), \quad \text{with } 0 = \text{none}, \ 1 = \text{non limiting}, \ \text{and } 2 = \text{exercise-limiting.}
\]

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.
The Duke Score provides an annual mortality estimate: <1% for low risk, 1-3% for intermediate risk, and >3% for high risk.

**Determinants of a 4 MET functional capacity:**
Examples of activities:
- **<4 METs:** Slow ballroom dancing, golfing with a cart, playing a musical instrument, and walking at approximately 2 mph to 3 mph
- **>4 METs:** Climbing a flight of stairs or walking up a hill, walking on level ground at 4 mph, and performing heavy work around the house

**Tools for Characterization of Unstable Angina:**

Risk Stratification in Acute Coronary Syndrome from 2007 ACC/AHA Guidelines

Three Principal Presentations of Unstable Angina (as defined within a two week time frame) (Braunwald)

<table>
<thead>
<tr>
<th>Class</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest angina*</td>
<td>Angina occurring at rest and prolonged, usually greater than 20 min</td>
</tr>
<tr>
<td>New-onset angina</td>
<td>New-onset angina of at least CCS class III severity</td>
</tr>
<tr>
<td>Increasing angina</td>
<td>Previously diagnosed angina that has become distinctly more frequent, longer in duration, or lower in threshold (i.e., increased by 1 or more CCS class to at least CCS class III severity)</td>
</tr>
</tbody>
</table>

Table 6: Likelihood that Symptoms Represent an Acute Coronary Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>High Likelihood</th>
<th>Intermediate Likelihood</th>
<th>Low Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Any of the following</td>
<td>Chest or left arm pain or discomfort as chief symptom reproducing prior documented angina</td>
<td>Chest or left arm pain or discomfort as chief symptom</td>
</tr>
<tr>
<td>Renal</td>
<td>Known history of CAD, including MI</td>
<td>Age greater than 70 years</td>
<td>Male sex</td>
</tr>
<tr>
<td>Examination</td>
<td>Transient MR murmur, hypotension, diaphoresis, pulmonary edema, or rales</td>
<td>Excardiac vascular disease</td>
<td></td>
</tr>
<tr>
<td>EKG</td>
<td>New, or presumably new, transient ST-segment deviation (5 mm or greater) or T-wave inversion in multiple precordial leads</td>
<td>Fixed Q waves</td>
<td>ST depression 0.5 to 1 mm or T-wave inversion greater than 1 mm</td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>Elevated cardiac TnT, TnT, or CK-MB</td>
<td>Normal</td>
<td>Normal</td>
</tr>
</tbody>
</table>


ACS = acute coronary syndrome; CAD = coronary artery disease; CK-MB = MB fraction of creatinine kinase; ECG = electrocardiogram; MI = myocardial infarction; MR = minor regurgitation; TnT = troponin T; TnT = troponin T.
### Table 7: Short Term Risk of Death or Nonfatal MI in Acute Coronary Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>High Risk</th>
<th>Intermediate Risk</th>
<th>Low Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History</strong></td>
<td>Accelerating tempo of ischemic symptoms in preceding 48 h</td>
<td>Prior MI, peripheral or cerebrovascular disease, or CAD; prior aspirin use</td>
<td>Increased angina frequency, severity, or duration</td>
</tr>
<tr>
<td><strong>Character of pain</strong></td>
<td>Prolonged ongoing (greater than 20 min) rest pain</td>
<td>Prolonged (greater than 20 min) rest angina, now resolved, with moderate or high likelihood of CAD</td>
<td>Angina provoked at a lower threshold</td>
</tr>
<tr>
<td><strong>Clinical findings</strong></td>
<td>Pulmonary edema, most likely due to ischemia</td>
<td>Age greater than 70 years</td>
<td>New onset angina with onset 2 weeks to 2 months prior to presentation</td>
</tr>
<tr>
<td><strong>ECG</strong></td>
<td>Angiographic ST-segment deviation greater than 0.5 mm</td>
<td>ST-segment deviation less than 1 mm in multiple lead groups (anterior, inferior, lateral)</td>
<td>Normal or unchanged ECG</td>
</tr>
<tr>
<td><strong>Cardiac markers</strong></td>
<td>Elevated cardiac TnT, Tnl, or CK-MB (e.g., TnT or Tnl greater than 0.1 ng per ml)</td>
<td>Slightly elevated cardiac TnT, Tnl, or CK-MB (e.g., TnT greater than 0.01 but less than 0.1 ng per ml)</td>
<td>Normal</td>
</tr>
</tbody>
</table>

The **TIMI Risk Score** is determined by the sum of the presence of seven (7) variables at admission: 1 point is given for each of the following variables:

1. age ≥65 years,
2. at least 3 risk factors for CAD,
3. prior coronary stenosis of ≥50%,
4. ST-segment deviation on ECG presentation,
5. at least 2 anginal events in prior 24 hours,
6. use of aspirin in prior 7 days, and
7. elevated serum cardiac biomarkers

**Low-Risk TIMI Score**: TIMI score <2; **High-Risk TIMI Score**: TIMI score ≥2. A low risk TIMI score might still warrant invasive coronary arteriography, when other features, such as symptoms, are compelling.

**Risk Calculators - Links to Cardiac/Vascular Risk Online Calculators**:

- **Pooled Cohort Equation (includes cardiac and cerebrovascular risk)**: [http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example](http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example)
ACC/AHA Risk Calculator (includes cardiac and cerebrovascular risk):
http://tools.acc.org/ASCVD-Risk-Estimator/

MESA Risk Calculator with addition of Coronary Artery Calcium Score:
https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

REFERENCES


****CCTA in the ER****


**Calcium Scoring**


**Reference for Kawasaki Disease**

CPT Codes: 75635

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:
- For known or suspected peripheral arterial disease.
- 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.

REFERENCES:


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:

- For the evaluation of a recurrent or residual brain tumor from post-treatment changes e.g., radiation necrosis.

ADDITIONAL INFORMATION RELATED TO BRAIN MRS:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial Magellan Healthcared aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

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.
REFERENCES:


76497 - Unlisted CT

IMPORTANT NOTE:

The CPT code that has been selected is considered to be an “unlisted code”.

For all other studies, another CPT code should be selected that describes the specific service being requested otherwise this procedure can not 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 can not be approved.
CPT Codes:
Unilateral  77058
Bilateral      77059

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. 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 results, 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:
- 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).
- A Breast Cancer Risk Assessment (by the 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).
- 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.) Approve annually starting at age 30.
- Patients with known BRCA mutation. Approve annually starting at age 30.
- Patients not yet tested for BRCA gene, but with known BRCA mutation in first degree relative. Approve annually starting at age 30.

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).
- Previous positive breast biopsy within the previous four (4) months and no intervening previous breast MRI.
• Inconclusive screening mammogram due to breast characteristics limiting the sensitivity of mammography (e.g., extremely or heterogeneously dense breasts, implants).
• Evaluation of palpable lesion on physical examination and not visualized on ultrasound or mammogram and MRI guided biopsy considered.
• For evaluation of axillary node metastasis or adenocarcinoma with normal physical examination and normal breast mammogram.
• Patients diagnosed with biopsy-proven lobular neoplasia or ADH (atypical ductal hyperplasia).
• Personal history of or first-degree relative with Le-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.

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 diagnosed breast cancer.
• 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.
• Evaluation of more than two (2) lesions to optimize surgical planning when requested by surgeon or primary care provider on behalf of surgeon who has seen the patient.

ADDITIONAL INFORMATION RELATED TO BREAST MRI:

CAD Breast MRI: There are no proven indications for use of CAD with/without an approved Breast MRI.

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

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 material-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 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. MRI is used in the evaluation of ILC and can measure the extent of the disease with high reliability.

**REFERENCES**


Breast MRI for the Early Detection of Breast Cancer. Approved by the Cancer.Net Editorial Board. 03/2014


Saslow et al American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography CA Cancer J Clin 2007;57:75–89


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:
- 65 years of age or older.
- 40 years of age or older AND at least ONE of the following risk factors:
  - Currently on medications associated with development of osteoporosis, e.g., steroids or glucocorticosteroids, anticonvulsants, heparin, lithium.
  - Currently a cigarette smoker and has a low body weight (<127 lbs.).
  - Caucasian with estrogen deficiency and low calcium intake or alcoholism.
  - Caucasian with adult history of fracture.
  - Evidence of osteoporosis or osteopenia from x-ray or ultrasound.
  - Patient’s parents or siblings have adult history of fracture.
- Steroid therapy equivalent to 7.5 mg of Prednisone or greater per day for more than three (3) months.
- Initiation of selective estrogen receptor modulators (SERMs), calcitonin, or biphosphonates, e.g., Actonel, Etidronate, Calcimar, Didronel, Evista, Fosamax, Miacalcin within last six (6) months.
- Back pain associated with loss of vertebral body height per x-ray.
- Loss of body height.
- Multiple fractures including compression fractures of the spine.
- Malabsorption syndrome.
- Metabolic bone disease.
- Hyperparathyroidism.
- Hypogonadism.
- Thyroid hormone therapy or hyperthyroidism.
- Chemotherapy.
- Long term Heparin therapy.
- Spinal deformities.
- Renal osteodystrophy.

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 following risk factor criteria:
  o Hormone replacement therapy
  o SERMs, calcitonin, or biphosphonates within the past 6 months (Actonel, Etidronate, Calcimar, Calcitonin, Didronel, Evista, Fosamax, Micacin)
  o Steroid therapy equivalent to 7.5 mg of Prednisone or greater per day for more than 3 months.
  o Back pain associated with loss of vertebral body height per x-ray.
  o Loss of body height.
  o Multiple fractures including compression fractures of the spine.
  o Malabsorption syndrome.
  o Metabolic bone disease. Metabolic bone disease, i.e. osteomalacia and vitamin D deficiency.
  o Hyperparathyroidism.
  o Hypogonadism
  o Thyroid hormone therapy or hyperthyroidism.
  o Chemotherapy
  o Long term Heparin therapy
  o Spinal deformities
  o Renal osteodystrophy

• In the following situations, follow-up imaging may be required in less than 23 months:
  o Glucocorticoid or anticonvulsant therapy greater than 3 months duration
  o Uncorrected hyperparathyroidism

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.

REFERENCES


CPT Codes: 78205, 78206

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 is insufficient alone:

- Evaluation of hepatic artery catheter placement.
- Detection of accessory splenic tissue or asplenia.
- Evaluation of suspected hepatic hemangioma or focal nodular hyperplasia.
- 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).

ADDITIONAL INFORMATION RELATED TO A LIVER SPECT SCAN:

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.
**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 scan**: (hepatobiliary iminodiacetic acid) an imaging procedure utilizing the IV administration of Tc99M labeled iminodiacetic acid which is excreted by hepatocytes like bile. Unlike Liver and spleen imaging 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 to evaluate cystic duct obstruction (cholecystitis), common bile duct obstruction, congenital biliary system anomalies and bile leaks.

**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 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.

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:

- 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.

- 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.

- Assess the distribution of osteoblastic activity before radionuclide therapy for bone pain.

ADDITIONAL INFORMATION RELATED TO BONE/JOINT SPECT SCAN:

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.
**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.

**REFERENCES**


Society of Nuclear Medicine Procedure Standards.  
http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=6414
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.

ADDITIONAL INFORMATION RELATED TO BONE MARROW MRI:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O2 tanks may also be contraindicated.

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 and it should be used as the first-line imaging method for detecting skeletal involvement in patients with multiple myeloma. Sensitive detection is mandatory in order to estimate prognosis and to determine adequate therapy.

REFERENCES:


CPT Code: 78451, 78452, 78453, 78454, 78466, 78468, 78469, 78481, 78483, 78499

INTRODUCTION: This guideline is organized around seven clinical scenarios:

I. Suspected Coronary Artery Disease (CAD)
II. Incompletely Evaluated CAD
III. Follow-up of Known Ischemic CAD
IV. CAD in Presence of Other New Cardiac Concerns
V. Prior to Noncardiac Surgery
VI. Prior to Cardiac Rehabilitation or Exercise Program
VII. Post Cardiac Transplantation

This guideline is for stress imaging, specifically myocardial perfusion imaging (MPI), with appropriate preference for suitable alternatives, such as stress echocardiography (stress echo) or stress EKG alone, when more suitable, using the following stream of logic:

- A stress EKG alone is often appropriate. A baseline EKG which does not allow interpretation of ischemic findings with exercise will sometimes, but not always, require the addition of stress imaging.
- When stress imaging is appropriate, as an addition to stress EKG alone, stress echo is preferred when the patient is able to exercise, MPI when the patient cannot exercise. This document does not endorse dobutamine echocardiography for pragmatic reasons.
- When stress echo is precluded by specific imaging difficulties (e.g. poor quality image despite contrast medium, uncontrolled atrial fibrillation, ventricular paced rhythm, baseline wall motion abnormalities, etc., as listed in the Additional Information section), then MPI is preferable.

Compelling indications (e.g. ACC Class I or IIA or Appropriate Use Criteria ‘A’) for stress imaging (MPI and echo) are the foundation, and the less compelling indications (IIB or ‘M’) have been selected as appropriate for those scenarios in which the clinical presentation incurs high risk. If a patient fits two or more clinical scenarios, the scenario which endorses stress imaging (MPI or echo) supersedes any category which does not.

Issues such as pretest probability, global risk of coronary or cardiovascular disease, anginal equivalent, aspects of different types of stress testing, etc. are discussed in the Additional Information section at the end of this document, and the reader is encouraged to refer to that section, in order to optimally utilize this guideline.

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 STRESS IMAGING (MPI or ECHO) BY CLINICAL SCENARIO

I. SUSPECTED (CAD):
   High Global Risk asymptomatic OR
   Stable symptomatic OR
   Low risk “unstable” symptomatic (Tables 6 & 7)

- SYMPTOMATIC: LOW PRETEST PROBABILITY patients should undergo a treadmill exercise stress EKG alone, with stress imaging (MPI or echo) reserved only for those unable to exercise OR with an uninterpretable EKG.

- SYMPTOMATIC: INTERMEDIATE OR HIGH PRETEST PROBABILITY patients are appropriate for stress imaging (MPI or echo).

- REPEAT STRESS TESTING FOR SIMILAR SYMPTOMS AND SAME PRETEST PROBABILITY should not be performed for at least 5 years following prior stress testing or invasive coronary arteriography, unless there has been a change in clinical presentation.

- ASYMPTOMATIC HIGH GLOBAL RISK (>20% coronary or vascular event rate over ensuing 10 years) based upon a COMPELLING HISTORY, such as patients with peripheral arterial disease (defined in additional information), cerebrovascular disease (history of stroke or TIA), or multiple simultaneous anti-rejection medications (e.g. cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine, long term supraphysiologic doses of glucocorticoids, but not everolimus or sirolimus/rapamycin), should be assessed with EKG STRESS TEST alone, with stress imaging (MPI or echo) reserved only for those unable to exercise OR with an uninterpretable EKG.

- ASYMPTOMATIC HIGH GLOBAL RISK (>20% coronary or vascular event rate over ensuing 10 years, based upon Framingham-ATP IV, Reynolds, Pooled Cohort Equation (includes cerebrovascular risk), ACC/AHA Risk Calculator, MESA Risk Calculator (includes calcium score), or very similar risk calculator) or based upon COMPELLING NON-INVASIVE DATA, such as clearly pathologic Q waves on the EKG, marked ST-segment and/or T wave abnormalities of myocardial ischemia without symptoms, clear regional wall motion abnormalities of the left ventricle, or reduced ejection fraction below 50%, should be assessed with EKG STRESS TEST alone, with stress imaging (MPI or echo) reserved only for those unable to exercise OR with an uninterpretable EKG. (Patients with ejection fraction < 50%, with contraindication to invasive coronary arteriography, are reasonable candidates for stress imaging (MPI or echo).

- REPEAT EKG STRESS TEST ALONE OF ASYMPTOMATIC HIGH GLOBAL RISK patients (as described in the 2 bullets immediately above), whose last invasive or non-invasive test was over two years ago and was negative for hemodynamically significant obstructive coronary artery disease (i.e. no ischemia on stress testing, no Fractional Flow Reserve (FFR) <= 0.80 for a major vessel, or no angiographic stenosis >70% for a major vessel), is reasonable.

- HIGH OCCUPATIONAL RISK patients (e.g. associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters) or HIGH PERSONAL RISK patients (e.g. scuba divers, etc.), should be assessed with EKG STRESS TEST alone, with stress imaging (MPI or echo) reserved only for those unable to exercise OR with an uninterpretable EKG. Determinations for screening of asymptomatic patients (without known...
coronary artery disease) in high-risk occupations should be deferred to those agencies that manage such non-medical necessity.

II. **INCOMPLETELY EVALUATED CAD:**
   Requires further evaluation within 2 years of a prior coronary evaluation for **CLARIFICATION OF DIAGNOSIS OR DISEASE SEVERITY**

- **NORMAL EXERCISE STRESS TEST EKG within the past 2 years and currently compelling coronary history or symptoms** should be considered appropriate indication for a repeat stress test with imaging (MPI or echocardiogram), particularly if there are reasons to avoid cardiac catheterization (CKD, dye allergy, etc.), unless invasive coronary arteriography is strongly indicated (e.g. compelling presentation of moderate or high risk unstable angina).

- **ABNORMAL OR INDETERMINATE EXERCISE STRESS EKG or CCTA (coronary computed tomographic angiography) within the past 2 years,** for whom a noninvasive approach is preferable to proceeding to invasive coronary arteriography (unclear nature of symptoms, mildly abnormal or borderline EKG stress test or CCTA, CKD, dye allergy, etc.), **is an appropriate indication for stress imaging (MPI or echo).**

- **A WELL DOCUMENTED MYOCARDIAL INFARCTION OR moderate to high risk ACUTE CORONARY SYNDROME WITHIN THE PAST 2 YEARS,** when stable, without subsequent stress imaging of invasive coronary arteriography, can be appropriate for stress imaging, especially when a non-invasive approach is documented to be preferable to invasive coronary arteriography.

- **SEVERITY/EXTENT OF ISCHEMIA ASSESSMENT,** in order to assist with the management strategy, in patients with prior invasive coronary arteriography **within the past 2 years** and unclear lesional significance, **is an appropriate indication for stress imaging (MPI or echo), if it will affect management.**

III. **FOLLOW-UP of KNOWN ISCHEMIC CAD:**

A. **In need of FOLLOW-UP TESTING for known ischemic coronary artery disease,** either **ASYMPTOMATIC OR WITH STABLE symptoms**

**ROUTINE FOLLOW-UP** when last invasive or non-invasive assessment of coronary artery disease showed **HEMODYNAMICALLY SIGNIFICANT CAD** (ischemia on stress test or FFR <= 0.80 for a major vessel or stenosis >=70% of a major vessel) **over two years ago,** without supervening coronary revascularization, **is an appropriate indication for stress imaging (MPI or echo) in patients with high risk clinical scenarios,** such as left ventricular dysfunction (ejection fraction less than 50%) or severe unrevascularized multivessel CAD (if it will alter management), **OR in patients with HIGH RISK OCCUPATIONS** (e.g. associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters) **OR a HIGH PERSONAL RISK** (e.g. scuba divers, etc.).

- **SEVERITY/EXTENT OF ISCHEMIA ASSESSMENT,** in order to assist with the management strategy, in patients with recent invasive coronary arteriography AND suspected residual ischemia post incomplete coronary revascularization, **is an appropriate indication for stress imaging (MPI or echo), if it will affect management.**
• **MYOCARDIAL VIABILITY TESTING BY REST MYOCARDIAL PERFUSION IMAGING** prior to coronary revascularization is reasonable in patients with ejection fraction less than or equal to 50%, if it could significantly alter the revascularization strategy.

B. **NEW, RECURRENT, OR WORSENING (PROGRESSIVE) SYMPTOMS** in patients with known ischemic CAD (ischemia on stress testing, lesion stenosis >=70%, or FFR <=0.80), which has not been revascularized.

• **PRIOR LOW RISK CORONARY EVALUATION AT LEAST TWO YEARS EARLIER** (e.g. limited extent of CORONARY ARTERY DISEASE, <5% myocardium at risk), AND NOW WITH NEW STABLE (or low risk unstable), RECURRENT, OR SLOWLY WORSENING (PROGRESSIVE) SYMPTOMS of coronary ischemia, is an appropriate indication for stress imaging (MPI or echo) in this patient group. However, regardless of timing of prior non-invasive assessment, clinical documentation of continued problematic symptoms or moderate to highly likely acute coronary syndrome (Table 6) of even low mortality risk (Table7) is often better assessed with invasive coronary arteriography, particularly when stress testing in the last 2 years and current clinical findings are at odds. This category is very documentation-sensitive and requires judgment.

• **INVASIVE CORONARY ARTERIOGRAPHY IS GENERALLY PREFERABLE** in those patients, who have a PRIOR MODERATE OR HIGH RISK STRESS TEST RESULT (especially if NOT previously evaluated by invasive coronary arteriography) or a current diagnosis of moderate to high risk UNSTABLE ANGINA, and inappropriate for repeat stress imaging (MPI or echo), unless supervening reasons to prefer a non-invasive approach are documented in the record (e.g. very unclear symptoms, CKD, dye allergy, etc.), and it could alter management.

C. **FOLLOW-UP OF PATIENTS POST CORONARY REVASCULARIZATION**

• **ASYMPTOMATIC, ROUTINE FOLLOW-UP, STRESS IMAGING (MPI OR ECHO)** at a minimum of 2 YEARS post coronary artery bypass grafting or 2 YEARS post percutaneous coronary intervention (whichever was the latter) is appropriate only for patients with high direct CORONARY-related risk, such as incomplete coronary revascularization with feasible additional revascularization of residual severe multivessel disease, need for otherwise unevaluated follow up of stenting of unprotected left main coronary artery (LM) disease or left ventricular dysfunction (ejection fraction less than 50%), OR for patients with HIGH OCCUPATIONAL RISK (e.g. associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters) or HIGH PERSONAL RISK (e.g. scuba divers, etc.),

• **NEW, RECURRENT, OR WORSENING SYMPTOMS POST CORONARY REVASCULARIZATION**, with good documentation, are an indication for stress imaging (MPI or echo) if it could affect management.

IV. **CAD IN PRESENCE OF OTHER NEW CARDIAC CONCERNS**

• **NON-CORONARY CARDIAC DIAGNOSES** support use of stress imaging (MPI or echo) in newly diagnosed systolic or diastolic heart failure, sustained VT (> 100 bpm), VF, exercise induced VT or nonsustained VT, frequent PVCs (over 30 per hour), and/or required initiation of antiarrhythmic drug (AAD) therapy when invasive coronary arteriography is not necessarily indicated.
• NEW ONSET ATRIAL FIBRILLATION, in patients with coronary artery disease and/or moderate or high global risk, are candidates for stress imaging if there has been no coronary evaluation by stress imaging or invasive coronary arteriography within the preceding two years.

• SYNCOPE (specifically, transient loss of consciousness due to global cerebral hypoperfusion characterized by rapid onset, short duration and spontaneous complete recovery, not just any light headedness or dizziness alone) with otherwise intermediate or high global risk of coronary artery disease warrants stress imaging (MPI or echo). Documentation supporting classic vasovagal syncope does not warrant stress testing.

• LEFT BUNDLE BRANCH BLOCK, when the history, physical examination, and/or noninvasive ejection fraction together support further evaluation, and invasive coronary arteriography is not already indicated, is an indication for stress imaging (MPI or echo).

• EKG STRESS TESTING without imaging is reasonable for EVALUATION OF EXERCISE-INDUCED ARRHYTHMIA (or long QT interval evaluation when the resting QTc is normal), when coronary artery disease is not suspected.

• EXERCISE HEMODYNAMICS can be obtained with Stress echocardiography with Doppler when it will affect management.

• KAWASAKI DISEASE long-term surveillance is better performed with CCTA, which includes aneurysm assessment.

V. Prior to NONCARDIAC SURGERY

• THORACOABDOMINAL AORTIC VASCULAR SURGERY is an indication for PREOPERATIVE STRESS IMAGING (MPI or echo) if the patient has less than a 4 MET (see Additional Information section) exercise functionality, AND that patient has at least one OPERATIVE clinical risk factor from the list: ischemic coronary artery disease (by study more than two years ago with lesions, which are: >=70% or ischemia producing on prior stress testing or with FFR <=0.80), cerebrovascular disease, insulin-requiring diabetes mellitus, history of congestive heart failure or ejection fraction less than 40%, or CKD with creatinine >= 2 mg/dl. (Such stress imaging is restricted to patients who have not had either stress imaging or invasive coronary arteriography within the past year.) If invasive coronary arteriography is preferable, then preoperative stress imaging is not appropriate.

• UNRELATED TO THE PLANNED SURGICAL PROCEDURE, stress imaging might be indicated for other reasons at the time patients are seen for preoperative cardiac risk evaluation. When such indications for stress imaging are unrelated to the need for the intended non-cardiac surgery, then the record must document those reasons in order to support proceeding with appropriate stress imaging (MPI or echo).

• BARIATRIC SURGERY is not considered an indication for preoperative stress testing.

• SOLID ORGAN TRANSPLANTATION is an indication for preoperative stress imaging (MPI or echo) if invasive coronary arteriography is not intended as the initial preoperative evaluation of choice, AND there has not been an adequate coronary evaluation within the past year.
VI. Prior to CARDIAC REHABILITATION or EXERCISE PROGRAM

- CARDIAC REHABILITATION ENTRY or DETERMINATION OF EXERCISE CAPACITY is an indication for stress testing with EKG alone, when performed as part of the cardiac rehabilitation program or for purposes of exercise prescription.

VII. Post CARDIAC TRANSPLANTATION

- During the first five years post cardiac transplantation, patients with glomerular filtration rates less than 40 mL/min/1.73 sq M, or who otherwise should not undergo invasive coronary arteriography every 1-2 years, are appropriate for stress imaging (MPI or echo) every 1-2 years.

- After the first five years post cardiac transplantation, in lieu of invasive coronary arteriography:
  1. patients considered at low risk for transplant vasculopathy (i.e., with normal invasive coronary arteriography) can have annual stress imaging (MPI or echo), and
  2. patients with transplant coronary vasculopathy can have annual stress imaging (MPI or echo), if the risk of annual invasive coronary arteriography is not acceptable (i.e., high risk of contrast nephropathy).

ADDITIONAL INFORMATION:

Definitions of Coronary Artery Disease:

1. Percentage stenosis refers to 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 (similar to an ankle brachia index, family history of coronary artery disease, or high sensitivity C-reactive protein). Its incorporation into Global Risk can be achieved by using the MESA risk calculator.

3. Stenoses less than 50% are considered nonobstructive coronary artery disease, while stenoses of 50% or more are considered obstructive coronary artery disease. However, the contents of this Guideline are very clear about specifying that ischemic heart disease requires one of three possible determinants:
   i. Percentage stenosis of at least 70% - by angiography or IVUS (intravascular ultrasound), as described above, for a major vessel
   ii. FFR (fractional flow reserve) of 0.80 or less for a major vessel
   iii. Demonstrable ischemic findings on stress testing (acceptable EKG or imaging), that are at least mild in degree

4. 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.” (i.e. A 50% lesion in a tiny septal would be limited obstructive coronary artery disease.)

5. 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.

6. 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 reduction in coronary flow.

Definition of Peripheral Arterial Disease/Cerebrovascular Disease:
Non-coronary arterial narrowing causing symptoms (claudication, related tissue demise, threatened limb loss), asymptomatic 70% or more narrowing by non-invasive or invasive evaluation, atherosclerotic arterial aneurysm by non-invasive or invasive evaluation, or aortic atheroma of at least 4 mm thickness. As a subset of peripheral arterial disease, cerebrovascular disease is also defined as a history of stroke or TIA.

**What is a valid 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 by itself is generally not considered an anginal equivalent, and is handled under a separate category in this guideline.

**Pretest Probability of CAD for Symptomatic Patients:**

Pretest probability is a reference to symptoms that need evaluation as potentially coronary in origin.

- **Typical Angina (Definite):** Defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.
- **Atypical Angina (Probable):** Chest pain or discomfort that lacks 1 of the characteristics of definite or typical angina.
- **Nonanginal Chest Pain:** Chest pain or discomfort that meets 1 or none of the typical angina characteristics.

Once the presence of symptoms (Typical Angina/Atypical Angina/Non angina chest pain/Asymptomatic) is determined, the probabilities of CAD can be calculated from the risk algorithms as follows:

<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>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</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>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>&gt;60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
</tbody>
</table>

- **Very low:** Less than 5% pretest probability of CAD
- **Low:** Less than 10% pretest probability of CAD
- **Intermediate:** Between 10% and 90% pretest probability of CAD
- **High:** Greater than 90% pretest probability of CAD

**Global Risk of CAD or Vascular Disease**

**Global risk** of CAD is defined as the probability of developing CAD, including myocardial infarction or CAD death over a given time period and refers to asymptomatic patients without known coronary artery
disease. It should be determined by the Framingham Risk Score (ATP IV risk tool), the Reynolds Risk Index, or the Pooled Cohort Equation (which includes cerebrovascular risk). A high risk is considered greater than a 20% risk of a coronary or major vascular event over the ensuing 10 years.

- **CAD Risk—Low**
  Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CAD risk less than 10%.

- **CAD Risk—Moderate**
  Defined by the age-specific risk level that is average or above average. In general, moderate risk will correlate with a 10-year absolute CAD risk between 10% and 20%.

- **CAD Risk—High**
  Defined as the presence of peripheral arterial disease, cerebrovascular disease, or a 10-year absolute CAD risk of greater than 20%.

**Duke Treadmill Score**

The equation for calculating the Duke treadmill score (DTS) is,

\[
DTS = \text{exercise time in minutes} - (5 \times ST \text{ deviation in mm or } 0.1 \text{ mV increments}) - (4 \times \text{exercise angina score}),
\]

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.

**What Type of Stress Test is Appropriate?**

**EKG Stress Test versus Stress Echocardiography versus Stress Myocardial Perfusion Imaging**

Appropriate resource utilization, cost effectiveness, and radiation exposure limitation dictate choices in stress testing options.

Five prominent scenarios for an EKG stress test WITHOUT imaging (i.e. exercise treadmill EKG test) are endorsed by 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 EKG for ischemia during exercise:

- The (symptomatic) low pretest probability patient who is able to exercise and has an interpretable EKG
- The (asymptomatic) high global risk patient who is able to exercise and has an interpretable EKG
- 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
- The patient who requires an entrance stress test EKG for a cardiac rehab program or for an exercise prescription

An uninterpretable baseline EKG includes:

- 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)
- EKG 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)
Prior false positive stress EKG

Exercise remains a valid stressor:

- In patients who can exercise to near maximal heart rate
- For entrance to cardiac rehabilitation or determination of an exercise prescription
- For exercise induced arrhythmia evaluation
- Even with an uninterpretable EKG if stress imaging is appropriate and EKG un-interpretablity is acknowledged

Scenarios for choosing stress echocardiography over myocardial perfusion imaging:

The patient can exercise to near maximal heart rate for at least 3 minutes of Bruce protocol and has an interpretable echocardiogram, with usage of contrast medium if necessary to enable quality imaging

AND

There is normal baseline systolic function, without moderately severe or severe valvular disease. Stress echocardiography with Doppler is appropriate in the patient for whom determination of exercise hemodynamics is required.

Exercise Doppler with hemodynamics is the main reason for stress testing.

When is Myocardial Perfusion Imaging Preferred Over Stress Echocardiography?

There are circumstances in which myocardial perfusion imaging is generally preferable to stress echocardiography:

- BMI >= 40
- Ventricular paced rhythm, LBBB, WPW
- Frequent PVCs interfering with wall motion assessment
- Prior coronary artery bypass grafting with resultant paradoxical septal motion
- Currently in poorly controlled atrial fibrillation
- Poor cardiac window on echo (documented on echo report as technically limited or difficult, without likely benefit of contrast medium)
- Documented regional wall motion abnormality: dyskinesia, akinesia, or hypokinesia
- Unable to perform ADL’s with documented extent of limitations
- Functional capacity <4 METS or < 3’ Bruce protocol
- Arthritis with documented limitations
- Leg/foot amputation
- Active foot wound/ulcer
- Ambulation requires cane or walker
- Confinement to a wheelchair
- Severe chronic obstructive pulmonary disease (based upon PFT findings), severe dyspnea on exertion, or requirement for home oxygen use
- Systolic congestive heart failure with ejection fraction <40%
- Recent orthopedic surgery limiting use of a lower extremity
Determinants of a 4 MET functional capacity:
Examples of activities:

<4 METs: Slow ballroom dancing, golfing with a cart, playing a musical instrument, and walking at approximately 2 mph to 3 mph

>4 METs: Climbing a flight of stairs or walking up a hill, walking on level ground at 4 mph, and performing heavy work around the house

Tools for Characterization of Unstable Angina:

Risk Stratification in Acute Coronary Syndrome from 2007 ACC/AHA Guidelines

Three Principal Presentations of Unstable Angina (as defined within a two week time frame) (Braunwald)

<table>
<thead>
<tr>
<th>Class</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest angina</td>
<td>Angina occurring at rest and prolonged, usually greater than 20 min</td>
</tr>
<tr>
<td>New-onset angina</td>
<td>New-onset angina of at least CCS class III severity</td>
</tr>
<tr>
<td>Increasing angina</td>
<td>Previously diagnosed angina that has become distinctly more frequent, longer in duration, or lower in threshold (i.e., increased by 1 or more CCS class to at least CCS class III severity)</td>
</tr>
</tbody>
</table>
Table 6: Likelihood that Symptoms Represent an Acute Coronary Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>Any of the following:</th>
<th>Absence of high-likelihood features and presence of any of the following:</th>
<th>Absence of high- or intermediate-likelihood features but may have:</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Chest or left arm pain or discomfort as chief</td>
<td>Chest or left arm pain or discomfort as chief symptom</td>
<td>Probable ischemic symptoms in absence of any of the intermediate likelihood characteristics</td>
</tr>
<tr>
<td></td>
<td>symptom reproducing prior documented</td>
<td>Age greater than 70 years</td>
<td>Recent cocaine use</td>
</tr>
<tr>
<td></td>
<td>angina</td>
<td>Male sex</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known history of CAD, including MI</td>
<td>Diabetes mellitus</td>
<td></td>
</tr>
<tr>
<td>Examination</td>
<td>Transient MR murmur; hypotension, diaphoresis,</td>
<td>Extradural vascular disease</td>
<td>Chest discomfort reproduced by palpation</td>
</tr>
<tr>
<td></td>
<td>pulmonary edema, or rales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG</td>
<td>New, or presumably new, transient ST-segment</td>
<td>Fixed Q waves</td>
<td>T-wave flattening or inversion less than 1 mm in leads with dominant R waves</td>
</tr>
<tr>
<td></td>
<td>deviation (1 mm or greater) or T-wave</td>
<td>ST depression 0.5 to 1 mm or T-wave inversion greater than 1 mm</td>
<td>Normal ECG</td>
</tr>
<tr>
<td></td>
<td>Inversion in multiple precordial leads</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>Elevated cardiac TnI, TnI, or CK-MB</td>
<td>Normal</td>
<td></td>
</tr>
</tbody>
</table>


ACS = acute coronary syndrome; CAD = coronary artery disease; CK-MB = MB fraction of creatine kinase; ECG = electrocardiogram; MI = myocardial infarction; MI = minor reperfusion; TnI = troponin I; TnI = troponin T; UA/NSTEMI = unstable angina/non-ST-elevation myocardial infarction.

Table 7: Short Term Risk of Death or Nonfatal MI in Acute Coronary Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>At least 1 of the following features must be present:</th>
<th>No high-risk feature, but must have 1 of the following:</th>
<th>No high- or intermediate-risk features but may have any of the following features:</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Accelerating tempo of ischemic symptoms</td>
<td>Prior MI, peripheral or cerebrovascular disease, or MI, prior explain use</td>
<td>Increased angina frequency, severity, or duration</td>
</tr>
<tr>
<td></td>
<td>in preceding 48 h</td>
<td>Prolonged (&gt;20 min) rest angina, now resolved, with moderate or high Likelihood of CAD</td>
<td>Angina provoked at a lower threshold</td>
</tr>
<tr>
<td>Character of pain</td>
<td>Prolonged angina (≥20 min) rest pain</td>
<td>Rest angina (≥20 min) or relieved with rest or statin therapy T/M (60)</td>
<td>New onset angina within 2 weeks to 2 months prior to presentation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nocturnal angina</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>New-onset or progressive CCS class III or IV angina in the past 2 weeks without</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>prolonged (&gt;20 min) rest pain but with intermediate or high likelihood of CAD (see Table 6)</td>
<td></td>
</tr>
<tr>
<td>Clinical findings</td>
<td>Pulmonary edema, most likely due to ischemia</td>
<td>Age greater than 70 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New or worsening MR murmur</td>
<td>T-wave changes</td>
<td>Normal or unchanged ECG</td>
</tr>
<tr>
<td></td>
<td>S. p. or new/worsening signs</td>
<td>Pathological Q waves or resting ST-depression less than 1 mm in multiple lead groups</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hypotension, headache, tachycardia</td>
<td>(anterior, inferior, lateral)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age greater than 75 years</td>
<td>Sustained ventricular tachycardia</td>
<td></td>
</tr>
<tr>
<td>ECG</td>
<td>Angina at rest with transient ST-segment changes</td>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(&lt;0.5 mm)</td>
<td>Pathological Q waves or resting ST-depression less than 1 mm in multiple lead groups</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bundle-branch block, new or presumed new</td>
<td>(anterior, inferior, lateral)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age greater than 75 years</td>
<td>Sustained ventricular tachycardia</td>
<td></td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>Elevated cardiac TnI, TnI, or CK-MB (e.g., TnI, TnI, or CK-MB)</td>
<td>Slightly elevated cardiac TnI, TnI, or CK-MB (e.g., TnI or TnI greater than 0.5 ng/ml)</td>
<td>Normal</td>
</tr>
</tbody>
</table>

*Estimation of the short-term risk of death and nonfatal cardiac ischemic events in UA (or NSTEMI) is a complex multivariable problem that cannot be fully specified in a table such as this. Therefore, this table is meant to offer general guidance and illustration rather than rigid algorithms. Adapted from AHCPR Clinical Practice Guidelines No. 10, Unstable Angina: Diagnosis and Management. May 1994 (124).*

CADS = coronary artery bypass graft surgery; CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; CK-MB = creatine kinase MB fraction; ECG = electrocardiogram; MI = myocardial infarction; MI = minor reperfusion; NTG = nitroglycerin tablet; TnI = troponin I; TnI = troponin T; UA/NSTEMI = unstable angina/non-ST-elevation myocardial infarction.

The **TIMI Risk Score** is determined by the sum of the presence of 7 variables at admission: 1 point is given for each of the following variables: age ≥65 years, at least 3 risk factors for CAD, prior coronary stenosis of ≥50%, ST-segment deviation on ECG presentation, at least 2 anginal events in prior 24 hours, use of aspirin in prior 7 days, and elevated serum cardiac biomarkers

**Low-Risk TIMI Score**: TIMI score <2; **High-Risk TIMI Score**: TIMI score ≥2. A low risk TIMI score might still warrant invasive coronary arteriography, when other features, such as symptoms, are compelling.
Abbreviations:

AAD  antiarrhythmic drug  
ADLs  activities of daily living  
CAD  coronary artery disease  
CCS  Canadian Cardiovascular Society  
CKD  chronic kidney disease  
EKG  electrocardiogram  
FFR  fractional flow reserve  
LBBB  left bundle-branch block  
LVH  left ventricular hypertrophy  
MI  myocardial infarction  
MET  estimated metabolic equivalent of exercise  
PFT  pulmonary function test  
PVCs  premature ventricular contractions  
TIMI  Thrombolysis in Myocardial Infarction (Study Group)  
WPW  Wolf Parkinson White

REFERENCES

General References


References for cardiovascular risk:  
(Also see links to Online Calculators at end of Reference Section)
http://content.onlinejacc.org/article.aspx?articleid=1879711

http://circ.ahajournals.org/content/circulationaha/129/25_suppl_2/S49.full.pdf


NIH Estimate of 10 Year coronary artery disease risk from Framingham Risk Score:

References for High Occupational Risk


Reference for peri-operative risk


Reference for unstable angina risk
http://dx.doi.org/10.1161/CIRCULATIONAHA.107.181940.

Reference for indications for cardiac catheterization/ invasive coronary arteriography:
http://content.onlinejacc.org/article.aspx?articleid=1182705

Reference for bariatric surgery risk

Reference for number of PVCs
http://circep.ahajournals.org/content/5/1/229.full

Reference for syncope
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3295536/

Reference for left bundle branch block
Sauer et al, Left Bundle Branch Block. Up to Date, November 4, 2014.  

Reference for right bundle branch block

Referenced for police, fireman, pilots, etc.


Referenced for Arrhythmias and Long QT Syndrome


Reference for Cardiac Transplantation Patients


Reference for Microvascular Coronary Disease


Reference for Kawasaki Disease

Reference for Anti-rejection Medication and Vascular Disease


Links to Cardiac/Vascular Risk Online Calculators:

Framingham-ATP IV:  
http://cvdrisk.nhlbi.nih.gov/

Reynolds Risk Score:  
http://www.reynoldsriskscore.org/

Pooled Cohort Equation (includes cardiac and cerebrovascular risk):  
http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example

ACC/AHA Risk Calculator (includes cardiac and cerebrovascular risk):  
http://tools.acc.org/ASCVD-Risk-Estimator/

MESA Risk Calculator with addition of Coronary Artery Calcium Score:  
https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx
CPT Codes: 78459, 78491, 78492

INTRODUCTION:

Cardiac PET has two major clinical uses. First, it can characterize myocardial blood flow (perfusion scan). The FDA has approved both rubidium-82 (Rb-82) and nitrogen-13(N-13) radiotracers for this purpose. Second, PET can identify regions of myocardial viability that appear scarred (dead) on standard rest or stress SPECT/MPI imaging. The FDA has approved use of fluorine 18 (F-18) fluorodeoxyglucose for this purpose.

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 CARDIAC PET SCAN WITH APPROVED FDA RADIOISOTOPES:

- Evaluation of myocardial viability prior to possible percutaneous or surgical revascularization if:
  - Previous SPECT/MPI imaging for viability is inadequate; AND
  - Patient has severe left ventricular dysfunction (LVEF ≤ 35%).
- Evaluation in patient with suspected or known Coronary Artery Disease.
  - To qualify for PET perfusion scan done either at rest or with pharmacologic stress, the patient must meet criteria for indicated nuclear cardiac imaging/myocardial perfusion study AND is likely to experience attenuation artifact with SPECT imaging due to factors such as morbid obesity, large breasts, breast implants, previous mastectomy, chest wall deformity, pleural/pericardial effusion; OR
  - Patient had a previous inadequate SPECT/MPI imaging due to inadequate findings, technical difficulties with interpretation, or discordant results with previous clinical data.
- For the diagnosis of suspected cardiac involvement in patients with sarcoidosis as evidenced by reduced heart function on transthoracic echocardiogram or heart block on baseline electrocardiogram
  - For patients who have a contraindication to MRI or who have had an MRI of the heart with results equivocal for sarcoid involvement.
  - Examples of patients who are unable to undergo MRI include, but are not limited to, patients with a pacemaker, automatic implanted cardioverter-defibrillator (AICDs), or other metal implant.

◊ ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009 APPROPRIATE USE CRITERIA for Nuclear Cardiac Imaging / Myocardial Perfusion Study:

<table>
<thead>
<tr>
<th>ACCF et al. Criteria</th>
<th>INDICATIONS</th>
<th>APPROPRIATE USE SCORE (4-9):</th>
</tr>
</thead>
<tbody>
<tr>
<td># MPI / Stress Echo</td>
<td>(*Refer to Additional Information section)</td>
<td>A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
<tr>
<td>□ Not subject to Stress Echocardiogram contraindications as noted in section “Indications for a Nuclear Cardiac Imaging / Myocardial Perfusion Study”. Please see explanation in Introduction, paragraph “6”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Detection of CAD/Risk Assessment: Symptomatic
**ACCF et al. Criteria # MPI / Stress Echo**

**INDICATIONS**

(*Refer to Additional Information section)

□ Not subject to Stress Echocardiogram contraindications as noted in section “Indications for a Nuclear Cardiac Imaging / Myocardial Perfusion Study”. Please see explanation in Introduction, paragraph “6”

| APPROPRIATE USE SCORE (4-9): | A= Appropriate; U=Uncertain (MPI / Stress Echo) |

**Evaluation of Ischemic Equivalent (Non-Acute)**

| 2 / 115 | Low pretest probability of CAD* • ECG uninterpretable OR unable to exercise | A(7) / A(7) |
| 3 / 116 | Intermediate pretest probability of CAD* • ECG interpretable AND able to exercise | A(7) / A(7) |
| 4 / 117 | Intermediate pretest probability of CAD* • ECG uninterpretable OR unable to exercise | A(9) / A(9) |
| 5 / 118 | High pretest probability of CAD* • Regardless of ECG interpretability and ability to exercise | A(8) / A(7) |

**Detection of CAD: Asymptomatic (Without Ischemic Equivalent)**

**Asymptomatic**

| 14 / 126 | Intermediate CHD risk (ATP III risk criteria)*** • ECG uninterpretable | U(5) / U(5) |
| 15 / 127 | High CHD risk (ATP III risk criteria)*** ✓ | A(8) / U(5) ✓ |

**New-Onset or Newly Diagnosed Heart Failure With LV Systolic Dysfunction Without Ischemic Equivalent**

| 16 / 128 | No prior CAD evaluation AND no planned coronary angiography | A(8) / A(7) |

**New-Onset Atrial Fibrillation †**

| 17 / 132 | Part of evaluation when etiology unclear | U(6) / U(6) |

**Ventricular Tachycardia †**

| 18 / NA | Low CHD risk (ATP III risk criteria)*** | A(7) / NA |
| 19 / NA | Intermediate or high CHD risk (ATP III risk criteria)*** | A(8) / NA |

**Syncope**

| 21 / 134 | Intermediate or high CHD risk (ATP III risk criteria)*** | A(7) / A(7) |

**Elevated Troponin**

| 22 / 135 | Troponin elevation without additional evidence of acute coronary syndrome (with ischemia is not subject to Stress Echocardiogram contraindications) ✓ | A(7) / A(7) ✓ |

**Risk Assessment With Prior Test Results and/or Known Chronic Stable CAD**

**Asymptomatic OR Stable Symptoms Normal Prior Stress Imaging Study**

<p>| 26 / 145 | Intermediate to high CHD risk (ATP III risk criteria)*** ✓ • Last stress imaging study done more than or equal to 2 | U(6) / U(4) ✓ |</p>
<table>
<thead>
<tr>
<th>ACCF et al. Criteria # MPI / Stress Echo</th>
<th>INDICATIONS</th>
<th>APPROPRIATE USE SCORE (4-9):</th>
</tr>
</thead>
</table>

(*Refer to Additional Information section)

\[\text{Not subject to Stress Echocardiogram contraindications as noted in section “Indications for a Nuclear Cardiac Imaging / Myocardial Perfusion Study”. Please see explanation in Introduction, paragraph “6”}\]

<table>
<thead>
<tr>
<th></th>
<th>Years ago</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If known CAD, not subject to Stress Echo contraindications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Asymptomatic OR Stable Symptoms Abnormal Coronary Angiography OR Abnormal Prior Stress Imaging Study, No Prior Revascularization</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 / 147</td>
</tr>
<tr>
<td>• Known CAD on coronary angiography OR prior abnormal stress imaging study</td>
</tr>
<tr>
<td>• Last stress imaging study done more than or equal to 2 years ago</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prior Noninvasive Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>29 / 153</td>
</tr>
<tr>
<td>• Equivocal, borderline, or discordant stress testing where obstructive CAD remains a concern</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>New or Worsening Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 / 151</td>
</tr>
<tr>
<td>• Abnormal coronary angiography OR abnormal prior stress imaging study</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Coronary Angiography (Invasive or Noninvasive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 / 152</td>
</tr>
<tr>
<td>• Normal coronary angiography OR normal prior stress imaging study</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Asymptomatic Prior Coronary Calcium Agatston Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>32 / 141</td>
</tr>
<tr>
<td>• Coronary stenosis or anatomic abnormality of uncertain significance</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Assessment: Preoperative Evaluation for Noncardiac Surgery Without Active Cardiac Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>34 / 137</td>
</tr>
<tr>
<td>• Low to intermediate CHD risk***</td>
</tr>
<tr>
<td>• Agatston score between 100 and 400</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duke Treadmill Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>35 / 138</td>
</tr>
<tr>
<td>• High CHD risk***</td>
</tr>
<tr>
<td>• Agatston score between 100 and 400</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Assessment: Preoperative Evaluation for Noncardiac Surgery Without Active Cardiac Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>36 / 139</td>
</tr>
<tr>
<td>• Agatston score greater than 400</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Vascular Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>43 / 157</td>
</tr>
<tr>
<td>• Greater than or equal to 1 clinical risk factor ✔</td>
</tr>
<tr>
<td>• Poor or unknown functional capacity (less than 4 METs)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>APPROPRIATE USE SCORE (4-9): A= Appropriate; U=Uncertain (MPI / Stress Echo)</td>
</tr>
<tr>
<td>ACCF et al. Criteria</td>
</tr>
<tr>
<td>----------------------</td>
</tr>
<tr>
<td># MPI / Stress Echo</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>47 / 161</td>
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<tr>
<td></td>
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<tr>
<td>50 / 164</td>
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<td>52 / 166</td>
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<td>55 / 169</td>
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<td>56 / 170</td>
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<td>58 / 172</td>
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<tr>
<td>60 / 174</td>
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<td></td>
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<tr>
<td>62 / 176</td>
</tr>
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<td></td>
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</tbody>
</table>

◊ INDICATIONS FOR A NUCLEAR CARDIAC IMAGING/MYOCARDIAL PERFUSION STUDY:

- To qualify for SPECT/MPI, the patient must meet ACCF/ASNC Appropriateness criteria for appropriate indications above and meets any one of the following conditions:
  - Stress echocardiography is not indicated; OR
Stress echocardiography has been performed however findings were inadequate, there were technical difficulties with interpretation, or results were discordant with previous clinical data; OR

MPI is preferential to stress echocardiography including but not limited to following conditions:

- Ventricular paced rhythm
- Evidence of ventricular tachycardia
- Severe aortic valve dysfunction
- Severe Chronic Obstructive Pulmonary Disease, (COPD) as defined as FEV1 < 30% predicted or FEV1 < 50% predicted plus respiratory failure or clinical signs of right heart failure. (GOLD classification of COPD access http://www.pulmonaryreviews.com/jul01/pr_jul01_copd.html)
- Congestive Heart Failure (CHF) with current Ejection Fraction (EF) < 40%
- Inability to get an echo window for imaging
- Prior thoracotomy, (CABG, other surgery)
- Obesity BMI > 40
- Poorly controlled hypertension (generally above 180 mm Hg systolic (both physical stress and dobutamine stress may exacerbate hypertension during stress echo)]
- Poorly controlled atrial fibrillation (Resting heart rate > 100 bpm on medication to control rate)
- Inability to exercise requiring pharmacological stress test
- Segmental wall motion abnormalities at rest (e.g. due to cardiomyopathy, recent MI, or pulmonary hypertension)

OR

Arrhythmias with Stress Echocardiography - any patient on a type 1C anti-arrhythmic drug (i.e. flecainide or propafenone) or considered for treatment with a type 1C anti-arrhythmic drug.

For all other requests, the patient must meet ACCF/ASNC Appropriateness criteria for indications with Appropriate Use Scores 4-9, as noted above.

ADDITIONAL INFORMATION:

The applications for Cardiac Viability Imaging with FDG PET are:

- The identification of patients with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization.
- Distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect management decisions in patients with ischemic cardiomyopathy and left ventricular dysfunction.

Use of class IC antiarrhythmic agents:

Flecainide (Tambocor) and propafenone (Rythmol) are class IC anti arrhythmic agents. They are used to treat ventricular and supraventricular tachyarrhythmias. They are contraindicated in patients with structural heart disease due to the risk of precipitating life-threatening ventricular arrhythmias. These drugs can depress systolic function. They can suppress the sinus node in patients with sick sinus syndrome and impair AV and infra nodal conduction in patients with conduction disease. Propafenone has beta adrenergic receptor blocking effect.

*Pretest Probability of CAD for Symptomatic (Ischemic Equivalent) Patients:

- Typical Angina (Definite): Defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.
- Atypical Angina (Probable): Chest pain or discomfort that lacks 1 of the characteristics of definite or typical angina.
- Nonanginal Chest Pain: Chest pain or discomfort that meets 1 or none of the typical
Once the presence of symptoms (Typical Angina/Atypical Angina/Non angina chest pain/Asymptomatic) is determined, the probabilities of CAD can be calculated from the risk algorithms as follows:

<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>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</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>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>&gt;60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

- **Very low**: Less than 5% pretest probability of CAD
- **Low**: Less than 10% pretest probability of CAD
- **Intermediate**: Between 10% and 90% pretest probability of CAD
- **High**: Greater than 90% pretest probability of CAD

**REFERENCES:**


CPT Codes: 78472, 78473, 78494, +78496

INTRODUCTION:

Multiple-gated acquisition (MUGA) scanning is a radionuclide ventriculography technique to evaluate the pumping function of the ventricles of the heart. During this noninvasive nuclear test, radioactive tracer is injected into a vein and a gamma camera detects the radiation released by the tracer, providing moving images of the heart. From these images, the health of the heart’s pumping chamber, the left ventricle, can be assessed. It is used to evaluate the left ventricular ejection fraction (LVEF), a measure of overall cardiac function. It may also detect areas of poor contractility following an ischemic episode and it is used to evaluate left ventricular hypertrophy.

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 MULTIPLE-GATED ACQUISITION (MUGA) SCAN:

- To evaluate left ventricular (LV) function at baseline before chemotherapy or cardiotoxic therapy; may be repeated prior to subsequent chemotherapy cycles until a total cardiotoxic dose has been reached.
- To evaluate ejection fraction in a patient with congestive heart failure (CHF), when prior cardiac imaging has proven inadequate for an accurate determination of ejection fraction.
- To evaluate patient, who is obese or who has chronic obstructive pulmonary disease (COPD), for coronary artery disease (CAD).
- As an alternative form of stress imaging instead of echocardiography or myocardial perfusion imaging, based upon similar necessity criteria for the evaluation of coronary or valvular heart disease.

COMBINATION OF 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.

ADDITIONAL INFORMATION RELATED TO MUGA:

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.

MUGA Scan Monitoring during Chemotherapy – Chemotherapeutic drugs that are used in cancer treatment may be toxic to the heart muscle. To minimize the risk of damaging the heart muscle with these drugs, the patient’s cardiac function may be monitored with the MUGA scan before and during administration of the drug. Before the first dose of the drug, a MUGA scan may be performed to establish a baseline left ventricle ejection fraction (LVEF). It may then be repeated after cumulative doses. If the LVEF begins to decrease, cardio toxicity risk must be considered if continuing the treatment.
REFERENCES


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.

Single-Photon Emission Computed Tomography (SPECT) brain imaging is based on the correlation between neuronal activity and cerebral perfusion. Technium labeled radiopharmaceuticals are injected into the patient and cross the blood brain barrier where they emit gamma rays that are detected by the imaging system. A 3D image of the brain is created using computerized techniques with the degree of radionuclide activity corresponding to neuronal activity and cerebral blood flow. Pathological conditions evaluated include cerebrovascular disease, dementia, detection of seizure foci, neuropsychological disorders, infection, and trauma. In the assessment of transient ischemic disease the technique can be performed with agents that enhance regional blood flow such as Acetazolamide which causes regional arterial dilatation by increasing local carbon dioxide.

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 A BRAIN SPECT:
- For the evaluation of suspected brain trauma for patient with recent neurological symptoms or deficits (such as one-sided weakness, speech impairments or vision defects) AND patient has had a recent Brain CT or Brain MRI.
- For the evaluation of suspected dementia, for patient who has had a recent Brain CT or MRI AND all three (3) of the following were completed:
  - Thyroid study
  - B12 assay
  - Mini Mental State Exam (MMSE)
- For pre-surgical localization of epileptic foci, patient has had either a Brain CT or Brain MRI AND surgery is tentatively scheduled.
- For patient with history of cerebral vascular accident or stroke with recent Brain CT and/or MRI AND there are acute neurological changes or deficits not explained on the recent imaging study.
- To evaluate cerebrovascular reserve in planning appropriate endovascular vascular intervention or neurovascular surgical approach.

ADDITIONAL INFORMATION RELATED TO A BRAIN SPECT:

Literature for evaluation of brain trauma indicates that SPECT can help evaluate perfusion abnormalities not only in cases evaluating blunt brain trauma, but also in cases of post-concussive syndrome and whiplash.
Evaluation of suspected dementia requires both specialty management and requires that several preliminary tests be performed. The majority of the literature indicates that SPECT can assist in the differential diagnosis of dementia disorders when used in conjunction with clinical examination and neuropsychological testing. However, there are several negative studies in the literature that suggest that the predictive value of SPECT is not high enough to be used on a routine clinical basis.

In addition, there are other pathological processes that can produce patterns consistent with AD and FLD patterns, most notably brain injury that affects the prefrontal cortex pole and anterior temporal lobes (like FLD) or a brain injury that affects the temporal and parietal lobes. As with any test it is important that SPECT be used and interpreted within a clinical context.

Pre operative evaluation for epilepsy seeks information as to whether an anatomic study (CT and/or MRI) has been performed and if the surgery has been scheduled. While a number of authors have evaluated the utility of brain SPECT and various structural techniques for the localization of seizure foci, at the time of writing the preferred examination under these circumstances (if available) is a functional MRI (fMRI). To put these advantages in perspective, functional images obtained by the earlier method of positron emission tomography, PET or SPECT, require injections of radioactive isotopes, multiple acquisitions, and, therefore, extended imaging times. Further, the expected resolution of PET images is much larger than the usual fMRI pixel size.

Evaluation of cerebral vascular disease = Perfusion SPECT can provide valuable information in acute stroke with respect to complications, but anatomic studies such as CT and/or MRI must have also been performed.

REFERENCES


CPT Codes: 78608, 78609

Positron Emission Tomography (PET) scanning is useful in brain tumor imaging and in the preoperative evaluation of refractory epilepsy. It is useful in the identification of epileptic foci in the brain as an adjunct to surgical planning and is useful for follow-up of brain tumor surgery or treatment. It helps in the evaluation of known brain tumor with new signs or symptoms indicative of a recurrence of 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 BRAIN PET SCAN:

For evaluation of known brain tumor or cancer:
- Known brain tumor or cancer with new signs or symptoms indicative of a reoccurrence of cancer.
- Brain tumor follow-up after surgery and/or after treatment recently completed.

For pre-operative evaluation:
- Pre-surgical evaluation for refractory epilepsy.

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.

For evaluation of Dementia:
- A scan is reasonable and necessary in patients (who meet all of the following) with:
  1. Documented cognitive decline of at least six months (request date of onset of symptoms).
  2. Recent assessment done of patient’s mental status - documented by neuro-diagnostic testing, such as:
     a. Change in mental status with a mental status score of either MMSE or MoCA of less than 26 or other similar mental status exams showing at least mild cognitive impairment AND a completed basic metabolic workup (such as thyroid function testing, liver function testing, complete blood count, etc).
  3. Appropriate baseline work-up for other treatable causes

ADDITIONAL INFORMATION RELATED TO BRAIN PET:

Information applicable to Dementia/Alzheimer’s:
- Cognition is the act or process of thinking, perceiving, and learning.
- Symptoms develop when the underlying condition affects areas of the brain involved with learning, memory, decision-making, and language.
- Memory impairment is often the first symptom to be noticed. Someone with dementia may be unable to remember ordinary information, such as their birth date and address, and may be unable to recognize friends and family members.
- There is progressive decline in these cognitive functions as well:
  o Decision making
  o Judgment
- Orientation in time and space
- Problem solving
- Verbal communication

- Behavioral changes may include the following:
  - Eating, dressing, toileting (e.g., unable to dress without help; becomes incontinent)
  - Interests (e.g., abandons hobbies)
  - Routine activities (e.g., unable to perform household tasks)
  - Personality (e.g., inappropriate responses, lack of emotional control).

- Frontotemporal dementia diagnostic criteria:
  - Behavioral symptoms that should be recorded include apathy, aspontaneity, or, oppositely, disinhibition.
  - Executive function should also be assessed - patients would show impairment in ability to perform skills that require complex planning or sequencing (multi-step commands, drawing the face of a clock).
  - Primitive reflexes showing frontal release should be assessed including palmomental reflex, rooting reflex and palmar grasp.

- Alzheimer’s criteria:
  - Memory impairment (assessed as part of mini-mental status exam MMSE)
  - Cognitive disturbance (one or more) evidenced by
    - Aphasia (language disturbance)
    - Apraxia (impaired ability to carry out motor activities despite intact motor function)
    - Agnosia - failure to recognize or identify objects despite intact sensory (vision, touch, etc) function
  - Disturbance in executive function: patients would show impairment in ability to perform skills that require complex planning or sequencing (multi-step commands, drawing the face of a clock).

- Metabolic testing (in addition to neurologic examination, MMSE):
  - Urinalysis (to r/o urinary tract infection as a cause of dementia)
  - CBC (to r/o infection or anemia as a cause of impaired mental function)
  - Serum electrolytes, including magnesium
  - Serum chemistries, including liver function testing
  - Thyroid function tests (TSH or super sensitive (ss) TSH)
  - Vitamin B12
  - Erythrocyte Sedimentation Rate (ESR, “Sed Rate”, etc)
  - Serologic test for syphilis (to r/o tertiary syphilis)
  - Possibly toxicology tests to r/o poisoning or overdose - salicylates, alcohol, other

- Medicines that may be causing cognitive impairment:
  - Anti-diarrheals
  - Anti-epileptic medications
  - Antihistamines, cold and flu medications
  - Lithium
  - Sleeping pills
  - Tricylic antidepressants
  - Opiates
  - Salicylates

**PET in Seizure Disorders** – Refractory epilepsy is defined as epilepsy that does not respond to medical treatment. These patients struggle with recurrent seizures even while undergoing treatment with antiepileptic drugs (AEDs). However, the definition is unclear as some of these patients will partially respond to treatment or will worsen when AEDs are discontinued. PET is helpful in locating the area of
the brain causing seizures and is used in the preoperative evaluation of patients who have failed to respond to conventional medical treatment of epilepsy.

**PET and Known Brain Tumor/Cancer** – Studies have shown that PET is useful in patients who have undergone surgery. PET, a biochemical and physiologic technology, provides precise information about brain tumors which helps to distinguish between brain tumors and other anatomic structures or surgical scars. It is useful in identifying tumors in the brain after surgery, radiation or chemotherapy. With the sensitivity and specificity of the radiotracer 18-F FDG, PET is able to evaluate recurrent tumor and treatment-induced changes.

**REFERENCES**


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.

CSF fluid flow studies for the evaluation of hydrocephalus or CSF leak are performed after the intrathecal administration of radionuclide. In the setting of suspected shunt obstruction the radiopharmaceutical is injected 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. In patients without hydrocephalus or CSF leak there is a predictable radiopharmaceutical distribution. In patients without 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.

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 routine dynamic planar imaging is insufficient alone:
- Evaluation of hydrocephalus and the patient has had a CT or MRI imaging of the head recently performed and compared to prior exams.
- Detection of CSF leak and the patient has had a recent surgical procedure.
- Detection of CSF leak AND patient experienced recent trauma.
- 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.

ADDITIONAL INFORMATION RELATED TO CSF SPECT SCAN:

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.

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.
REFERENCES


Society of Nuclear Medicine Procedure Standards.
http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=6414

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 routine dynamic planar imaging is insufficient alone:

- Evaluation of renal perfusion and function, with signs, symptoms and laboratory findings supporting the need for such an evaluation.
- Evaluation of renal, ureteral, or other urinary tract trauma or surgery, with signs, symptoms and laboratory findings supporting the need for such an evaluation.
- For diagnosis of reno-vascular hypertension, with signs, symptoms and laboratory findings supporting the need for such a diagnosis.
- Detection and evaluation of renal collecting system obstruction.
- Diagnosis of acute tubular necrosis.
- Diagnosis of renal transplant complications.
- Evaluation of renal infections and discrimination of pyelonephritis from cortical scarring.

ADDITIONAL INFORMATION RELATED TO KIDNEY SPECT SCAN:

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.
**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.

**REFERENCES**


**INTRODUCTION:**

Positron emission tomography (PET) is a rapidly developing technology that is able to detect biochemical processes, most often glucose uptake and utilization, within body tissues. A radioactive tracer is used during the procedure. Though multiple PET radiotracers are FDA approved, the most commonly used PET radiotracer is 18F Fluorodeoxyglucose (FDG). Unlike other nuclear medicine examinations, FDG PET measures metabolic activity of the cells of body tissues, providing information about the functionality and structure of the particular organ or tissue examined. PET may 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. Cancer cells tend to show increased radioactive tracer accumulation relative to tissue not involved with tumor. Radioactive tracer uptake is generally higher in fast-growing tumors; FDG PET is not as sensitive for slow growing tumors.

Radioactive tracer uptake may occur in various types of active inflammation and is not specific for cancer. Thus it is generally not used for the initial specific diagnosis of cancer, but is more useful in monitoring cancer cell viability and for the diagnosis and detection of recurrence of cancer. FDG PET is also useful for monitoring the response to treatment of various cancers. Finally FDG PET is useful in the management of indeterminate pulmonary nodules/masses that are, for both anatomic and clinical reasons, difficult to biopsy.

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.

The following guidelines are for FDG PET imaging in oncology.

**IMPORTANT NOTE:**

- 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)
- SPN – solitary (or clearly dominant) indeterminate pulmonary nodule ≥ to 8mm in size without existing tissue diagnosis (note: patient may have other non-suspicious nodules in the lung, such as granulomas and hamartomas.)

Excluding
- ALL - acute lymphoblastic leukemia
- AML – acute myelogenous leukemia
- BCC – basal cell carcinoma (of the skin)
- Prostate cancer

- 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.)

- 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

Subsequent PET Scans may be performed only if other imaging (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
• Neuroendocrine cancer (e.g. carcinoid, pheochromocytoma, etc)
• Pancreatic cancer
• Prostate cancer
• Soft tissue sarcoma
• Testicular cancer
• Tumors of unknown origin

**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:
  o A thyroidectomy and radioiodine ablation initially, *and*
  o Current serum thyroglobulin > 10ng/mL, *and*
  o Current whole body I-131 scan is negative.
  o Medullary thyroid cancer when calcitonin levels are elevated post-operatively.

**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.

**ADDITIONAL INFORMATION RELATED TO PET SCANS:**

**Initial Treatment Strategy** - "Initial Anti-tumor Treatment Strategy" or "Initial Treatment Strategy" is replacing "diagnosis and initial staging".

**Subsequent Treatment Strategy** - "Subsequent Anti-tumor Treatment Strategy" or "Subsequent Treatment Strategy" is replacing "restaging and monitoring response to treatment".

**PET in the setting of immunotherapy** - Be aware that cancer immunotherapy with cytokines, immune-modulating antibodies, and cancer vaccines, is changing the landscape of imaging evaluation of cancer treatment response. Early experience with these therapies has demonstrated a delayed imaging response to therapy as compared to traditional chemotherapy. Transient enlargement and intensification of radiotracer activity in tumors, nodal and metastatic disease is well documented. This “pseudoprogression” may necessitate additional PET/CT surveillance. Literature currently supports repeat interval PET/CT after such a transient worsening on imaging so as to determine whether the changes seen are true progression or merely brisk immune response.

**PET/CT or PET with CT Attenuation Correction** – In contrast to the simple PET scan which requires a complex process of evaluation of body habitus to adjust for tissue density, modern scanners have the capacity to obtain a preliminary, general assessment of a patient’s habitus through the use of CT technology. Automatic adjustments to the PET data (based on tissue attenuation) are made. This is one study, not a combination study. This is interchangeably referred to as a PET/CT or PET/CT fusion examination. These provide the anatomical detail of a CT with PET’s ability to measure tissue metabolic activity. The ability to view both the morphology and metabolic activity simultaneously helps to evaluate tumors with speed and clarity. PET alone is normally not the standard of care and is significantly less accurate than PET/CT. The combination of PET and computed tomography (PET/CT) has advantages
over PET alone because areas of tracer uptake are better localized and the image acquisition time is reduced.

**PET and Breast Cancer** - PET provides important qualitative and quantitative metabolic information that is important in the initial staging and re-staging of breast cancer.

**PET and Cervical Cancer** – Studies have shown that PET may be useful for the pre-treatment detection of retroperitoneal nodal metastasis in cervical cancer.

**PET and Colorectal Cancer** – PET is useful in the detection of recurrent disease, the localization of recurrence in patients with a rise of carcinoembryonic antigen (CEA), the assessment of residual masses after treatment, and in staging patients before surgery.

**PET and Esophageal Cancer** – The most common use of PET in esophageal cancer is to detect distant metastases and distant lymph node disease. It may also be used to assess therapy response and evaluate for esophageal tumor recurrence after treatment. PET findings do not specify each separate type of lesion. It is very helpful in detecting distant spread from invasive thymic carcinomas.

**PET and Head and Neck Cancer** – PET is used to evaluate cancer/tumor in the head and neck region, e.g., face, orbit, temporal, neck and is useful to rule out head and/or neck cancer/tumor as the “primary” when there is evidence of tumor elsewhere in the body and clinical examination or conventional imaging has failed to localize the lesion. It is also used to distinguish a benign tumor from a malignant tumor.

**PET and Lung Cancer** – The most common cause of death from cancer in western countries is lung cancer. PET is helpful in the evaluation of patients diagnosed with early-stage non small lung cancer. It is valuable in picking up otherwise occult metastasis. PET identifies areas of hypermetabolism such as neoplasia or inflammation and reveals occult metastases. The detection of hidden or unsuspected metastasis prevents unnecessary surgery or treatments.

**PET and Lymphoma** – PET is used in the early assessment of response to chemotherapy in Hodgkin lymphoma (HL) as well as in aggressive non-Hodgkin lymphoma (NHL). Soon after the initiation of therapy, changes in radioactive tracer uptake may occur and these changes precede changes in tumor volume. This information may be used to guide treatment for patients with HL and NHL. However, PET/CT scan at early/interim restaging can lead to increased false positives and should be carefully considered in select cases.

**PET and Melanoma** – PET is not used in the diagnosis of melanoma. It may be used in the evaluation of stage III melanoma for detection of distant metastases and to identify candidates for further treatment or surgery.

**PET and Pancreatic Cancer** – In difficult cases, the presence of diffuse uptake of radioactive tracer by the pancreas or concomitant extrapancreatic uptake by the salivary glands on PET/CT can be used to aid in differentiation of autoimmune pancreatitis and pancreatic cancer.

**PET and Solitary Pulmonary Nodule** – PET may be used in the evaluation of patients with a single solitary nodule. It measures glucose metabolism which is different between benign and malignant nodules. FDG-PET is accurate in evaluation of the nodule. However, it may provide false positive results in patients who have inflammatory disease or active infections.
**PET and Thyroid Cancer** – The differentiated thyroid carcinoma (DTC) represents the most common type of thyroid cancer. It can be cured with surgical treatment and adjunctive therapy, but tumor recurrence is associated with significant morbidity and mortality. PET is used to evaluate DTC patients with negative radiiodine scans and elevated thyroglobulin (Tg) levels to detect recurrent or metastatic DTC. When thyroid carcinoma is differentiated it tends to retain the ability to accumulate iodine and iodine-based imaging is therefore the most appropriate imaging exam. When thyroid carcinoma becomes dedifferentiated, it tends to lose the ability to accumulate iodine and instead begins to act like other aggressive carcinomas.

PET in pediatric age group – While radiation dose and stochastic effects of radiation are of greater concern in the pediatric age group as compared to the adult age group, there are no PET/CT-specific radiation safety precautions. Prudence with all forms of imaging requiring ionizing radiation is recommended.

**REFERENCES**


CPT Codes: 0042T

INTRODUCTION:

Cerebral perfusion computed tomography (CT) is a relatively new 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 the identification of ischemic regions of the brain. It is useful in the 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:

- For noninvasive diagnosis of cerebral ischemia and infarction and for evaluation of vasospasm after subarachnoid hemorrhage.
- 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.
- For the evaluation of patients undergoing temporary balloon occlusion to assess collateral flow and cerebrovascular reserve.
- For the assessment of microvascular permeability in patients with intracranial neoplasms.
- For the assessment of cerebral blood flow after carotid artery stent placement in patients with severe carotid artery stenosis.
- For early detection of acute cerebral ischemia.

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.

ADDITIONAL INFORMATION RELATED TO CEREBRAL PERFUSION CT:

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.

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 stenoses 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 – Temporary balloon occlusion along with a quantitative analysis of cerebral blood flow may be useful in identifying patients who may not tolerate permanent or prolonged occlusion.

Intracranial Health care 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 – 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. It 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 that the use of CAD systems would maintain or increase the sensitivity, specificity, and recall rates 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".
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 for the initial diagnosis of Breast Cancer is considered to be not medically necessary and is therefore a non-covered study.
CPT Codes: S8037, 74181, 74182, 74183

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 (MR) 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 when a noninvasive exam is desired.

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:

- For evaluation of suspected congenital anomaly of the pancreaticobiliary tract, e.g., aberrant ducts, choledochal cysts, pancreas divisum or related complications.
- For evaluation of chronic pancreatitis or the complications related to such (pseudocysts and bile duct strictures).
- Preoperative evaluation: Prior to surgery or other invasive procedure.
- Post operative evaluation: For evaluation of suspected biliary abnormalities after surgery or invasive procedure.
- For further evaluation of inconclusive abnormalities identified on other imaging (ultrasound, CT, or MRI).
- For evaluation of abnormality related to the biliary tree based on symptoms or laboratory findings and initial imaging has been performed.

ADDITIONAL INFORMATION RELATED TO MRCP:

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.

MRI imaging – Metal devices or foreign body fragments within the body, such as indwelling pacemakers and intracranial aneurysm surgical clips that are not compatible with the use of MRI, may be contraindicated. Other implanted metal devices in the patient as well as external devices such as portable O₂ tanks may also be contraindicated.

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, MRP is more sensitive than ERCP in 
differentiating mural nodules from mucin globules (40–44). It also consistently demonstrates the internal 
arquitectures of the main duct and the extent of IPMN better than ERP. (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 
anastomatic 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)**: Magnetic resonance cholangiography is increasingly available but 
does not yet visualize the intrahepatic bile ducts sufficiently to replace direct cholangiography. 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. (Insights into Imaging)

**REFERENCES:**

MRCP in patient care: A Prospective Survey of Gastroenterologists. *American Journal of 

https://acsearch.acr.org/list.

findings of the pancreas in patients with diabetes mellitus: Compared analysis with pancreatic 
doi: 10.1097/MCG.0b013e3181587912


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 S8032) 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:

- 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.

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.
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). Most ICD implantations are for primary prevention in patients with ischemic cardiomyopathy. Studies published in the last decade have confirmed improved survival in patient with reduced left ventricular ejection fraction (LVEF) even when no cardiac arrhythmias have been noted.

Approximately one third of patients who receive ICDs are also candidates for cardiac resynchronization therapy (CRT) because of congestive heart failure (CHF) and an abnormally wide QRS. CRT typically requires three leads, one each to pace the right and left ventricles, and a third to pace the atrium. This allows near-simultaneous stimulation (resynchronization) of both ventricles. CRT improves cardiac function and quality of life and 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. Criteria for CRT are based on a 2012 focused update of the ACC/AHA/HRS 2008 ICD guideline. This guideline supports approval of ICD and CRT indications that are classed as IIb or higher. Relevant considerations are assigning designations I, IIa, and IIb are LVEF, QRS pattern and duration, and whether atrial fibrillation is present.

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 ICD INSERTION:**

- Cardiac arrest secondary to ventricular fibrillation (VF) or hemodynamically unstable sustained (at least 30 seconds) ventricular tachycardia (VT) after evaluation of etiology of event and exclusion of completely reversible causes.
- Spontaneous sustained VT in patients with structural heart disease, whether hemodynamically stable or unstable.
- Syncope of undetermined origin with hemodynamically significant sustained (30 seconds duration, causing hemodynamic collapse, or requiring cardioversion) VT or VF induced at electrophysiological study.
- LVEF ≤35% due to prior myocardial infarction (MI), New York Heart Association (NYHA) functional Class II or III and at least 40 days post-MI and 90 days post-revascularization.
- Non-ischemic dilated cardiomyopathy (DCM) with LVEF less than or equal to 35% and NYHA functional Class I, II, or III and at least 90 days after diagnosis of DCM.
- LVEF ≤30% due to prior MI and at least 40 days post-MI and 90 days post-revascularization.
• Non-sustained VT with prior MI and LVEF less than or equal to 40% and inducible VF or sustained VT at electrophysiological study.
• Unexplained syncope with significant LV dysfunction and nonischemic DCM.
• Sustained VT with normal or near-normal LV function.
• Hypertrophic cardiomyopathy (HCM) who have one or more major risk factors for Sudden Cardiac Death (SCD). Risk factors include syncope, nonsustained VT, family history of sudden death, 30 mm septal thickness, or abnormal blood pressure response to exercise.
• Arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) and one or more risk factors for SCD, which include positive EP study, nonsustained VT, male gender, severe right ventricular (RV) dilatation, extensive RV involvement, LV involvement, unexplained syncope, or high-risk genotype.
• Long-QT syndrome with syncope and/or VT despite beta blocker therapy.
• Non-hospitalized patients awaiting cardiac transplantation.
• Brugada syndrome with syncope or documented VT.
• Catecholaminergic polymorphic VT with syncope and/or documented sustained VT while receiving beta blockers.
• Cardiac sarcoidosis or giant cell myocarditis or Chagas disease, accompanied by clinically relevant arrhythmia.
• Long-QT syndrome and risk factors for SCD, including syncope despite drug therapy, family history of sudden cardiac death, concern regarding medication compliance or intolerance, or high-risk genotype.
• Syncope and advanced structural heart disease (including congenital) in which thorough invasive and noninvasive investigations have failed to define a cause.
• Familial cardiomyopathy associated with SCD.
• LV noncompaction.

CONTRAINDICATIONS FOR ICD IMPLANTATION:

• 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 CRT-D.
• Syncope of undetermined origin with no inducible ventricular tachyarrhythmias or structural heart disease.
• VF or VT amenable to surgical or 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.
• Ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (e.g., electrolyte imbalance, drugs, or trauma).

INDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY (CRT):

• LVEF < 35%
  o sinus rhythm with left bundle-branch block (LBBB) with a QRS duration ≥ 120 ms and NYHA class II, III, or ambulatory IV symptoms on Guideline-Directed Medical Therapy (GDMT).
• sinus rhythm with a non-LBBB pattern with a QRS duration ≥120 ms and NYHA class III, or ambulatory class IV symptoms on GDMT.
• sinus rhythm with a non-LBBB pattern with a QRS duration ≥150 ms and NYHA class II
• atrial fibrillation if:
  ▪ the patient requires ventricular pacing or otherwise meets CRT criteria and
  ▪ AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT.
• planned new or replacement device placement and anticipated requirement for significant (40%) ventricular pacing.
• LVEF <30% and ischemic heart failure with sinus rhythm and LBBB with a QRS duration ≥150 ms and NYHA class I symptoms on GDMT.

CONTRAINDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY (CRT):
• NYHA class I or II symptoms and non-LBBB pattern with QRS duration less than 150 ms.
• A projected survival of less than 1 year.

ADDITIONAL INFORMATION:
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: An important issue in the timing of ICD insertion for primary prevention, which has garnered increasing attention recently, is the “waiting period” prior to ICD implantation for certain indications. 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 90 days) or recent myocardial infarction (under 40 days). In addition, studies of patients who have received ICDs early after myocardial infarction have not demonstrated a mortality benefit.
  o A recent study of a large Medicare database, which received a great deal of media attention, concluded that over 20% of ICD insertions in the United States are “inappropriate”, predominantly due to violations of these waiting periods.
  o Most thought leaders and practicing clinicians feel that the waiting periods are largely reasonable and appropriate, but there are certain clinical scenarios in which following them reduces the quality of care and increases patient risk without any benefit. 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.

- This scenario would be rendered even more problematic if the patient required a pacemaker, since waiting 40 days to upgrade a pacemaker to an ICD would subject the patient (and payer) to two procedures instead of one. Therefore, these guidelines will adhere to the current waiting periods but also provide an opportunity to request exemptions where patient benefit is clearly documented.

**NYHA Class Definitions:**
- Class I: No limitation of functional activity or only at levels of exertion that would limit normal individuals.
- Class II: Slight limitation of activity. Dyspnea and fatigue with moderate exercise.
- Class III: Marked limitation of activity. Dyspnea with minimal activity.
- Class IV: Severe limitation of activity. Symptoms even at rest.

**ABBREVIATIONS**

- ARVD/C = Arrhythmogenic right ventricular dysplasia/cardiomyopathy
- AV = Atrioventricular
- CHF = Congestive heart failure
- CRT = Cardiac resynchronization therapy
- CRT-D = Cardiac resynchronization therapy ICD system
- DCM = Dilated cardiomyopathy
- EKG = Electrocardiogram
- EPS = Electrophysiologic Study
- GDMT = Guideline-Directed Medical Therapy
- HCM = Hypertrophic cardiomyopathy
- HRS = Heart Rhythm Society
- HV = His-ventricle
- ICD = Implantable cardioverter-defibrillator
- LBBB = Left bundle-branch block
- LV = Left ventricular/left ventricle
- LVEF = Left ventricular ejection fraction
- MI = Myocardial infarction
- MS = Milliseconds
- NYHA = New York Heart Association
- RV = Right ventricular/right ventricle
- STEMI = ST-elevation Myocardial Infarction
- SND = Sinus node dysfunction
- VT = Ventricular tachycardia
- VF = Ventricular fibrillation
REFERENCES:


CPT Codes: 33206, 33207, 33208, 33212, 33213, 33214, 33227, 33228

INTRODUCTION

Pacemakers are implantable devices used to treat bradycardia, certain tachycardias and occasionally certain cardiomyopathies. Dual chamber devices are helpful for many of patients in improving quality of life and congestive heart failure. Many patients with dilated cardiomyopathy receive implantable defibrillators with cardiac resynchronization therapy (CRT) capability. However, CRT requires separate authorization as CRT has specific criteria.

Appropriate use criteria have not been established for pacemaker insertion. Clinicians rely upon ACC/AHA/HRS guidelines, which were updated for bradycardia indications in 2008. A focused guideline update was published in 2012, which considered left ventricular ejection fraction (LVEF), QRS pattern, QRS duration, and consideration regarding the presence of atrial fibrillation in its differentiation between classes, I, IIa, and IIb 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 AND CONTRAINDICATIONS FOR PACEMAKERS BY CONDITION

- **Pacing for Sinus Node Dysfunction:**
  - Symptomatic bradycardia, which includes syncope, near-syncope, dizziness, lethargy, congestive heart failure (CHF), fatigue, or dyspnea, whether spontaneous or as a result of clinically indicated medications or procedures (e.g. medical or catheter treatment for atrial fibrillation) that intentionally slow the heart rate, documented by EKG or telemetry.
  - Symptomatic heart beat pauses, documented by EKG or telemetry.
  - Chronotropic incompetence, documented by stress test or telemetry.
  - Heart rate less than 40 with symptoms consistent with bradycardia.
  - Syncope with electrophysiologic study (EPS) findings of abnormal sinus node function.

- **Contraindications for Sinus Node Dysfunction:**
  - Asymptomatic.
  - Symptoms in the absence of bradycardia.
  - Bradycardia resulting from nonessential drug therapy.

- **Pacing for Acquired Third-Degree and Advanced Second-Degree Atrioventricular (AV) Block:**
  - Persistent third-degree atrioventricular block, with or without symptoms.
  - In atrial fibrillation and while awake, pauses in heartbeat ≥ 5 seconds with or without symptoms.
  - In sinus rhythm 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.
  - Following cardiac surgery, if expected to be permanent.
  - In neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy.
Exercise-induced heart block without myocardial ischemia.

**Contraindications 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.

**Pacing for Other Presentations of First- and Second-Degree AV Block:**
- Symptomatic second-degree AV block.
- Type II second-degree AV block, with or without symptoms.
- Second-degree AV block due to EP-documented intra- or infra-His levels.
- First- or second-degree AV block with “pacemaker syndrome” symptoms or hemodynamic compromise (i.e. hypotension, syncope and pulmonary edema).
- 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.

**Contraindications 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.

**Permanent Pacing for 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.

**Contraindications for Permanent Pacing for Chronic Bifascicular Block:**
- Asymptomatic fascicular block without AV block.
- Asymptomatic fascicular block with first-degree AV block.

**Permanent Pacing After the Acute Phase of Myocardial Infarction:**
- 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.

**Contraindications for Permanent Pacing After the Acute Phase of Myocardial Infarction:**
- Bradycardia 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.

- **Permanent Pacing in 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.

Contraindications 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.

- **Pacing following Cardiac Transplantation:**
  - Persistent inappropriate or symptomatic bradycardia not expected to resolve and for all other indications for permanent pacing.
  - Prolonged bradycardia limiting rehabilitation or discharge.
  - Syncope after transplantation even when bradyarrhythmia has not been documented.

Contraindications for Pacing following Cardiac Transplantation:
- Bradycardia secondary to nonessential drug therapy.

- **Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardia:**
  - Symptomatic recurrent supraventricular tachycardia documented to be pacing terminated in the setting of failed catheter ablation and/or drug treatment or intolerance.

Contraindications for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardia:
- Presence of an accessory pathway with capacity for rapid anterograde conduction.

- **Pacing to Prevent Tachycardia:**
  - Sustained pause-dependent Ventricular tachycardia (VT), with or without QT prolongation.
  - High-risk congenital long-QT syndrome.
  - Symptomatic, drug-refractory, recurrent atrial fibrillation in patients with coexisting Sinus Node Dysfunction (SND).

Contraindications for Pacing to Prevent Tachycardia:
- Ventricular ectopic without sustained VT in the absence of the long-QT syndrome.
- Reversible, e.g., drug-related, Torsade de pointes VT.

- **Pacing in Patients with Hypertrophic Cardiomyopathy:**
  - Symptomatic hypertrophic cardiomyopathy and hemodynamically significant resting or provoked LV outflow tract obstruction AND refractory to medical therapy.
Contraindications for Pacing in Patients with Hypertrophic Cardiomyopathy:
- Asymptomatic OR symptoms controlled on medical therapy.
- Without significant LV outflow tract obstruction.

Pacing in Children, Adolescents, and Patients with Congenital Heart Disease:
- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output.
- SND with symptoms and age-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 at the end.
- 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, or ventricular dysfunction.
- 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 heart disease and sinus bradycardia for the prevention of recurrent episodes of intra-atrial reentrant tachycardia, either intrinsic or secondary to anti-arrhythmic treatment.
- 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.
- 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.
- 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.
- Asymptomatic sinus bradycardia following biventricular repair of congenital heart disease with a resting heart rate < 40 bpm or pauses in ventricular rate > 3 seconds.

Contraindications 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 type I second-degree AV block.
- Asymptomatic sinus bradycardia with the longest RR interval < 3 seconds and a minimum heart rate > 40 bpm.
- Bradycardia secondary to nonessential drug therapy.

ADDITIONAL INFORMATION:

For Cardiac Resynchronization Pacemaker Implementations, see separate CRT Pacemaker guideline.
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. It contains a battery, a microprocessor that governs timing and function, and a radio antenna to allow for noninvasive 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 sent from the pulse generator down the leads to the heart, where stimulation results in heart muscle contraction.

The most recent guidelines stress that asymptomatic bradycardia rarely qualifies as a class I 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. In addition, there are also a small number of situations in which the electrocardiogram (EKG) or an invasive electrophysiologic study (EPS) can reveal evidence of specific disease in the cardiac conduction system that warrants pacemaker insertion in the absence of symptoms, for the same reason. 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 among a subset of patients. 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 received implantable defibrillators with CRT capability, but pacemakers are sometimes chosen due to patient and physician preference. A focused ACCF/AHA/HRS guideline update was published in 2012, which considered LVEF, QRS pattern, QRS duration, and consideration regarding the presence of atrial fibrillation in its differentiation between classes, I, IIa, and IIb indications. This document will provide criteria for approval of all CRT indications that are presently defined as IIb or stronger.

Current guidelines group pacemaker indications together according to anatomic source and clinical syndromes, and this document follows this approach. Class I through IIb indications are condensed and included as approvable in this document. Generally speaking, for indications that are listed in this summary without reference to symptoms, the presence or absence of symptoms differentiate between class I and II indications.

**NYHA Class Definitions:**
- **Class I:** No limitation of functional activity or only at levels of exertion that would limit normal individuals.
- **Class II:** Slight limitation of activity. Dyspnea and fatigue with moderate exercise.
- **Class III:** Marked limitation of activity. Dyspnea with minimal activity.
- **Class IV:** Severe limitation of activity. Symptoms even at rest.

**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.
  - **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.
- **Third Degree:** No atrial beats are conducted from atrium to ventricle
Abbreviations:

AV = Atrioventricular
CHF = congestive heart failure
CRT = Cardiac resynchronization therapy
EKG = Electrocardiogram
EPS = Electrophysiologic Study
GDMT = Guideline-Directed Medical Therapy
HRS = Heart Rhythm Society
HV = His-ventricle
ICD = Implantable cardioverter-defibrillator
LBBB = left bundle-branch block
LV = Left ventricular/left ventricle
LVEF = Left ventricular ejection fraction
MI = myocardial infarction
MS = milliseconds
NYHA = New York Heart Association
STEMI = ST-elevation Myocardial Infarction
SND = Sinus node dysfunction
VT = Ventricular tachycardia


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REFERENCES


INTRODUCTION:

Echocardiography also known as ‘cardiac ultrasound’ is a diagnostic test that uses ultrasound waves to create an image of the heart muscle. Ultrasound waves that rebound or echo off the heart can show the size, shape, and movement of the heart’s valves and chambers as well as the flow of blood through the heart.

Transthoracic Echocardiograms (TTE) are used to evaluate structural heart disease, ventricular function and valve function. In children and small adults TTE provides accurate anatomic definition of most congenital heart diseases. Coupled with Doppler hemodynamic measurements, Transthoracic Echocardiograms (TTE) usually provides accurate diagnosis and noninvasive serial assessment. Transesophageal echocardiogram (TEE) is an alternative way to perform an echocardiogram where the probe is passed into patient’s esophagus. (See separate guideline on TEE.)

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 pediatric patients are presented first followed by indications for adult patients.

PEDIATRIC PATIENTS (PATIENTS UNDER THE AGE OF 18):

Indications for a transthoracic echocardiography (TTE) for pediatric patients:

- A heart murmur (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.
- Chest pain upon presentation that is not obviously non-cardiac.
- Syncope that is not clearly vasovagal syncope.
- Clearly abnormal ECG.
- Abnormal cardiac structure on a chest x-ray.
- Signs and/or symptoms of heart failure.
- Abnormal physical findings, including clicks, snaps, gallops, a fixed and/or split S2, and decreased pulses.
- Arrhythmia/palpitations, for evaluation of structural heart disease.
- Syndromic patients with a known syndrome associated with congenital or acquired heart disease (Downs syndrome, Noonans syndrome, 22Q deficiency syndrome, Williams syndrome, Trisomy Thirteen, Trisomy Eighteen, Allagille syndrome).
- Failed Pulse oximetry test for any newborn.
- Known or suspected connective tissue diseases that are associated with congenital or acquired heart disease.
- Known or suspected muscular dystrophies associated with congenital heart disease.
- Exposure to anthracycline medications generally in relation to chemotherapy.
- Premature birth where there is suspicion of a Patent Ductus Arteriosus.
- Kawasaki Disease.
- Suspected Rheumatic Fever.
- Family history of sudden death related to a finding that could be present on an echocardiogram.
• 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.
• Cyanotic patients without explanation.
• Suspicion of a fetal abnormality.
• Difficulty breathing with stridor and eating solid foods that might suggest a vascular ring.
• Hypertension.
• Known or suspected endocarditis, including all patients with an indwelling catheter who present with unexplained fever.
• Patients on anticoagulants (to evaluate for thrombus).
• Patients with prosthetic valves.
• Systemic diseases that are associated with cardiac findings, such as connective tissue diseases, sickle cell disease, and HIV infection.
• Patients with a first degree relative who is known to have a genetic acquisition, such as cardiomyopathies (HCM, DCM, ARVD/C, RCM, and LVNC).
• Thromboembolic events.
• Suspected pulmonary hypertension.
• Ventricular pre-excitation with no clinical or holter findings to suggest an arrhythmia, but with suspicion of Ebsteins anomaly, Tumors, HCM or clinical signs of heart failure.

**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.

**Indications for follow-up echocardiograms for 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.
- Valvular regurgitation that is more than mild in asymptomatic child may require annual echocardiogram to assess chamber size and progressive regurgitation.
- Valvular stenosis:
  - Pulmonic Stenosis (PS):
    - Mild to moderate PS in an infant: repeat at 2 weeks and 6 weeks to assess for increasing gradient as PVR drops.
    - Moderate PS in an infant: every 1-3 months for on-going surveillance after the 6-week study.
    - Mild PS in asymptomatic child: every 2-3 years to assess for progression of stenosis.
    - Moderate to severe: annually to assess for progression of stenosis and development of RVH.
  - Aortic Stenosis (AS):
    - Mild AS in an infant: every 6 months, or more depending on the patient’s clinical status and rate of progression.
    - Mild in an asymptomatic child: every 1-2 years to assess for progression of stenosis.
    - Moderate AS in an infant: every 1-3 months to assess for progression and indication for valvuloplasty.
    - Moderate to severe AS: at least every 6-12 months to assess for progressive stenosis, LVH, post-stenotic dilation.
- 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):
    - 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.
    - Moderate to large VSD: Close follow up in response to patient’s clinical status, to assess for LV dilation, mitral regurgitation, associated lesions.
  - Atrial Septal Defect (ASD):
    - Moderate to large ASD: at 6 months intervals to assess for progressive RV dilation, tricuspid regurgitation.
    - Small 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.

See “Additional Information” below

**ADULT PATIENTS**

**Indications for a transthoracic echocardiography (TTE):**

**ACCF/ASE/AHA/ASNC/HFSA/HRS/SCAI/SCCM/SCCT/SCMR 2011 APPROPRIATE USE CRITERIA FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE)**

<table>
<thead>
<tr>
<th>ACCF et al. Criteria # TTE (Indication and Appropriate Use Score)</th>
<th>INDICATIONS</th>
<th>PROPER USE SCORE (4-9); A= Appropriate; U=Uncertain</th>
</tr>
</thead>
</table>

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<table>
<thead>
<tr>
<th>ACCF et al. Criteria #</th>
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<tbody>
<tr>
<td>TTE (Indication and Appropriate Use Score)</td>
<td>General Evaluation of Cardiac Structure and Function</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Suspected Cardiac Etiology—General With TTE</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>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</td>
<td>A(9)</td>
</tr>
<tr>
<td>2</td>
<td>Prior testing that is concerning for heart disease or structural abnormality including but not limited to chest X-ray, baseline scout images for stress echocardiogram, ECG, or cardiac biomarkers</td>
<td>A(9)</td>
</tr>
<tr>
<td></td>
<td>Arrhythmias With TTE</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Frequent VPCs or exercise-induced VPCs</td>
<td>A(8)</td>
</tr>
<tr>
<td>5</td>
<td>Sustained or nonsustained atrial fibrillation, SVT, or VT</td>
<td>A(9)</td>
</tr>
<tr>
<td></td>
<td>Lightheadedness/Presyncope/Syncope With TTE</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Clinical symptoms or signs consistent with a cardiac diagnosis known to cause lightheadedness /presyncope / syncope (including but not limited to aortic stenosis, hypertrophic cardiomyopathy, or HF)</td>
<td>A(9)</td>
</tr>
<tr>
<td>9</td>
<td>Syncope when there are no other symptoms or signs of cardiovascular disease</td>
<td>A(7)</td>
</tr>
<tr>
<td></td>
<td>Perioperative Evaluation With TTE</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Routine perioperative evaluation of cardiac structure and function prior to noncardiac solid organ transplantation</td>
<td>U(6)</td>
</tr>
<tr>
<td></td>
<td>Pulmonary Hypertension With TTE</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Evaluation of suspected pulmonary hypertension including evaluation of right ventricular function and estimated pulmonary artery pressure</td>
<td>A(9)</td>
</tr>
<tr>
<td>17</td>
<td>Routine surveillance (≥1 y) of known pulmonary hypertension without change in clinical status or cardiac exam</td>
<td>A(7)</td>
</tr>
<tr>
<td>18</td>
<td>Re-evaluation of known pulmonary hypertension if change in clinical status or cardiac exam or to guide therapy</td>
<td>A(9)</td>
</tr>
<tr>
<td></td>
<td>TTE for Evaluation of Valvular Function</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Murmur or Click With TTE</td>
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<td>---------------------------------------------------------</td>
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<tr>
<td>TTE (Indication and Appropriate Use Score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>• Initial evaluation when there is a reasonable suspicion of valvular or structural heart disease</td>
<td>A(9)</td>
</tr>
<tr>
<td>37</td>
<td>• Re-evaluation of known valvular heart disease with a change in clinical status or cardiac exam or to guide therapy</td>
<td>A(9)</td>
</tr>
<tr>
<td><strong>Native Valvular Stenosis With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>• Routine surveillance (≥3 y) of mild valvular stenosis without a change in clinical status or cardiac exam</td>
<td>A(7)</td>
</tr>
<tr>
<td>41</td>
<td>• Routine surveillance (≥1 y) of moderate or severe valvular stenosis without a change in clinical status or cardiac exam</td>
<td>A(8)</td>
</tr>
<tr>
<td><strong>Native Valvular Regurgitation With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>44</td>
<td>• Routine surveillance (≥3 y) of mild valvular regurgitation without a change in clinical status or cardiac exam</td>
<td>U(4)</td>
</tr>
<tr>
<td>45</td>
<td>• Routine surveillance (&lt;1 y) of moderate or severe valvular regurgitation without a change in clinical status or cardiac exam</td>
<td>U(6)</td>
</tr>
<tr>
<td>46</td>
<td>• Routine surveillance (≥1 y) of moderate or severe valvular regurgitation without change in clinical status or cardiac exam</td>
<td>A(8)</td>
</tr>
<tr>
<td><strong>Prosthetic Valves With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>47</td>
<td>• Initial postoperative evaluation of prosthetic valve for establishment of baseline</td>
<td>A(9)</td>
</tr>
<tr>
<td>49</td>
<td>• Routine surveillance (≥3 y after valve implantation) of prosthetic valve if no known or suspected valve dysfunction</td>
<td>A(7)</td>
</tr>
<tr>
<td>50</td>
<td>• Evaluation of prosthetic valve with suspected dysfunction or a change in clinical status or cardiac exam</td>
<td>A(9)</td>
</tr>
<tr>
<td>51</td>
<td>• Re-evaluation of known prosthetic valve dysfunction when it would change management or guide therapy</td>
<td>A(9)</td>
</tr>
<tr>
<td>** Infective Endocarditis (Native or Prosthetic Valves) With TTE**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>52</td>
<td>• Initial evaluation of suspected infective endocarditis with positive blood cultures or a new murmur</td>
<td>A(9)</td>
</tr>
<tr>
<td>55</td>
<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>
<td>A(9)</td>
</tr>
</tbody>
</table>

**TTE for Evaluation of Intracardiac and Extracardiac Structures and Chambers**
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>TTE (Indication and Appropriate Use Score)</td>
<td>57</td>
<td>Suspected cardiac mass</td>
</tr>
<tr>
<td>58</td>
<td>Suspected cardiovascular source of embolus</td>
<td>A(9)</td>
</tr>
<tr>
<td>59</td>
<td>Suspected pericardial conditions</td>
<td>A(9)</td>
</tr>
<tr>
<td>61</td>
<td>Re-evaluation of known pericardial effusion to guide management or therapy</td>
<td>A(8)</td>
</tr>
<tr>
<td>62</td>
<td>Guidance of percutaneous noncoronary cardiac procedures including but not limited to pericardiocentesis, septal ablation, right ventricular biopsy, cardiac valvular and structural interventions, radiofrequency ablation, or pericardiocentesis.</td>
<td>A(9)</td>
</tr>
</tbody>
</table>

**TTE for Evaluation of Aortic Disease**

| 63 | 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) | A(9) |
| 64 | Re-evaluation of known ascending aortic dilation or history of aortic dissection to establish a baseline rate of expansion or when the rate of expansion is excessive | A(9) |
| 65 | 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 | A(9) |

**TTE for Evaluation of Hypertension, HF, or Cardiomyopathy**

**Hypertension With TTE**

| 67 | Initial evaluation of suspected hypertensive heart disease | A(8) |
| 69 | Re-evaluation of known hypertensive heart disease without a change in clinical status or cardiac exam | U(4) |

**HF With TTE**

<p>| 70 | Initial evaluation of known or suspected HF (systolic or diastolic) based on symptoms, signs, or abnormal test results | A(9) |
| 71 | 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 | A(8) |
| | Re-evaluation of known HF (systolic or | U(4) |</p>
<table>
<thead>
<tr>
<th>ACCF et al. Criteria # TTE (Indication and Appropriate Use Score)</th>
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<th>APPROPRIATE USE SCORE (4-9); A= Appropriate; U=Uncertain</th>
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</thead>
<tbody>
<tr>
<td>72</td>
<td>diastolic) with a change in clinical status or cardiac exam with a clear precipitating change in medication or diet</td>
<td></td>
</tr>
<tr>
<td>73</td>
<td>• Re-evaluation of known HF (systolic or diastolic) to guide therapy</td>
<td>A(9)</td>
</tr>
<tr>
<td>75</td>
<td>• Routine surveillance (≥1 y) of HF (systolic or diastolic) when there is no change in clinical status or cardiac exam</td>
<td>U(6)</td>
</tr>
<tr>
<td><strong>Device Evaluation (Including Pacemaker, ICD, or CRT) With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>76</td>
<td>• Initial evaluation or re-evaluation after revascularization and/or optimal medical therapy to determine candidacy for device therapy and/or to determine optimal choice of device</td>
<td>A(9)</td>
</tr>
<tr>
<td>77</td>
<td>• Initial evaluation for CRT device optimization after implantation</td>
<td>U(6)</td>
</tr>
<tr>
<td>78</td>
<td>• Known implanted pacing device with symptoms possibly due to device complication or suboptimal pacing device settings</td>
<td>A(8)</td>
</tr>
<tr>
<td><strong>Ventricular Assist Devices and Cardiac Transplantation With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>81</td>
<td>• To determine candidacy for ventricular assist device</td>
<td>A(9)</td>
</tr>
<tr>
<td>82</td>
<td>• Optimization of ventricular assist device settings</td>
<td>A(7)</td>
</tr>
<tr>
<td>83</td>
<td>• Re-evaluation for signs/symptoms suggestive of ventricular assist device-related complications</td>
<td>A(9)</td>
</tr>
<tr>
<td>84</td>
<td>• Monitoring for rejection in a cardiac transplant recipient</td>
<td>A(7)</td>
</tr>
<tr>
<td>85</td>
<td>• Cardiac structure and function evaluation in a potential heart donor</td>
<td>A(9)</td>
</tr>
<tr>
<td><strong>Cardiomyopathies With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>86</td>
<td>• Initial evaluation of known or suspected cardiomyopathy (e.g., restrictive, infiltrative, dilated, hypertrophic, or genetic cardiomyopathy)</td>
<td>A(9)</td>
</tr>
<tr>
<td>87</td>
<td>• Re-evaluation of known cardiomyopathy with a change in clinical status or cardiac exam or to guide therapy and manage post transplantation or post VAD patients</td>
<td>A(9)</td>
</tr>
<tr>
<td>89</td>
<td>• Routine surveillance (≥1 y) of known cardiomyopathy without a change in clinical status or cardiac exam</td>
<td>U(5)</td>
</tr>
<tr>
<td>ACCF et al. Criteria #</td>
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<td>APPROPRIATE USE SCORE (4-9)</td>
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</tr>
<tr>
<td>TTE (Indication and Appropriate Use Score)</td>
<td>• Screening evaluation for structure and function in first-degree relatives of a patient with an inherited cardiomyopathy</td>
<td>A(9)</td>
</tr>
<tr>
<td>90</td>
<td>• Baseline and serial re-evaluations in a patient undergoing therapy with cardiotoxic agents</td>
<td>A(9)</td>
</tr>
<tr>
<td><strong>TTE for Adult Congenital Heart Disease</strong></td>
<td></td>
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</tr>
<tr>
<td>92</td>
<td>• Initial evaluation of known or suspected adult congenital heart disease</td>
<td>A(9)</td>
</tr>
<tr>
<td>93</td>
<td>• Known adult congenital heart disease with a change in clinical status or cardiac exam</td>
<td>A(9)</td>
</tr>
<tr>
<td>94</td>
<td>• Re-evaluation to guide therapy in known adult congenital heart disease.</td>
<td>A(9)</td>
</tr>
</tbody>
</table>
| 96                    | • Routine surveillance (≥2 y) of adult congenital heart disease following complete repair  
  o without residual structural or hemodynamic abnormality  
  o without a change in clinical status or cardiac exam | U(6)                       |
| 97                    | • Routine surveillance (<1 y) of adult congenital heart disease following incomplete or palliative repair  
  o with residual structural or hemodynamic abnormality  
  o without a change in clinical status or cardiac exam | U(5)                       |
| 98                    | • Routine surveillance (≥1 y) of adult congenital heart disease following incomplete or palliative repair  
  o with residual structural or hemodynamic abnormality  
  o without a change in clinical status or cardiac exam | A(8)                       |

**ADDITIONAL INDICATION:**

- For evaluation of asymptomatic patients following repair of Atrial Septal Defect (ASD), Patent Foramen Ovale (PFO), Ventricular Septal Defect (VSD) or Patent Ductus Arteriosus (PDA), follow-up examination is only indicated within the first year following correction.

**ACC GUIDELINES WITH “INAPPROPRIATE” DESIGNATION:**

- Requests that meet ACCF/ASNC Inappropriate use score of (1-3) noted below OR meet any one of the following are not approvable:
  - 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 (such as Heart MRI/CT) unless specific guideline criteria states otherwise (i.e. CT/MRI and now wants Echocardiogram) without high level review to evaluate for medical necessity.
- Additional images for same-study (poor quality, etc).

**ACCF/ASE/AHA/ASNC/HFSA/HRS/SCAI/SCCM/SCCT/SCMR 2011 APPROPRIATE USE CRITERIA FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE):**

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<tr>
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<tbody>
<tr>
<td>General Evaluation of Cardiac Structure and Function</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Arrhythmias With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>• Infrequent APCs or infrequent VPCs without other evidence of heart disease</td>
<td>I(2)</td>
</tr>
<tr>
<td>6</td>
<td>• Asymptomatic isolated sinus bradycardia</td>
<td>I(2)</td>
</tr>
<tr>
<td><strong>Lightheadedness/Presyncope/Syncope With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>• Lightheadedness/presyncope when there are no other symptoms or signs of cardiovascular disease</td>
<td>I(3)</td>
</tr>
<tr>
<td><strong>Evaluation of Ventricular Function</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>• Initial evaluation of ventricular function (e.g., screening) with no symptoms or signs of cardiovascular disease</td>
<td>I(2)</td>
</tr>
<tr>
<td>11</td>
<td>• Routine surveillance of ventricular function with known CAD and no change in clinical status or cardiac exam</td>
<td>I(3)</td>
</tr>
<tr>
<td>12</td>
<td>• Evaluation of LV function with prior ventricular function evaluation showing normal function (e.g., prior echocardiogram, left ventriculogram, CT, SPECT MPI, CMR) in patients in whom there has been no change in clinical status or cardiac exam</td>
<td>I(1)</td>
</tr>
<tr>
<td><strong>Perioperative Evaluation With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>• Routine perioperative evaluation of ventricular function with no symptoms or signs of cardiovascular disease transplantation</td>
<td>I(2)</td>
</tr>
<tr>
<td><strong>Pulmonary Hypertension With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>• Routine surveillance (&lt;1 y) of known pulmonary hypertension without change in clinical status or cardiac</td>
<td>I(3)</td>
</tr>
<tr>
<td>ACCF et al. Criteria # TTE (Indication and Appropriate Use Score)</td>
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</tr>
<tr>
<td><strong>TTE for Evaluation of Valvular Function</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Murmur or Click With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>• Initial evaluation when there are no other symptoms or signs of valvular or structural heart disease</td>
<td>I(2)</td>
</tr>
<tr>
<td>36</td>
<td>• Re-evaluation in a patient without valvular disease on prior echocardiogram and no change in clinical status or cardiac exam</td>
<td>I(1)</td>
</tr>
<tr>
<td><strong>Native Valvular Stenosis With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38</td>
<td>• Routine surveillance (≥3 y) of mild valvular stenosis without a change in clinical status or cardiac exam</td>
<td>I(3)</td>
</tr>
<tr>
<td>40</td>
<td>• Routine surveillance (≥1 y) of moderate or severe valvular stenosis without a change in clinical status or cardiac exam</td>
<td>I(3)</td>
</tr>
<tr>
<td><strong>Native Valvular Regurgitation With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>42</td>
<td>• Routine surveillance of trace valvular regurgitation</td>
<td>I(1)</td>
</tr>
<tr>
<td>43</td>
<td>• Routine surveillance (&lt;3 y) of mild valvular regurgitation without a change in clinical status or cardiac exam</td>
<td>I(2)</td>
</tr>
<tr>
<td><strong>Prosthetic Valves With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>48</td>
<td>• Routine surveillance (&lt;3 y after valve implantation) of prosthetic valve if no known or suspected valve dysfunction</td>
<td>I(3)</td>
</tr>
<tr>
<td><strong>Infective Endocarditis (Native or Prosthetic Valves) With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>53</td>
<td>• Transient fever without evidence of bacteremia or a new murmur</td>
<td>I(2)</td>
</tr>
<tr>
<td>54</td>
<td>• Transient bacteremia with a pathogen not typically associated with infective endocarditis and/or a documented nonendovascular source of infection</td>
<td>I(3)</td>
</tr>
<tr>
<td>56</td>
<td>• Routine surveillance of uncomplicated infective endocarditis when no change in management is contemplated</td>
<td>I(2)</td>
</tr>
<tr>
<td><strong>TTE for Evaluation of Intracardiac and Extracardiac Structures and Chambers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>• Routine surveillance of known small pericardial effusion with no change in clinical status</td>
<td>I(2)</td>
</tr>
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<td>INDICATIONS</td>
<td>PROPRIATE USE SCORE (1-3); I= Inappropriate</td>
</tr>
<tr>
<td>-----------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td><strong>TTE for Evaluation of Aortic Disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66</td>
<td>• Routine re-evaluation for surveillance of known ascending aortic dilation or history of aortic dissection without a change in clinical status or cardiac exam when findings would not change management or therapy</td>
<td>I(3)</td>
</tr>
<tr>
<td><strong>TTE for Evaluation of Hypertension, HF, or Cardiomyopathy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypertension With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>68</td>
<td>• Routine evaluation of systemic hypertension without symptoms or signs of hypertensive heart disease</td>
<td>I(3)</td>
</tr>
<tr>
<td><strong>HF With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>74</td>
<td>• Routine surveillance (&lt;1 y) of HF (systolic or diastolic) when there is no change in clinical status or cardiac exam</td>
<td>I(2)</td>
</tr>
<tr>
<td><strong>Device Evaluation (Including Pacemaker, ICD, or CRT) With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>79</td>
<td>• Routine surveillance (&lt;1 y) of implanted device without a change in clinical status or cardiac exam</td>
<td>I(1)</td>
</tr>
<tr>
<td>80</td>
<td>• Routine surveillance (&gt;1 y) of implanted device without a change in clinical status or cardiac exam</td>
<td>I(3)</td>
</tr>
<tr>
<td><strong>Cardiomyopathies With TTE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>88</td>
<td>• Routine surveillance (&lt;1 y) of known cardiomyopathy without a change in clinical status or cardiac exam</td>
<td>I(2)</td>
</tr>
<tr>
<td><strong>TTE for Adult Congenital Heart Disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Routine surveillance (&lt;2 y) of adult congenital heart disease following complete repair o without a residual structural or hemodynamic abnormality o without a change in clinical status or cardiac exam</td>
<td>I(3)</td>
</tr>
</tbody>
</table>

**TEE in Critical Care:**

TEE is a useful test that can be performed relatively quickly at the bedside in critically ill patients. Indications for TEE in the critically ill are similar to standard TEE indications in all patients. However, certain scenarios in a critically ill patient may be more quickly and thoroughly invested with TEE as the initial diagnostic procedure, including:
• Unexplained hypotension
• Unexplained hypoxemia
• Suspected complications following a myocardial infarction (i.e., acute mitral regurgitation, ventricular septal defect, free wall rupture with cardiac tamponade)
• Uncertain volume status
• Blunt chest trauma

ADDITIONAL INFORMATION:

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 IE and for identifying vegetations in cases where cardiac structures-of-interest are well visualized. Contemporary TTE has improved the diagnostic accuracy of infective endocarditis by ameliorating image quality; it provides an accurate assessment of endocarditis and 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.

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 periannular complications, children with complex congenital cardiac lesions, selected patients with Staphylococcus aureus bacteremia, and certain pre-existing valvular abnormalities that make TTE interpretation problematic (e.g., calcific aortic stenosis). Transthoracic echocardiography is a valuable tool in the perioperative period.

Abbreviations
  ACS = acute coronary syndrome
  APC = atrial premature contraction
  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
REFERENCES


Department of the Brazilian Society of Cardiology recommendations for the use of cardiac imaging to assess and follow patients after heart transplantation. Eur Heart J Cardiovasc Imaging. 2015 Sep;16(9):919-48. doi: 10.1093/ehjci/jev139. Epub 2015 Jul 2


CPT codes: 93312, 93313, 93314, 93315, 93316, 93317, 93318, +93320, +93321, +93325

INTRODUCTION:

Echocardiography also known as ‘cardiac ultrasound’ is a diagnostic test that uses ultrasound waves to create an image of the heart muscle. Ultrasound waves that rebound or echo off the heart can show the size, shape, and movement of the heart’s valves and chambers as well as the flow of blood through the heart.

Transesophageal Echocardiogram (TEE) is an alternative way to perform an echocardiogram where the probe is passed into patient’s esophagus and appropriately used as an adjunct or subsequent test to TTE when suboptimal TTE images preclude obtaining a diagnostic study.

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 TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE):

ACCF/ASE/AHA/ASNC/HFSA/HRS/SCAI/SCCM/SCCT/SCMR 2011 APPROPRIATE USE CRITERIA FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE):

<table>
<thead>
<tr>
<th>ACCF et al. Criteria # TEE (Indication and Appropriate Use Score)</th>
<th>INDICATIONS</th>
<th>APPROPRIATE USE SCORE (4-9); A= Appropriate; U=Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TEE as Initial or Supplemental Test—General Uses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>• 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 a prosthetic valve dysfunction, left atrial thrombus, patent foramen ovale, etc.</td>
<td>A(8)</td>
</tr>
<tr>
<td>101</td>
<td>• 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 anticipated</td>
<td>A(8)</td>
</tr>
<tr>
<td>103</td>
<td>• Guidance during percutaneous noncoronary cardiac interventions including but not limited to closure device placement, radiofrequency ablation, and percutaneous</td>
<td>A(9)</td>
</tr>
</tbody>
</table>
### ACCF et al. Criteria # TEE (Indication and Appropriate Use Score)

<table>
<thead>
<tr>
<th>INDICATIONS</th>
<th>APPROPRIATE USE SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>valve procedures OR • 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</td>
<td>A(9)</td>
</tr>
<tr>
<td>• Suspected acute aortic pathology including but not limited to dissection/transsection</td>
<td>A(9)</td>
</tr>
<tr>
<td><strong>TEE as Initial or Supplemental Test—Valvular Disease</strong></td>
<td></td>
</tr>
<tr>
<td>104</td>
<td></td>
</tr>
<tr>
<td>106</td>
<td>• Evaluation of valvular structure, native and prosthetic, and function to assess suitability for, and assist in planning of, an intervention</td>
</tr>
<tr>
<td>108</td>
<td>• 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)</td>
</tr>
<tr>
<td><strong>TEE as Initial or Supplemental Test—Embolic Event</strong></td>
<td></td>
</tr>
<tr>
<td>109</td>
<td>• Evaluation for cardiovascular source of embolus with no identified noncardiac source</td>
</tr>
<tr>
<td>110</td>
<td>• Evaluation for cardiovascular source of embolus with a previously identified noncardiac source</td>
</tr>
<tr>
<td><strong>TEE as Initial Test—Atrial Fibrillation/Flutter</strong></td>
<td></td>
</tr>
<tr>
<td>112</td>
<td>• Evaluation to facilitate clinical decision making with regards to anticoagulation, cardioversion, and/or radiofrequency ablation</td>
</tr>
</tbody>
</table>

### TEE in Critical Care:

TEE is a useful test that can be performed relatively quickly at the bedside in critically ill patients. Indications for TEE in the critically ill are similar to standard TEE indications in all patients. However, certain scenarios in a critically ill patient may be more quickly and thoroughly invested with TEE as the initial diagnostic procedure, including:

- Unexplained hypotension
- Unexplained hypoxemia
- Suspected complications following a myocardial infarction (i.e., acute mitral regurgitation, ventricular septal defect, free wall rupture with cardiac tamponade)
- Uncertain volume status
- Blunt chest trauma
INDICATIONS IN ACC GUIDELINES WITH “INAPPROPRIATE” DESIGNATION:

Patients that meet ACCF/ASNC Inappropriate use score of (1-3) noted below OR meet any one of the following:

- 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 (such as Heart MRI/CT) unless specific guideline criteria states otherwise (i.e. CT/MRI and now wants Echocardiogram) without high level review to evaluate for medical necessity.
- Additional images for same-study (poor quality, etc).

ACCF/ASE/AHA/ASNC/HFSA/HRS/SCAI/SCCM/SCCT/SCMR 2011 APPROPRIATE USE CRITERIA FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE):

<table>
<thead>
<tr>
<th>ACCF et al. Criteria # TEE (Indication and Appropriate Use Score)</th>
<th>INDICATIONS</th>
<th>APPROPRIATE USE SCORE (1-3); I= Inappropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TEE as Initial or Supplemental Test—General Uses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>• Routine use of TEE when a diagnostic TTE is reasonably anticipated to resolve all diagnostic and management concerns</td>
<td>I(1)</td>
</tr>
<tr>
<td>102</td>
<td>• Surveillance of prior TEE finding for interval change (e.g., resolution of thrombus after anticoagulation, resolution of vegetation after antibiotic therapy) when no change in therapy is anticipated</td>
<td>I(2)</td>
</tr>
<tr>
<td>105</td>
<td>• Routine assessment of pulmonary veins in an asymptomatic patient status post pulmonary vein isolation</td>
<td>I(3)</td>
</tr>
<tr>
<td><strong>TEE as Initial or Supplemental Test—Valvular Disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>107</td>
<td>• To diagnose infective endocarditis with a low pretest probability (e.g., transient fever, known alternative source of infection, or negative blood cultures/atypical pathogen for endocarditis)</td>
<td>I(3)</td>
</tr>
<tr>
<td><strong>TEE as Initial or Supplemental Test—Emolic Event</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>111</td>
<td>• Evaluation for cardiovascular source of embolus with a known cardiac source in which a TEE would not change management</td>
<td>I(1)</td>
</tr>
<tr>
<td><strong>TEE as Initial Test—Atrial Fibrillation/Flutter</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>113</td>
<td>• Evaluation when a decision has been made to anticoagulate and not to perform</td>
<td>I(2)</td>
</tr>
<tr>
<td>ACCF et al. Criteria # TEE (Indication and Appropriate Use Score)</td>
<td>INDICATIONS</td>
<td>APPROPRIATE USE SCORE (1-3); I= Inappropriate</td>
</tr>
<tr>
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</tr>
<tr>
<td></td>
<td></td>
<td>cardioversion</td>
</tr>
</tbody>
</table>

**ADDITIONAL INFORMATION:**

**Abbreviations:**

- ACS = acute coronary syndrome
- APC = atrial premature contraction
- CABG = coronary artery bypass grafting surgery
- CAD = coronary artery disease
- CMR = cardiovascular magnetic resonance
- CRT = cardiac resynchronization therapy
- CT = computed tomography
- ECG = electrocardiogram
- HF = heart failure
- ICD = implantable cardioverter-defibrillator
- LBBB = left bundle-branch block
- LV = left ventricular
- MET = estimated metabolic equivalents of exercise
- MI = myocardial infarction
- RNI = radionuclide imaging
- SPECT MPI = single-photon emission computed tomography myocardial perfusion imaging
- STEMI = ST-segment elevation myocardial infarction
- SVT = supraventricular tachycardia
- TEE = transesophageal echocardiogram
- TIA = transient ischemic attack
- TIMI = Thrombolysis in Myocardial Infarction
- TTE = transthoracic echocardiogram
- UA/NSTEMI = unstable angina/non–ST-segment elevation myocardial infarction
- VPC = ventricular premature contraction
- VT = ventricular tachycardia
- PCI = percutaneous coronary intervention

**REFERENCES**


Ayers, NA, Miller-Hance W., Fyfe DA., Stevenson JG., Sahn DJ., Young LT., Minich LL., et al. (2005) Indications and Guidelines for Performance of Transesophageal Echocardiography in the Patient with

Badano LP, Miglioranza MH., Edvardsen T., Colafranceschi AS., Murare D., Bacal F., Nieman K., et al. (2015) European Association of Cardiovascular Imaging/ Cardiovascular Imaging Department of the Brazilian Society of Cardiology recommendations for the use of cardiac imaging to assess and follow patients after heart transplantation. DOI: http://dx.doi.org/10.1093/ehjci/jev139 919-948 First published online: 2 July 2015


Guidelines for the Use of Echocardiography as a Monitor for Therapeutic Intervention in Adults: A


the Management of Patients with Left Ventricular Assist Devices: Recommendations from the
American Society of Echocardiography, J Am Soc Echocardiogr 2015;28:853-909. DOI:
http://dx.doi.org/10.1016/j.echo.2015.05.008

Thys, DM., Abel MD., Brooker RF., Cahalan MK., Connis RT., Duke PG., Nickinovich DG. et al. (2010)
Practice Guidelines for Perioperative Transesophageal
Echocardiography - An Updated Report by the American Society of Anesthesiologists and the Society
of Cardiovascular Anesthesiologists Task Force on Transesophageal Echocardiography,
Anesthesiology, May 2010, No 5, V 112: 1-7
INTRODUCTION: This guideline is organized around eight clinical scenarios:

VIII. Suspected Coronary Artery Disease (CAD)
IX. Incompletely Evaluated CAD
X. Follow-up of Known Ischemic CAD
XI. CAD in Presence of Other New Cardiac Concerns
XII. Chronic Valvular Disease and Pulmonary Hypertension
XIII. Prior to Noncardiac Surgery
XIV. Prior to Cardiac Rehabilitation or Exercise Program
XV. Post Cardiac Transplantation

This guideline is for stress imaging, specifically stress echocardiography, with exercise or dobutamine, with appropriate preference for suitable alternatives, such as stress EKG alone or stress testing with myocardial perfusion imaging, when more suitable, using the following stream of logic:

- A stress EKG alone is often appropriate. A baseline EKG, which does not allow interpretation of ischemic findings with exercise, will sometimes, but not always, require the addition of stress imaging (echo or MPI).

- When stress imaging is appropriate, as an addition to stress EKG alone, stress echo is preferred when the patient is able to exercise, MPI when the patient cannot exercise. This document does not actively endorse dobutamine echocardiography as a recommended alternative to stress myocardial perfusion imaging for pragmatic reasons, but dobutamine echocardiography can certainly be an acceptable alternative to stress myocardial perfusion imaging when preferred by the clinical provider.

- When stress echo is precluded by specific imaging difficulties (e.g. poor quality image despite contrast medium, uncontrolled atrial fibrillation, ventricular paced rhythm, baseline wall motion abnormalities, etc., as listed in the Additional Information section), then MPI is referred to as the preferable or default strategy.

- Echocardiographic contrast medium is appropriate for those studies in which at least 2 contiguous myocardial segments (of the 16 ACC/AHA myocardial segments) are not visible on the study.

- Hemodynamic assessment can be a reason for preference of stress echocardiography over alternative stress testing.

Compelling indications (e.g. ACC Class I or IIA or Appropriate Use Criteria ‘A’) for stress imaging (echo and MPI) are the foundation, and the less compelling indications (IIB or ‘M’) have been selected as appropriate for those scenarios in which the clinical presentation incurs high risk. If a patient fits two or more clinical scenarios, the scenario which endorses stress echo (MPI only if the default) supersedes any category which does not.
Issues such as pretest probability, global risk of coronary or cardiovascular disease, anginal equivalent, aspects of different types of stress testing, etc. are discussed in the Additional Information section at the end of this document, and the reader is encouraged to refer to that section, in order to optimally utilize this guideline.

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 STRESS ECHO (MPI only if the default) BY CLINICAL SCENARIO

VI. SUSPECTED (CAD):
High Global Risk asymptomatic OR
Stable symptomatic OR
Low risk “unstable” symptomatic (Tables 6 & 7)

• SYMPTOMATIC: LOW PRETEST PROBABILITY patients should undergo a treadmill exercise stress EKG alone, with stress echocardiography reserved for those whose EKG is uninterpretable. (MPI is to be chosen only when it is the default strategy.)

• SYMPTOMATIC: INTERMEDIATE OR HIGH PRETEST PROBABILITY patients are appropriate for stress echo (or MPI if it is the default strategy).

• REPEAT STRESS TESTING FOR SIMILAR SYMPTOMS AND SAME PRETEST PROBABILITY should not be performed for at least 5 years following prior stress testing or invasive coronary arteriography, unless there has been a change in clinical presentation.

• ASYMPTOMATIC HIGH GLOBAL RISK (>20% coronary or vascular event rate over ensuing 10 years) based upon a COMPELLING HISTORY, such as patients with peripheral arterial disease (defined in additional information), cerebrovascular disease (history of stroke or TIA), or multiple simultaneous anti-rejection medications (e.g. cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine, long term supraphysiologic doses of glucocorticoids, but not everolimus or sirolimus/rapamycin), should be assessed with EKG STRESS TEST alone, with stress echocardiography reserved for those whose EKG is uninterpretable. (MPI is to be chosen only when it is the default strategy.)

• ASYMPTOMATIC HIGH GLOBAL RISK (>20% coronary or vascular event rate over ensuing 10 years) based upon Framingham-ATP IV, Reynolds, Pooled Cohort Equation (includes cerebrovascular risk), ACC/AHA Risk Calculator, MESA Risk Calculator (includes calcium score), or very similar risk calculator) or based upon COMPELLING NON-INVASIVE DATA, such as clearly pathologic Q waves on the EKG, marked ST-segment and/or T wave abnormalities of myocardial ischemia without symptoms, clear regional wall motion abnormalities of the left ventricle, or reduced ejection fraction below 50%, should be assessed with EKG STRESS TEST alone, with stress echocardiography reserved for those whose EKG is uninterpretable. (Patients with ejection fraction < 50%, with contraindication to invasive coronary arteriography, are reasonable candidates for stress echocardiogram, with MPI used only if it is the default strategy, e.g. segmental wall motion abnormality, ejection fraction < 40%, unable to exercise, etc.).
• REPEAT EKG STRESS TEST ALONE OF ASYMPTOMATIC HIGH GLOBAL RISK patients (as described in the 2 bullets immediately above), whose last invasive or non-invasive test was over two years ago and was negative for hemodynamically significant obstructive coronary artery disease (i.e. no ischemia on stress testing, no Fractional Flow Reserve (FFR) <= 0.80 for a major vessel, or no angiographic stenosis >70% for a major vessel), is reasonable.

• HIGH OCCUPATIONAL RISK patients (e.g. associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters) or HIGH PERSONAL RISK patients (e.g. scuba divers, etc.), should be assessed with EKG STRESS TEST alone, with stress echocardiography reserved for those whose EKG is uninterpretable. (MPI is to be chosen only when it is the default strategy.) Determinations for screening of asymptomatic patients (without known coronary artery disease) in high-risk occupations should be deferred to those agencies that manage such non-medical necessity.

VII. INCOMPLETELY EVALUATED CAD:
Requires further evaluation within 2 years of a prior coronary evaluation for CLARIFICATION OF DIAGNOSIS OR DISEASE SEVERITY

• NORMAL EXERCISE STRESS TEST EKG within the past 2 years and currently compelling coronary history or symptoms should be considered appropriate indication for a repeat stress test with stress echocardiography (or MPI if it is the default strategy), particularly if there are reasons to avoid cardiac catheterization (CKD, dye allergy, etc.), unless invasive coronary arteriography is strongly indicated (e.g. compelling presentation of moderate or high risk unstable angina).

• ABNORMAL OR INDETERMINATE EXERCISE STRESS EKG or CCTA (coronary computed tomographic angiography) within the past 2 years, for whom a noninvasive approach is preferable to proceeding to invasive coronary arteriography (unclear nature of symptoms, mildly abnormal or borderline EKG stress test or CCTA, CKD, dye allergy, etc.), is an appropriate indication for stress echocardiography (or MPI only if it is the default strategy).

• A WELL DOCUMENTED MYOCARDIAL INFARCTION OR moderate to high risk ACUTE CORONARY SYNDROME WITHIN THE PAST 2 YEARS, when stable, without subsequent stress imaging or invasive coronary arteriography, can be appropriate for stress echocardiography, (MPI only if it is the default strategy), especially when a non-invasive approach is documented to be preferable to invasive coronary arteriography.

• SEVERITY/EXTENT OF ISCHEMIA ASSESSMENT, in order to assist with the management strategy, in patients with prior invasive coronary arteriography within the past 2 years and unclear lesional significance, is an appropriate indication for stress echo (MPI only if it is the default strategy), if it will affect management.

VIII. FOLLOW-UP of KNOWN ISCHEMIC CAD:

D. In need of FOLLOW-UP TESTING for known ischemic coronary artery disease, either ASYMPTOMATIC OR WITH STABLE symptoms

• ROUTINE FOLLOW-UP when last invasive or non-invasive assessment of coronary artery disease showed HEMODYNAMICALLY SIGNIFICANT CAD (ischemia on stress test or FFR <= 0.80 for a major vessel or stenosis >=70% of a major vessel) over two years ago, without supervening
coronary revascularization, is an appropriate indication for stress echocardiography (MPI only if it is the default strategy) in patients with high risk clinical scenarios, such as left ventricular dysfunction (ejection fraction less than 50%) or severe un-revascularized multivessel CAD (if it will alter management), OR in patients with HIGH RISK OCCUPATIONS (e.g. associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters) or a HIGH PERSONAL RISK (e.g. scuba divers, etc.).

- SEVERITY/EXTENT OF ISCHEMIA ASSESSMENT, in order to assist with the management strategy, in patients with recent invasive coronary arteriography AND suspected residual ischemia post incomplete coronary revascularization, is an appropriate indication for stress echo (MPI only if it is the default strategy), if it will affect management.

- MYOCARDIAL VIABILITY TESTING BY Dobutamine Stress Echocardiography (myocardial perfusion imaging at rest is equally suitable), prior to coronary revascularization is reasonable in patients with ejection fraction less than or equal to 50%, if it could significantly alter the revascularization strategy.

E. NEW, RECURRENT, OR WORSENING (PROGRESSIVE) SYMPTOMS in patients with known ischemic CAD (ischemia on stress testing, lesion stenosis >=70%, or FFR <=0.80), which has not been revascularized.

- PRIOR LOW RISK CORONARY EVALUATION AT LEAST TWO YEARS EARLIER (e.g. limited extent of CORONARY ARTERY DISEASE, <5% myocardium at risk), AND NOW WITH NEW STABLE (or low risk unstable), RECURRENT, OR SLOWLY WORSENING (PROGRESSIVE) SYMPTOMS of coronary ischemia, is an appropriate indication for stress echo (MPI only if it is the default strategy) in this patient group. However, regardless of timing of prior non-invasive assessment, clinical documentation of continued problematic symptoms or moderate to highly likely acute coronary syndrome (Table 6) of even low mortality risk (Table 7) is often better assessed with invasive coronary arteriography, particularly when stress testing in the last 2 years and current clinical findings are at odds. This category is very documentation-sensitive and requires judgment.

- INVASIVE CORONARY ARTERIOGRAPHY IS GENERALLY PREFERABLE in those patients, who have a PRIOR MODERATE OR HIGH RISK STRESS TEST RESULT (especially if NOT previously evaluated by invasive coronary arteriography) or a current diagnosis of moderate to high risk UNSTABLE ANGINA, and inappropriate for repeat stress echo (or MYOCARDIAL PERFUSION IMAGING when it is the default strategy), unless supervening reasons to prefer a non-invasive approach are documented in the record (e.g. very unclear symptoms, CKD, dye allergy, etc.), and it could alter management.

F. FOLLOW-UP OF PATIENTS POST CORONARY REVASCULARIZATION

- ASYMPTOMATIC, ROUTINE FOLLOW-UP, stress echocardiography (MPIx only if it is the default strategy) at a minimum of 2 YEARS post coronary artery bypass grafting or 2 YEARS post percutaneous coronary intervention (whichever was the latter) is appropriate only for patients with high direct CORONARY-related risk, such as incomplete coronary revascularization with feasible additional revascularization of residual severe multivessel disease, need for otherwise unevaulated follow up of stenting of unprotected left main coronary artery (LM) disease or left ventricular dysfunction (ejection fraction less than 50%), OR for patients with HIGH
OCCUPATIONAL RISK (e.g. associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters) or HIGH PERSONAL RISK (e.g. scuba divers, etc.).

- NEW, RECURRENT, OR WORSENING SYMPTOMS POST CORONARY REvascularization, with good documentation, are an indication for stress echocardiography (MPI only if it is the default strategy) if it could affect management.

IX. CAD IN PRESENCE OF OTHER NEW CARDIAC CONCERNS

- NON-CORONARY CARDIAC DIAGNOSES support use of stress echocardiography (MPI only if it is the default strategy) in newly diagnosed systolic or diastolic heart failure, sustained VT (> 100 bpm), VF, exercise induced VT or nonsustained VT, frequent PVCs (over 30 per hour), and/or required initiation of antiarrhythmic drug (AAD) therapy when invasive coronary arteriography is not necessarily indicated.

- NEW ONSET ATRIAL FIBRILLATION, in patients with coronary artery disease and/or moderate or high global risk, are candidates for stress echocardiography (MPI only if it is the default strategy) if there has been no coronary evaluation by stress imaging or invasive coronary arteriography within the preceding two years.

- SYNCOPE (specifically, transient loss of consciousness due to global cerebral hypoperfusion characterized by rapid onset, short duration and spontaneous complete recovery, not just any light headedness or dizziness alone) with otherwise intermediate or high global risk of coronary artery disease warrants stress echocardiography (MPI only if it is the default strategy). Documentation supporting classic vasovagal syncope does not warrant stress testing.

- LEFT BUNDLE BRANCH BLOCK, when the history, physical examination, and/or noninvasive ejection fraction together support further evaluation, and invasive coronary arteriography is not already indicated, is an indication for stress echocardiography (MPI only if it is the default strategy).

- EKG STRESS TESTING without imaging is reasonable for EVALUATION OF EXERCISE-INDUCED ARRHYTHMIA (or long QT interval evaluation when the resting QTc is normal), when coronary artery disease is not suspected.

- KAWASAKI DISEASE long-term surveillance is better performed with CCTA, which includes aneurysm assessment.

X. CHRONIC VALVULAR DISEASE AND PULMONARY HYPERTENSION - HEMODYNAMIC ASSESSMENT:

EXERCISE HEMODYNAMICS can be obtained with Stress echocardiography with Doppler when it will affect management of chronic valvular heart disease (e.g. lead to surgery, valvuloplasty, transvalvular heart valve replacement, mitral clip, etc.) and/or pulmonary hypertension (e.g. lead to major change in medical management, surgery for congenital heart disease, etc):
• Asymptomatic patients with moderate or severe chronic valvular heart disease, is an appropriate indication for stress echocardiography, if it will affect management.

• Symptomatic patients with mild or moderate mitral stenosis, moderate mitral regurgitation, or equivocal aortic stenosis (low cardiac output, low stroke volume index <35 ml/sq. M, and/or left ventricular systolic dysfunction), if it will affect management, is an appropriate indication for stress echocardiography, with dobutamine required for the patients with equivocal aortic stenosis.

• For documented suspicion of pulmonary hypertension with normal or borderline elevated pressures on resting echocardiogram, and when needed to assess the effect of therapy for pulmonary hypertension, if it will affect management, stress echocardiography is appropriate.

XI. Prior to NONCARDIAC SURGERY

• THORACOABDOMINAL AORTIC VASCULAR SURGERY is an indication for PREOPERATIVE Stress echo (MPI only if it is the default strategy) if the patient has less than a 4 MET (see Additional Information section) exercise functionality, AND that patient has at least one OPERATIVE clinical risk factor from the list: ischemic coronary artery disease (by study more than two years ago with lesions, which are: >=70% or ischemia producing on prior stress testing or with FFR <=0.80), cerebrovascular disease, insulin-requiring diabetes mellitus, history of congestive heart failure or ejection fraction less than 40%, or CKD with creatinine >= 2 mg/dl. (Such stress imaging is restricted to patients who have not had either stress imaging or invasive coronary arteriography within the past year.) If invasive coronary arteriography is preferable, then preoperative stress imaging is not appropriate.

• UNRELATED TO THE PLANNED SURGICAL PROCEDURE, stress imaging might be indicated for other reasons at the time patients are seen for preoperative cardiac risk evaluation. When such indications for stress imaging are unrelated to the need for the intended non-cardiac surgery, then the record must document those reasons in order to support proceeding with appropriate stress echocardiography (MPI only if it is the default strategy).

• BARIATRIC SURGERY is not considered an indication for preoperative stress testing.

• SOLID ORGAN TRANSPLANTATION is an indication for preoperative stress echocardiography (MPI only if it is the default strategy) if invasive coronary arteriography is not intended as the initial preoperative evaluation of choice, AND there has not been an adequate coronary evaluation within the past year.

VII. Prior to CARDIAC REHABILITATION or EXERCISE PROGRAM

• CARDIAC REHABILITATION ENTRY or DETERMINATION OF EXERCISE CAPACITY is an indication for stress testing with EKG alone, when performed as part of the cardiac rehabilitation program or for purposes of exercise prescription.

VIII. Post CARDIAC TRANSPLANTATION

• During the first five years post cardiac transplantation, patients with glomerular filtration rates less than 40 mL/min/1.73 sq M, or who otherwise should not undergo invasive coronary
arteriography every 1-2 years, are appropriate for stress echocardiography (MPI only if it is the default strategy) every 1-2 years.

- **After the first five years post cardiac transplantation,** in lieu of invasive coronary arteriography:
  1) **patients considered at low risk for transplant vasculopathy** (i.e., with normal invasive coronary arteriography) can have annual stress echocardiography (MPI only if it is the default strategy), and
  2) **patients with transplant coronary vasculopathy** can have annual stress echocardiography (MPI only if it is the default strategy), if the risk of annual invasive coronary arteriography is not acceptable (i.e., high risk of contrast nephropathy).

**ADDITIONAL INFORMATION:**

**Definitions of Coronary Artery Disease:**

7. Percentage stenosis refers to diameter stenosis when angiography is the method and refers to cross sectional narrowing when IVUS (intravascular ultrasound) is the method of determination.

8. 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 (similar to an ankle brachia index, family history of coronary artery disease, or high sensitivity C-reactive protein). Its incorporation into Global Risk can be achieved by using the MESA risk calculator.

9. Stenoses less than 50% are considered nonobstructive coronary artery disease, while stenoses of 50% or more are considered obstructive coronary artery disease. However, the contents of this Guideline are very clear about specifying that ischemic heart disease requires one of three possible determinants:
   - i. Percentage stenosis of at least 70% - by angiography or IVUS (intravascular ultrasound), as described above, for a major vessel
   - ii. FFR (fractional flow reserve) of 0.80 or less for a major vessel
   - iii. Demonstrable ischemic findings on stress testing (acceptable EKG or imaging), that are at least mild in degree

10. 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.” (i.e. A 50% lesion in a tiny septal would be limited obstructive coronary artery disease.)

11. 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.

12. 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 reduction in coronary flow.

**Definition of Peripheral Arterial Disease/Cerebrovascular Disease:**

Non-coronary arterial narrowing causing symptoms (claudication, related tissue demise, threatened limb loss), asymptomatic 70% or more narrowing by non-invasive or invasive evaluation, atherosclerotic arterial aneurysm by non-invasive or invasive evaluation, or aortic atheroma of at least 4 mm thickness. As a subset of peripheral arterial disease, cerebrovascular disease is also defined as a history of stroke or TIA.

**What is a valid 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 by itself is generally not considered an anginal equivalent, and is handled under a separate category in this guideline.

**Pretest Probability of CAD for Symptomatic Patients:**

Pretest probability is a reference to symptoms that need evaluation as potentially coronary in origin.

- **Typical Angina (Definite):** Defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.
- **Atypical Angina (Probable):** Chest pain or discomfort that lacks 1 of the characteristics of definite or typical angina.
- **Nonanginal Chest Pain:** Chest pain or discomfort that meets 1 or none of the typical angina characteristics.

Once the presence of symptoms (Typical Angina/Atypical Angina/Non angina chest pain/Asymptomatic) is determined, the probabilities of CAD can be calculated from the risk algorithms as follows:

<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>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</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>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>50–59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>&gt;60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td></td>
<td>Low</td>
</tr>
</tbody>
</table>

- **Very low:** Less than 5% pretest probability of CAD
- **Low:** Less than 10% pretest probability of CAD
- **Intermediate:** Between 10% and 90% pretest probability of CAD
- **High:** Greater than 90% pretest probability of CAD

**Global Risk of CAD or Vascular Disease**

Global risk of CAD is defined as the probability of developing CAD, including myocardial infarction or CAD death over a given time period and refers to asymptomatic patients without known coronary artery disease. It should be determined by the Framingham Risk Score (ATP IV risk tool), the Reynolds Risk Index, or the Pooled Cohort Equation (which includes cerebrovascular risk). A high risk is considered greater than a 20% risk of a coronary or major vascular event over the ensuing 10 years.

- **CAD Risk—Low**
  Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CAD risk less than 10%.
• **CAD Risk—Moderate**
  Defined by the age-specific risk level that is average or above average. In general, moderate risk will correlate with a 10-year absolute CAD risk between 10% and 20%.

• **CAD Risk—High**
  Defined as the presence of peripheral arterial disease, cerebrovascular disease, or a 10-year absolute CAD risk of greater than 20%.

**Duke Treadmill Score**

The equation for calculating the Duke treadmill score (DTS) is,

\[
DTS = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or 0.1 mV increments}) - (4 \times \text{exercise angina score}),
\]

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 \(\geq +5\)), intermediate risk (with scores ranging from -10 to +4), and high-risk (with a score of \(\leq -11\)) categories.

**What Type of Stress Test is Appropriate?**

**EKG Stress Test versus Stress Echocardiography versus Stress Myocardial Perfusion Imaging**

Appropriate resource utilization, cost effectiveness, and radiation exposure limitation dictate choices in stress testing options.

Five prominent scenarios for an EKG stress test WITHOUT imaging (i.e. exercise treadmill EKG test) are endorsed by 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 EKG for ischemia during exercise:

- The (symptomatic) low pretest probability patient who is able to exercise and has an interpretable EKG
- The (asymptomatic) high global risk patient who is able to exercise and has an interpretable EKG
- 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
- The patient who requires an entrance stress test EKG for a cardiac rehab program or for an exercise prescription

An uninterpretable baseline EKG includes:

- 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)
- EKG 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)
- Prior false positive stress EKG

Exercise remains a valid stressor:

- In patients who can exercise to near maximal heart rate
- For entrance to cardiac rehabilitation or determination of an exercise prescription
- For exercise induced arrhythmia evaluation
• Even with an uninterpretable EKG if stress imaging is appropriate and EKG un-interpretability is acknowledged

Scenarios for choosing stress echocardiography over myocardial perfusion imaging:

The patient can exercise to near maximal heart rate for at least 3 minutes of Bruce protocol, with usage of contrast medium if necessary to enable quality imaging

AND

There is normal baseline systolic function or mild global hypokinesia (ejection fraction 40-50%), without moderate or severe valvular disease. Stress echocardiography with Doppler is appropriate in the patient for whom determination of exercise hemodynamics is helpful.

Exercise Doppler with hemodynamics is the main reason for stress testing.

**When is Myocardial Perfusion Imaging Preferred Over Stress Echocardiography?**
There are circumstances in which myocardial perfusion imaging is generally preferable to stress echocardiography:

- BMI \( \geq 40 \)
- Ventricular paced rhythm, LBBB, WPW
- Frequent PVCs interfering with wall motion assessment
- Prior coronary artery bypass grafting with resultant paradoxical septal motion
- Currently in poorly controlled atrial fibrillation
- Poor cardiac window on echo (documented on echo report as technically limited or difficult, without likely benefit of contrast medium)
- Documented regional wall motion abnormality: dyskinesia, akinesia, or hypokinesia
- Unable to perform ADL’s with documented extent of limitations
- Functional capacity \(<4\) METS or \(<3’\) Bruce protocol
- Arthritis with documented limitations
- Leg/foot amputation
- Active foot wound/ulcer
- Ambulation requires cane or walker
- Confinement to a wheelchair
- Severe chronic obstructive pulmonary disease (based upon PFT findings), severe dyspnea on exertion, or requirement for home oxygen use
- Systolic congestive heart failure with ejection fraction \(<40\%\)
- Recent orthopedic surgery limiting use of a lower extremity

**Determinants of a 4 MET functional capacity:**

Examples of activities:

<4 METs: Slow ballroom dancing, golfing with a cart, playing a musical instrument, and walking at approximately 2 mph to 3 mph

>4 METs: Climbing a flight of stairs or walking up a hill, walking on level ground at 4 mph, and performing heavy work around the house
Tools for Characterization of Unstable Angina:

Risk Stratification in Acute Coronary Syndrome from 2007 ACC/AHA Guidelines

Three Principal Presentations of Unstable Angina (as defined within a two week time frame) (Braunwald)

<table>
<thead>
<tr>
<th>Class</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest angina</td>
<td>Angina occurring at rest and prolonged, usually greater than 20 min</td>
</tr>
<tr>
<td>New-onset angina</td>
<td>New-onset angina of at least CCS class III severity</td>
</tr>
<tr>
<td>Increasing angina</td>
<td>Previously diagnosed angina that has become distinctly more frequent, longer in duration, or lower in threshold (i.e., increased by 1 or more CCS class to at least CCS class III severity)</td>
</tr>
</tbody>
</table>

Table 6: Likelihood that Symptoms Represent an Acute Coronary Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>High Likelihood</th>
<th>Intermediate Likelihood</th>
<th>Low Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Chest or left arm pain or discomfort as chief symptom reproducing prior documented angina</td>
<td>Chest or left arm pain or discomfort as chief symptom</td>
<td>Probable ischemic symptoms in absence of any of the intermediate likelihood characteristics</td>
</tr>
<tr>
<td>Known history of CAD, including MI</td>
<td>Transient MR murmur, hypotension, diaphoresis, pulmonary edema, or rales</td>
<td>Extracardiac vascular disease</td>
<td>Chest discomfort reproduced by palpation</td>
</tr>
<tr>
<td>ECG</td>
<td>New, or presumably new, transient ST-segment deviation (0.5 mm or greater) or T-wave inversion in multiple precordial leads</td>
<td>Fixed Q waves</td>
<td>T-wave flattening or inversion less than 1 mm in leads with dominant R waves</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST depression 0.5 to 1 mm or T-wave inversion greater than 1 mm</td>
<td>Normal ECG</td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>Elevated cardiac TnT, TnT, or CK-MB</td>
<td>Normal</td>
<td>Normal</td>
</tr>
</tbody>
</table>


ACS = acute coronary syndrome; CAD = coronary artery disease; CK-MB = MB fraction of creatine kinase; ECG = electrocardiogram; MI = myocardial infarction; MR = mitral regurgitation; TnT = troponin T; TnT = troponin T.
Table 7: Short Term Risk of Death or Nonfatal MI in Acute Coronary Syndrome

<table>
<thead>
<tr>
<th>Feature</th>
<th>High Risk</th>
<th>Intermediate Risk</th>
<th>Low Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Accelerating tempo of ischemic symptoms in preceding 48 h</td>
<td>Prior MI, peripheral or cerebrovascular disease, or CAD; prior aspirin use</td>
<td>Increased angina frequency, severity, or duration</td>
</tr>
<tr>
<td>Character of pain</td>
<td>Prolonged ongoing (greater than 20 min) rest pain</td>
<td>Prolonged (greater than 20 min) rest angina, now resolute, with moderate or high likelihood of CAD</td>
<td>Angina provoked at a lower threshold</td>
</tr>
<tr>
<td>Clinical findings</td>
<td>Pulmonary edema, most likely due to ischemia</td>
<td>Rest angina (greater than 20 min) or relieved with rest or sublingual NTG</td>
<td>New onset angina with onset 2 weeks to 2 months prior to presentation</td>
</tr>
<tr>
<td></td>
<td>New or worsening MR murmur</td>
<td>Nocturnal angina</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hypotension, bradycardia, tachycardia</td>
<td>New-onset or progressive CCS class III or IV angina in the past 2 weeks without prolonging (greater than 20 min) rest pain but with intermediate or high likelihood of CAD (see Table 6)</td>
<td></td>
</tr>
<tr>
<td>ECG</td>
<td>Angina at rest with transient ST-segment changes greater than 0.5 mm Bundle-branch block, new or presumed new</td>
<td>T-wave changes Pathological Q waves or resting ST-depression less than 1 mm in multiple lead groups (anterior, inferior, lateral)</td>
<td>Normal or unchanged ECG</td>
</tr>
<tr>
<td></td>
<td>Sustained ventricular tachycardia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>Elevated cardiac TnT, TnI, or CK-MB (e.g., TnT or TnI greater than 0.1 µg per ml)</td>
<td>Slightly elevated cardiac TnT, TnI, or CK-MB (e.g., TnT greater than 0.01 but less than 0.1 µg per ml)</td>
<td>Normal</td>
</tr>
</tbody>
</table>

The **TIMI Risk Score** is determined by the sum of the presence of 7 variables at admission: 1 point is given for each of the following variables: age ≥65 years, at least 3 risk factors for CAD, prior coronary stenosis of ≥50%, ST-segment deviation on ECG presentation, at least 2 anginal events in prior 24 hours, use of aspirin in prior 7 days, and elevated serum cardiac biomarkers

**Low-Risk TIMI Score**: TIMI score <2; **High-Risk TIMI Score**: TIMI score ≥2. A low risk TIMI score might still warrant invasive coronary arteriography, when other features, such as symptoms, are compelling.

**Abbreviations**:

AAD antiarrhythmic drug  
ADLs activities of daily living  
CAD coronary artery disease  
CCS Canadian Cardiovascular Society  
CKD chronic kidney disease  
EKG electrocardiogram  
FFR fractional flow reserve  
LBBB left bundle-branch block  
LVH left ventricular hypertrophy  
MI myocardial infarction  
MET estimated metabolic equivalent of exercise  
PFT pulmonary function test  
PVCs premature ventricular contractions  
TIMI Thrombolysis in Myocardial Infarction (Study Group)
REFERENCES

General References for Stress Testing and Ischemic Heart Disease


General References for Stress Echocardiography


Yao S et al Practical Application in Stress Echocardiography, Risk Stratification and Prognosis in Patients with Known or suspected Ischemic Heart disease, JACC Vol 42, No 6, September 17, 2003:1084–90

References for cardiovascular risk:
(Also see links to Online Calculators at end of Reference Section)
References for High Occupational Risk


Reference for peri-operative risk


Reference for unstable angina risk
http://dx.doi.org/10.1161/CIRCULATIONAHA.107.181940.

**Reference for indications for cardiac catheterization/ invasive coronary arteriography:**

http://content.onlinejacc.org/article.aspx?articleid=1182705

**Reference for bariatric surgery risk**

DOI:10.1016/j.jamcollsurg.2012.02.011

**Reference for number of PVCs**

http://circep.ahajournals.org/content/5/1/229.full

**Reference for syncope**


**Reference for left bundle branch block**

Sauer et al, Left Bundle Branch Block. Up to Date, November 4, 2014.

**Reference for right bundle branch block**

**Referenced for police, fireman, pilots, etc.**


**Referenced for Arrhythmias and Long QT Syndrome**


**Reference for Cardiac Transplantation Patients**


**Reference for Microvascular Coronary Disease**


**Reference for Kawasaki Disease**

Reference for Anti-rejection Medication and Vascular Disease


Links to Cardiac/Vascular Risk Online Calculators:

Framingham-ATP IV: http://cvdrisk.nhlbi.nih.gov/

Reynolds Risk Score: http://www.reynoldsriskscore.org/

Pooled Cohort Equation (includes cardiac and cerebrovascular risk): http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example

ACC/AHA Risk Calculator (includes cardiac and cerebrovascular risk): http://tools.acc.org/ASCVD-Risk-Estimator/

MESA Risk Calculator with addition of Coronary Artery Calcium Score: https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx
INTRODUCTION:

Heart Catheterization is an invasive angiographic procedure used to evaluate the presence and extent of coronary artery disease (CAD) as well as ventricular and valvular function. It can be used to perform various tests, including angiography, intravascular ultrasonography, and measurement of cardiac output (CO), detection and quantification of shunts, endomyocardial biopsy, and measurements of myocardial metabolism.

It should be primarily used in acute coronary syndromes and when an intervention is anticipated. These guidelines apply to patients with chronic stable conditions or new but stable conditions. In many but not all of these patients, exercise testing should be done prior to consideration of a left heart catheterization. However, a positive stress test should not automatically lead to cardiac catheterization since angioplasty/stenting may not be the best first-line therapy for stable coronary artery disease.

This guideline may also apply to patients in the acute setting, e.g. patients with acute coronary syndrome or unstable angina, who should receive emergency medical care.

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 LEFT HEART CATHETERIZATION:

- **Acute coronary syndromes:**
  - ST elevation or non-ST elevation myocardial infarction.
  - Acute chest pain suspicious for unstable angina with or without ECG changes.
- **Identification of clinical syndromes in which revascularization may result in prolonged survival:**
  - Left main coronary artery disease.
  - Three vessel coronary artery disease with left ventricular Ejection Fraction (EF) < 50%.
  - Strongly positive stress study, [abnormal hemodynamics, reduced exercise tolerance, strongly positive symptoms, (chest pain/ashen complexion)] and multiple wall motion defects on imaging.
- The clinical diagnosis of unstable angina, even in cases lacking additional supportive noninvasive cardiac testing.
- **Evaluation of patients with known CAD**:
  - Results of noninvasive cardiac studies are equivocal or non-diagnostic, AND
  - Symptoms are not responding adequately to optimized medical therapy
- **Evaluation of patients who**:
  - Are unresponsive to optimized medical therapy, AND
  - Require invasive procedures for pain relief.
- **Further evaluation of the presence and/or extent of coronary artery disease, identified by noninvasive imaging studies, for those cases in which the results of catheterization will have a material impact on the patient management.**
• Causal evaluation of left ventricular dysfunction (congestive heart failure) (EF<50%) in patients suspected of having coronary artery disease.
• Further evaluation of patients in whom non-invasive testing raised concerns for potential significant (>10%) jeopardized myocardium.
• Further evaluation in cases where recent noninvasive cardiac testing resulted in:
  o inability to delineate the clinical problem, or
  o indication for intervention or evaluation of the following conditions:
    ▪ suspicion of cardiomyopathy, or myocarditis.
    ▪ progression of known CAD when symptoms are worsening.
    ▪ coronary grafts.
    ▪ previously placed coronary artery stents.
    ▪ structural disease.
• To rule out coronary artery disease prior to non-coronary cardiac or great vessel surgery (cardiac valve surgery, aortic dissection, aortic aneurysm, congenital disease repair such as atrial septal defect, or pericardial surgery).
• Significant ventricular arrhythmia such as Ventricular Tachycardia/Ventricular Fibrillation (VT/VF).
• Assessment of cardiac transplant for rejection.

ADDITIONAL INFORMATION:

Persistent symptoms indicative of CAD can include typical angina (e.g. exertional chest pain), atypical angina (e.g. arm or jaw pain, chest pressure or tightness), or angina equivalent (e.g. shortness of breath)

Optimized Medical Therapy Optimized Medical Therapy is defined as medical therapy for patients with known CAD consisting of at least an antplatelet, antianginal, and lipid lowering agent. If a patient has a documented contraindication to any of these medications, they have met the criteria for being on OMT. Pharmaceutical agents may include(where tolerated): antiplatelet agents, calcium channel antagonists, partial fatty acid oxidase inhibitors (e.g. ranolazine), statins, short-acting nitrates as needed, long-acting nitrates, beta blocker drugs (if no contraindication and patient can tolerate), angiotensin converting enzyme (ACE) inhibitors/angiotensin receptor blocking (ARB) agents (if no contraindication and patient can tolerate).

* NOTE: For those patients in whom heart catheterization is being requested for the diagnosis of CAD, this may not be required.

REFERENCES


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:

A. Anterior Cervical Decompression with Fusion (ACDF) - Single Level
   Anterior cervical disectomy 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*:
   - 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:
     - upper extremity weakness
     - unsteady gait related to myelopathy/balance or generalized lower extremity weakness
     - disturbance with coordination
     - hyperreflexia
     - Hoffmann sign
     - positive Babinski sign;
   OR
• 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.

OR
• When All of the following criteria are met:
  o **Cervical radiculopathy** or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity; **AND**
  o Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least 6 weeks of conservative treatment; **AND**
  o **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. Imaging studies may include:
    - MRI (preferred study for assessing cervical spine soft tissue); **OR**
    - 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).

* Cervical spine decompression with fusion as first-line treatment without conservative care measures in the following clinical cases:
  • As outlined above for myelopathy or progressive neurological deficit scenarios.
  • Significant spinal cord or nerve root compression due to tumor, infection or trauma.
  • Fracture or instability on radiographic films measuring:
    o Sagittal plan angulation of greater than 11 degrees at a single interspace greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction **OR**
    o Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

Not Recommended:
• In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
• 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 E. Cervical Fusion for Treatment of Axial Neck Pain Criteria*

**B. Anterior Cervical Decompression with Fusion (ACDF) - Multiple Level**
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**:

• 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:
  • upper extremity weakness
  • unsteady gait related to myelopathy/balance or generalized lower extremity weakness
  • disturbance with coordination
  • hyperreflexia
  • Hoffmann sign
  • positive Babinski sign;
OR

- 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.

OR

- **When ALL** of the following criteria are met:
  - Cervical radiculopathy or myelopathy due to ruptured disc, spondylosis, spinal instability, or deformity: **AND**
  - Persistent or recurrent pain/symptoms are unresponsive to **at least 6 weeks** of conservative treatment: **AND**
  - 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:
    - MRI (preferred study for assessing cervical spine soft tissue): OR
    - 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)

* Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases:
  - As outlined above for myelopathy or progressive neurological deficit scenarios.
  - Significant spinal cord or nerve root compression due to tumor, infection or trauma.
  - Fracture or instability on radiographic films measuring:
    - Sagittal plan angulation of greater than 11 degrees at a single interspace greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction: **OR**
    - Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

Not Recommended:

- In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
- 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 E. Cervical Fusion for Treatment of Axial Neck Pain Criteria.

C. **Cervical Posterior Decompression with Fusion - Single Level**

Surgical indications for cervical spine stenosis/cervical spondylotic myelopathy (CSM) must meet the following criteria*:

- 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:
  - upper extremity weakness
  - unsteady gait related to myelopathy/balance or generalized lower extremity weakness
  - disturbance with coordination
  - hyperreflexia
  - Hoffmann sign
  - positive Babinski sign;

OR
• 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.

OR
• When **ALL of the following criteria are met**:  
  o Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or
deformity; **AND**  
  o Persistent or recurrent symptoms/pain with functional limitations that is unresponsive to at
least 6 weeks of conservative treatment; **AND**  
  o 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.  
Imaging studies may include:  
  - MRI (preferred study for assessing cervical spine soft tissue); **OR**  
  - 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**  
  o Single level **symptomatic cervical** disease as evidence by:  
    - cervical spinal stenosis due to cervical spondylotic myelopathy (CSM); or
    - cervical spinal stenosis due to ossification of the posterior longitudinal ligament (OPLL); or
    - single level spinal cord or nerve root compression due to herniated disc.

* Cervical spine decompression with fusion performed as first-line treatment without
conservative care measures in the following clinical cases:
  • As outlined above for myelopathy or progressive neurological deficit scenarios.
  • Significant spinal cord or nerve root compression due to tumor, infection or trauma.
  • Fracture or instability on radiographic films measuring:
    o Sagittal plan angulation of greater than 11 degrees at a single interspace greater than
5.5mm anterior subluxation in association with radicular/cord dysfunction; **OR**  
    o Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult
and 5 mm in a child.

Not Recommended:
• In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
• 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 E. Cervical Fusion for Treatment of Axial Neck
  Pain Criteria.
• In patients with kyphosis or at risk for development of postoperative kyphosis.

D. **Cervical Posterior Decompression with Fusion - Multiple Levels**
Surgical indications for cervical spine stenosis/cervical spondylotic myelopathy (CSM) must meet the
following criteria*:

• 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:  
  • upper extremity weakness
- unsteady gait related to myelopathy/balance or generalized lower extremity weakness
- disturbance with coordination
- hyperreflexia
- Hoffmann sign
- positive Babinski sign

OR
- 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.

OR
- **When ALL of the following criteria are met:**
  - Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity: **AND**
  - Persistent or recurrent symptoms/pain with functional limitations that is unresponsive to at least 6 weeks of conservative treatment: **AND**
  - Imaging studies indicate significant spinal cord or spinal nerve root compression at **multiple levels corresponding with the clinical findings.** Imaging studies may include:
    - MRI (preferred study for assessing cervical spine soft tissue); OR
    - 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**
  - **Multilevel (>=2) symptomatic cervical disease as evidence by:**
    - cervical spinal stenosis due to cervical spondylotic myelopathy (CSM); or
    - cervical spinal stenosis due to ossification of the posterior longitudinal ligament (OPLL); or
    - evidence of significant spinal cord or nerve root compression from herniated discs at two or more levels.

* Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases:
  - As outlined above for myelopathy or progressive neurological deficit scenarios.
  - Significant spinal cord or nerve root compression due to tumor, infection or trauma.
  - Fracture or instability on radiographic films measuring:
    - Sagittal plan angulation of greater than 11 degrees at a single interspace greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction: **OR**
    - Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

Not Recommended:
- In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
- 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 E. Cervical Fusion for Treatment of Axial Neck Pain Criteria.*
- In patients with kyphosis or at risk for development of postoperative kyphosis.

E. **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:**

- 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 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**
- All pain generators are adequately defined and treated: **AND**
- All physical medicine and manual therapy interventions are completed: **AND**
- X-ray, MRI, or CT demonstrating disc pathology or spinal instability: **AND**
- Spine pathology limited to one or two levels unless other complicating factors are involved: **AND**
- Psychosocial evaluation for confounding issues addressed.

**NOTE:** The effectiveness of three-level or greater cervical fusion for non-radicular pain has not been established.

**F. Cervical Posterior Decompression**

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:**

- 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:
  - upper extremity weakness
  - unsteady gait related myelopathy/balance or generalized lower extremity weakness
  - disturbance with coordination
  - hyperreflexia
  - Hoffmann sign
  - positive Babinski sign;

**OR**

- 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.

**OR**

- **When ALL of the following criteria are met:**
  - Cervical radiculopathy from ruptured disc, spondylosis, or deformity: **AND**
  - Persistent or recurrent symptoms/pain with functional limitations that is unresponsive to at least 6 weeks of conservative treatment: **AND**
  - Imaging studies confirm the presence of spinal cord or spinal nerve root compression at the level(s) **corresponding with the clinical findings**. Imaging studies may include any of the following:
    - MRI (preferred study for assessing cervical spine soft tissue): **OR**
    - 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):

* Cervical decompression performed as first-line treatment without conservative care in the following clinical cases:
  - As outlined above for myelopathy or progressive neurological deficit scenarios.
  - Spinal cord or nerve root compression due to tumor, infection or trauma.

Not Recommended:
- In asymptomatic or mildly symptomatic cases.
- In cases of pain alone, without neurological deficits and abnormal imaging findings. See E. Cervical Fusion for Treatment of Axial Neck Pain Criteria.

G. 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.

Indications for artificial cervical disc replacement are as follows:
- Skeletally mature patient; \textbf{AND}
- Patient has intractable radiculopathy caused by one or two level disease (either herniated disc or spondolytic osteophyte) located at C3-C7; \textbf{AND}
- Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least 6 weeks of appropriate conservative treatment. (Appropriate conservative treatment must include a dedicated program of physical therapy / rehabilitation); \textbf{AND}
- Imaging studies confirm the presence of compression at the level(s) corresponding with the clinical findings (MRI or CT); \textbf{AND}
- Patient must be \textbf{free from smoking and/or nicotine use} for at least six weeks prior to surgery and during the entire period of healing.
- No prior neck surgery; \textbf{AND}
- Use of an FDA-approved prosthetic intervertebral discs

Cervical Artificial Disc Replacement is NOT indicated when any of the following clinical scenarios exists:
- Symptomatic multiple level disease affecting 3 or more levels
- Adjacent level disease: degenerative disease adjacent to a previous cervical fusion
- Infection (at site of implantation or systemic)
- Osteoporosis or osteopenia
- Instability
  - Translation greater than 3mm difference between lateral flexion-extension views at the symptomatic levels;
  - 11 degrees of angular difference between lateral flexion-extension views at the symptomatic levels
- Sensitivity or allergy to implant materials
- Severe spondylosis defined as:
  - > 50% disc height loss compared to minimally or non-degenerated levels; OR
  - Bridging osteophytes; OR
  - Absence of motion on lateral flexion-extension views at the symptomatic site
- Severe facet arthropathy
- Ankylosing spondylitis
• Rheumatoid arthritis
• Previous fracture with anatomical deformity
• Ossification of the posterior longitudinal ligament (OPLL)
• Active cervical spine malignancy

H. 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.

I. Cervical Anterior Decompression (without fusion)
All requests for anterior decompression without fusion will be reviewed on a case-by-case basis.

ADDITIONAL INFORMATION:

*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 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).

A comprehensive assimilation of factors should lead to a specific diagnosis with positive identification of the pathologic condition(s).

• Early intervention may be required in acute incapacitating pain or in the presence of progressive neurological deficits.
• Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.
• 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.
• 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.
• 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.
• 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.
• 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.

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. 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 spondylotic.

Anterior Approaches – Additional Information:
• 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.
• 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 postoperative 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).
• 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).
• 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.

Posterior Approaches
• 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.
• 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 degenerative spinal stenosis.
• 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


**Fusion References**


CPT Codes:
Lumbar Fusion (Single level) = 22533, 22558, 22612, 22630, 22633  Plus Decompression
Lumbar Fusion (Multiple levels) = 22533, +22534, 22558, +22585, 22612, +22614, 22630, +22632, 22633, +22634  (+ indicates multiple level)  Plus Decompression
Lumbar Decompression = 63030, +63035, 63005, 63012, 63017, 63042, +63044, 63047, +63048, 63056,
+63057
Lumbar Microdiscectomy = 63030, +63035

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

A. 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.

B. Lumbar Decompression (Laminectomy, Facetectomy and Foraminotomy): Laminectomy is 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.

C. 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 & PRE-SACRAL SURGERY: (This section of the clinical guidelines provides the clinical criteria each of the lumbar and pre-sacral spine surgery categories.)
• **Indications for Lumbar Discectomy/Microdiscectomy** - Surgical indications for inter-vertebral disc herniation*:
  o Primary radicular symptoms noted upon clinical exam that significantly hinders daily activities: **AND**
  o Failure to improve with at least six consecutive weeks of appropriate conservative treatment. Appropriate conservative treatment should include a structured program of physical therapy and / or lumbar epidural steroid injections at minimum. Other treatments (chiropractic, NSAIDS, etc.) may also be employed: **AND**
  o Imaging studies showing evidence of inter-vertebral disc herniation that correlate exactly with the patients symptoms / signs

• **Other indications**: Microdiscectomy may be used as the first line of treatment (**no conservative treatment required**) in the following clinical scenarios:
  o 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**
  o Cauda equina syndrome (loss of bowel or bladder control).

**NOTE**: Percutaneous lumbar discectomy or radiofrequency disc decompression procedures are deemed investigational procedures and are not approved.

• **Indications for Lumbar Decompression** - Laminectomy, 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*:
  o Neurogenic claudication, and/or radicular leg pain that impairs daily activities for **at least twelve (12) weeks**: **AND**
  o Failure to improve with at least 6 weeks of appropriate conservative therapy. Appropriate conservative treatment should include a structured program of physical therapy and / or lumbar epidural steroid injections at minimum. Other treatments (chiropractic, NSAIDS, etc.) may also be employed: **AND**
  o Imaging findings consistent with clinical signs/symptoms: **AND**
  o Imaging studies do not show evidence of **significant spinal instability**. Significant instability is defined as greater than 3mm spondylolisthesis or greater than 3mm shift on lateral flexion / extension films.

*Other Indications*: Lumbar decompression may be used as the first line of treatment (**no conservative treatment required**) in any of the following clinical scenarios:
  o 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.
  o Cauda equina syndrome (loss of bowel or bladder control)
  o Spinal stenosis due to tumor, infection, or trauma

A. **Indications for Lumbar Spine Fusion** - Single Level 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. The following indicators must be present*:

- Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for at least 6 months; AND
- Failure to improve with at least 6 weeks of appropriate conservative therapy. Appropriate conservative treatment should include a structured program of physical therapy and/or lumbar epidural steroid injections at minimum. Other treatments (chiropractic, NSAIDS, etc.) may also be employed; AND
- Imaging studies corresponding to the clinical findings; AND
- At least one of the following clinical conditions:
  - Spondylolisthesis [Neural Arch Defect - Spondylolytic spondylolisthesis, degenerative spondylolisthesis, and congenital unilateral neural arch hypoplasia]; OR
  - Evidence of segmental instability - Excessive motion, as in degenerative spondylolisthesis, segmental instability, and surgically induced segmental instability; OR
  - 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; OR
  - Revision surgery for failed previous operation(s) repeat disk herniations if significant functional gains are anticipated; OR
  - Fusion for the treatment of spinal tumor, cancer, or infection; OR
  - Chronic low back pain or degenerative disc disease must have failed at least 6 months of active non-operative treatment (completion of a comprehensive cognitive-behavioral rehabilitation program is mandatory) and must be evaluated on a case-by-case basis.

*Other Indications: Lumbar spinal fusion may be used as the first line of treatment (no conservative treatment required) in the following clinical scenarios:

- 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.
- Cauda equina syndrome (loss of bowel or bladder control)

** 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:

- Rationale as to why surgery is preferred over other non-invasive or less invasive treatment procedures.
- 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. Pre-Sacral Fusion Codes: 0195T, +0196T, 22586, 0309T. Artificial lumbar disc replacement or other lumbar implants are not an approved procedure due to insufficient evidence. Lumbar Artificial Disc Replacement/Implant Codes: 22857, +0163T, 22862, +0164T, 22865, +0165T, 0221T, +0222T.

Indications for multi-level fusions 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. The following clinical indications must be present*:

- Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for at least 6 months; AND
- Failure to improve with at least 6 weeks of appropriate conservative therapy. Appropriate conservative treatment should include a structured program of physical therapy and/or lumbar epidural steroid injections at minimum. Other treatments (chiropractic, NSAIDS, etc.) may also be employed; AND
- Imaging studies corresponding to the clinical findings; AND
- At least one of the following clinical conditions:
  - Multiple level spondylolisthesis; OR
  - Fusion for the treatment of spinal tumor, trauma, cancer, or infection affecting multiple levels; OR
  - Intra-operative segmental instability

*Other Indications: Lumbar spinal fusion may be used as the first line of treatment (no conservative treatment required) in the following clinical scenarios:

Progressive nerve compression resulting in an acute neurologic deficit (motor), AND one of the aforementioned clinical conditions. 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.

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.

This lumbar surgery guideline does not address spinal deformity surgeries or the clinical indications for spinal deformity surgery [CPT codes 22800-22812].

NOTE: Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is not an approved surgical approach due to insufficient evidence. Pre-Sacral Fusion Codes: 0195T, +0196T, 22586, 0309T. Artificial lumbar disc replacement or other lumbar implants are not an approved procedure due to insufficient evidence. Lumbar Artificial Disc Replacement/Implant Codes: 22857, +0163T, 22862, +0164T, 22865, +0165T, 0221T, +0222T

CONTRAINDICATIONS FOR SPINE SURGERY (Note: Cases will not be approved if the below contraindications exist):
• **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

• **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. 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.

  o **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.

• **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. These cases will be reviewed on a case-by-case basis and may be denied given the risk of failure.

### ADDITIONAL INFORMATION

**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.

**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 trocar 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.

**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.

**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.

**Nucleus Pulpous 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.

**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. Lumbar Artificial Disc Replacement Codes: 22857, +0163T, 22862, +0164T, 22865, +0165T, 0221T, +0222T

**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.

**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 4-6 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).

**Claims Billing & Coding:**
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:

- **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.

- **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.
  - 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.
  - 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.

- **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.

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:

- Intertransverse Fusion or Posterolateral Fusion
- Anterior Interbody Fusion (ALIF)
- Lateral or Transpsoas Interbody Fusion (XLIF)
- Posterior or Trans-foraminal Interbody Fusion (PLIF or TLIF)
- Anterior/posterior Fusion (360-degree)
- Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is still being investigated and is not recommended.

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).

All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. 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.

Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.

- 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.
- 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).

In general, if the program of non-operative treatment fails, operative treatment is indicated when:

- 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
- 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.
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.

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.

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


CPT Codes:
Cervical Thoracic Region: 62310 (+77003), 64479 (+64480), 0228T, +0229T
Lumbar Sacral Region: 62311 (+77003), 64483 (+64484), 0230T, +0231T

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:

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. Interlaminar epidural injections are the most common type of epidural injection.

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 transforaminal epidural injections. These procedures are always aided with fluoroscopic guidance.

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. 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.

**INDICATIONS FOR EPIDURAL INJECTIONS OR SELECTIVE NERVE BLOCKS (caudal, interlaminar, and transforaminal) (Injection of local anesthetics with corticosteroids)**

- Acute pain or exacerbation of chronic radicular pain with the following clinical timeframes:
  - Neck or Back Pain with acute radicular pain:
    - after 2 weeks or more of acute radicular pain that has failed to respond or poorly responded to active conservative (including medication) management unless the medical reason this conservative treatment cannot be done is clearly documented; OR
  - Failed back surgery syndrome or epidural fibrosis causing radicular pain:
    - typically not done immediately post-surgery. Documentation requires a medical reason that clearly indicates why an injection is needed.
    - patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months prior to epidural injections unless the medical reason this conservative treatment cannot be done is clearly documented; OR
  - Spinal stenosis (foraminal, central or disc disease) causing radicular pain
    - patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months prior to epidural injections unless the medical reason this conservative treatment cannot be done is clearly documented.

**AND**

- Average pain levels of ≥ 6 on a scale of 0 to 10 or intermittent or continuous pain causing functional disability.

**FREQUENCY OF REPEAT THERAPEUTIC INJECTIONS:**

- 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:
  - Documented proof that the prior injection had a positive response by significantly decreasing the patient’s pain (at least 30-50% reduction in pain after initial injections or significant documented functional improvement). 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; AND
  - The patient continues to have ongoing pain or documented functional disability (≥ 6 on a scale of 0 to 10); AND
  - The patient is actively engaged in other forms of active conservative non-operative treatment (unless pain prevents the patient from participating in conservative therapy*); AND
Injections meet the following criteria:

- There must be at least 14 days between injections;
- No more than 3 procedures in a 12-week period of time per region;
- Limited to a maximum total of 6 procedures per region per 12 months.

Course of treatment, up to three epidural injections, regardless of approach must provide at least:

- At least 50% or more cumulative pain relief obtained for a minimum of 6 weeks to be considered a positive and effective response.
- NOTE: Each epidural injection requires an authorization.

If the neural blockade is applied for different regions, injections may be administered at intervals of no sooner than 14 days for most types of procedures.

Injecting multiple regions or performing multiple procedures during the same visit may be deemed medically unnecessary unless documentation is provided outlining an unusual situation.

No more than 2 levels of transforaminal blocks should be done in one day.

NOTE: An injection of opioid or other substance for the purpose of completing a trial for an implantable infusion pump is approvable.

CONTRAINDICATIONS FOR EPIDURAL INJECTIONS

- Bleeding diathesis and full anticoagulation (risk of epidural hematoma);
- Severe spinal stenosis resulting in intraspinal obstruction;
- Local infection at injection site;
- Predominantly psychogenic pain;
- Sepsis;
- Hypovolemia;
- Uncontrolled diabetes;
- Uncontrolled glaucoma;
- High concentrations of local anesthetics in patients with multiple sclerosis;
- For diagnosis or treatment of facet mediated pain;
- Known or suspected allergic reaction to steroid medications;
- Spinal infection;
- Malignancy; OR
- Acute fracture.

ADDITIONAL INFORMATION:

*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, 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 4-6 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).

**Terminology**: Interlaminar Epidural; Selective Nerve Root Injection (transforaminal only);
Transforaminal Injection; Injections of Spinal Canal

**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.

**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.

**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.

**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.

**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.

**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.
inflammation resulting from the surgical procedure may start the process of fibrosis and cause pain. Epidural steroid injections are administered to reduce pain.

**Discogenic pain** - Discogenic pain is predominant low back pain without disc herniation. 80% to 90% of low back pain is commonly believed to be of unknown etiology. The term, discogenic disc disease, may refer to degenerative disc disease or to internal disc disruption syndrome. Patients with the latter condition may have painful invertebral discs despite minimal degenerative changes. In the U.S., discogenic pain accounts for 25% of cases of chronic low back pain. Evidence has shown that epidural steroid injections are effective for short-term improvement of discogenic pain.

**REFERENCES**


CPT Codes:
Cervical Thoracic Region: 64490 (+ 64491, +64492), 0213T, +0214T, +0215T
Lumbar Sacral Region: 64493 (+64494, +64495), 0216T, +0217T, +0218T

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.

INDICATIONS FOR FACET JOINT INJECTIONS OR MEDIAL BRANCH NERVE BLOCKS:
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:
  o history, consisting of mainly axial or non-radicular pain; AND
  o Lack of evidence, either for discogenic or sacroiliac joint pain; AND
  o Lack of disc herniation or evidence of radiculitis; AND
  o Facet blocks should not be performed at same levels as previous surgical fusion; AND
  o Intermittent or continuous pain with average pain levels of ≥ 6 on a scale of 0 to 10 or functional disability prior to each injection, including each unilateral facet block; AND
  o Duration of pain of at least 2 months; AND
  o Failure to respond to active conservative non-operative therapy management for a minimum of 6 weeks in the last 6 months prior to facet injections unless the medical reason this treatment cannot be done is clearly documented.
  o All procedures must be performed using fluoroscopic or CT guidance.

NOTE: Ultrasound guidance is not a covered benefit and procedure performed using ultrasound guidance are not reimbursable.

FREQUENCY OF FACET BLOCK:

  o There must be a minimum of 14 days between injections.
  o There must be a positive response of ≥ 50% pain relief or improved ability to function. 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*).
  o Maximum of 3 procedures per region every 6 months. (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.)
  o If the procedures are applied for different regions, they may be performed at intervals of no sooner than 2 weeks for most types of procedures.
  o Maximum of 3 levels injected on same date of service.
  o Radiofrequency neurolysis procedures should be considered in patients with positive facet blocks (with at least 50% pain relief and/or improved ability to function, but with insufficient sustained relief (less than 2-3 months improvement).

CONTRAINDICATIONS FOR FACET JOINT INJECTIONS:

  o History of allergy to contrast administration, local anesthetics, steroids, or other drugs potentially utilized;
  o Hypovolemia;
  o Infection over puncture site;
  o Bleeding disorders or coagulopathy;
  o History of allergy to medications to be administered;
  o Inability to obtain percutaneous access to the target facet joint;
  o Progressive neurological disorder which may be masked by the procedure;
  o Pregnancy;
  o Spinal infection; OR
  o Acute Fracture

ADDITIONAL INFORMATION:
*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 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).

Terminology: Facet Injections; Facet Joint Blocks; Paravertebral Facet Injections; Paravertebral Facet Joint Injections; Paravertebral Facet Joint Nerve Injections; Zygapophyseal 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. Used most often for facet joint pain, radiofrequency neurolysis is recently emerging for sacroiliac joint pain. However, it has been shown to have limited evidence in treating sacroiliac joint pain and is considered investigational and not medically necessary.

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.

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)

- Positive response to one or two controlled local anesthetic blocks of the facet joint, with at least 50% pain relief and/or improved ability to function, 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; OR

- Positive response to prior radiofrequency neurolysis procedures with at least 50% pain relief and/or improved ability to function for at least 6 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*); AND

- The presence of ALL of the following:
  - Lack of evidence that the primary source of pain being treated is from discogenic pain, sacroiliac joint pain, disc herniation or radiculitis;
  - Intermittent or continuous facet-mediated pain [average pain levels of ≥ 6 on a scale of 0 to 10] causing functional disability prior to each radiofrequency procedure including radiofrequency procedures done unilaterally on different days;
  - Duration of pain of at least 3 months.

FREQUENCY:

- Relief typically lasts between 6 and 12 months and sometimes provides relief for greater than 2 years.
- Limit to 2 facet neurolysis procedures every 12 months, per region (cervical, thoracic and lumbar are each considered one region). 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.

CONTRAINDICATIONS FOR PARAVERTEBRAL FACET JOINT DENERVATION (RADIOFREQUENCY NEUROLYSIS):

- History of allergy to local anesthetics or other drugs potentially utilized;
- Lumbosacral radicular pain (dorsal root ganglion);
- Conditions/diagnosis for which procedure is used are other than those listed in Indications;
- Absence of positive diagnostic blocks; OR
- For any nerve other than the medial branch nerve.
ADDITIONAL INFORMATION:

*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 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).

**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


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—anteriortly, 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:
  - upper or lower extremity weakness
  - unsteady gait related to myelopathy/balance or generalized lower extremity weakness
  - disturbance with coordination
  - hyperreflexia
  - Hoffmann sign
  - 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:**

- Deformity Cases—please refer to our *Deformity Spine Surgery (Adult) Guideline.*

OR

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.

- 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:
  - upper extremity weakness
  - unsteady gait related to myelopathy/balance or generalized lower extremity weakness
  - impaired coordination
  - hyperreflexia
  - Hoffmann sign
  - 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;

AND

- Anticipated intra-operative destabilization due to extensive thoracic decompression surgery;

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 commensurate with the clinical findings (MRI or CT);

AND

- Anticipated intra-operative destabilization due to extensive thoracic decompression surgery.

**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 four 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

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 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 and Bogduk, 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.

Indications for Sacroiliac Joint Injections (SIJ)

For the treatment of SIJ pain:

- All of the following must be met:
  - Low back pain maximal below level of L5 which may radiate to the groin or lower extremity persisting at least 3 months; AND
  - 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; AND
  - 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.

For the treatment of spondyloarthropathy
• **All** of the following must be met:
  o The patient has experienced ≥ 3 months of low back pain; AND
  o Age of onset < 45 years; AND
  o Comprehensive pain management program including physical therapy, home exercise, patient education, psychosocial support and/or oral medication is in place; AND
  o 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
  o **1 or more** spondyloarthropathy features:
    a. Inflammatory back pain with **at least 4** of the following criteria present:
      i. Age at onset < 45 years
      ii. Insidious onset
      iii. Improvement with exercise
      iv. No improvement with rest
      v. Pain at night (with improvement upon getting up)
    b. Arthritis
    c. Enthesitis of the heel (irritability of muscles, tendons, or ligaments where they enter the bone)
    d. Uveitis (inflammation of the uvea, the middle layer of the eye)
    e. Dactylitis (inflammation of a finger or toe)
    f. Psoriasis
    g. Crohn’s/colitis
    h. Good response to NSAIDs
    i. Family history of spondyloarthropathy
    j. Positive testing for HLA-B27
    k. Elevated C-reactive protein (CRP)

**FREQUENCY OF REPEAT THERAPEUTIC INJECTIONS**

• SIJ injections may only be repeated if symptoms recur and the patient has had at least a 50% improvement after each injection; AND
• The injections are performed as one part of a comprehensive treatment program, which will nearly always include an exercise program to improve or maintain spinal mobility; AND
• Repeat injections should not be done more frequently than every six weeks for a total of 4 injections in a 12 month period. (Cardone and Tallia, 2002).

**CONTRAINDICATIONS FOR SACROILIAC JOINT INJECTIONS**

• Active systemic infection
• Skin infection at the site of needle puncture
• Bleeding disorder or anticoagulation therapy
• Uncontrolled high blood pressure
• Uncontrolled diabetes
• Unstable angina
• Congestive heart failure
• Allergies to contrast, anesthetics, or steroids (AAOS, 2009)

**ADDITIONAL INFORMATION**
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.

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 4-6 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, spondyloarthritis (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 spondyloarthritis. 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; Luukkanen et al., 2002; Hawkins and Schofferman, 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 spondyloarthritis 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


Medicine, 22(4), 207-213. doi: 10.1136/aim.22.4.207. Retrieved from http://aim.bmj.com/content/22/4/207.long


INTRODUCTION:

This guideline outlines the indications for four hip arthroplasty categories: total hip, partial/hemi-arthroplasty, resurfacing, and revision/conversion. Arthroplasty describes the surgical replacement or reconstruction of a joint with implanted devices when the joint has been damaged by an arthritic, traumatic, or malignant process.

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.

This guideline is structured with clinical indications outlined for each of the following hip arthroplasty applications:

a) Total Hip Arthroplasty (THA)/Hip Resurfacing
   - THA describes the reconstruction of the entire joint articular surfaces, including the femoral head and acetabular sides.
   - Hip resurfacing arthroplasty replaces the articular surface of the femoral head with limited removal of femoral bone and the entire surface of the acetabulum.

b) Revision/Conversion Arthroplasty
   - Revision/Conversion hip arthroplasty describes surgical reconstruction due to failure or complication of a previous arthroplasty or reconstruction.

c) Hemiarthroplasty (Partial Arthroplasty)
   - Hemiarthroplasty is reconstruction of the femoral head but not the acetabulum and is indicated for the treatment of trauma (no additional clinical guidelines included)

Elective arthroplasty surgery may be considered when pain and documented loss of function (deviation from normal hip function which may include painful weight bearing; painful or inadequate range of motion to accomplish activities of daily living (ADLs) and/or employment; and mechanical catching, locking, popping):

1. Cause a diminished quality of life
2. Symptoms have been present for at least 6 months and have not responded to non-operative care, including rest, activity modification, weight reduction, oral anti-inflammatory medications, physical therapy, gait aides (cane, walking stick, walker, crutches), and injections (corticosteroid, viscosupplementation, PRP [platelet-rich plasma]).
3. Are associated with typical objective findings on physical exam, including reduced hip flexion and rotation, positive impingement testing, crepitus, hip flexion contracture, antalgic gait limp.
4. Are associated with radiographic or chondral changes consistent with significant arthritis, including joint space narrowing, subchondral sclerosis, subchondral cysts, and osteophytes (radiographs); joint space narrowing, subchondral bone marrow edema, loss of articular cartilage, effusion, subchondral and paralabral cysts, and osteophytes (MRI).

CLINICAL INDICATIONS:

A. Total Hip Arthroplasty (THA)/Resurfacing
This guideline breaks out the criteria for total hip arthroplasty (THA) and hip resurfacing procedures.

**Total Hip Arthroplasty (THA):**
THA may be considered medically necessary when the following criteria are met:

- Hip pathology is due to rheumatoid arthritis, femoral neck fracture in the setting of pre-existing arthritis, malignancy, or failure of previous surgery, dysplasia, or avascular necrosis with collapse, confirmed by imaging.

  OR

- When ALL of the following criteria are met:
  - Pain and documented loss of function (deviation from normal hip function which may include painful weight bearing; painful or inadequate range of motion to accomplish activities of daily living (ADLs) and/or employment; and mechanical catching, locking, popping); are present for at least 6 months; AND
  - 6 months of non-operative treatment* have failed to improve symptoms; AND
  - Physical exam has typical findings of hip pathology as evidenced by one or more of the following:
    - Painful, limited range of motion or antalgic gait, or
    - Contracture, or
    - Crepitus, or
    - Leg length difference; AND
  - Imaging demonstrates advanced hip joint arthritis of at least **Kellgren-Lawrence grade 3-4 or ***Tönnis grade 2 or 3;

- Relative Contraindications:
  - Metal allergy (dependent upon implant choice)
  - Chronic renal insufficiency (due to metal ions circulating and potential renal toxicity)

- Absolute Contraindications:
  - Local or remove active infection
  - Female of child-bearing age (due to metal ions circulating in blood with potential risk to fetus) \( \text{metal on metal replacements} \)

**Kellgren-Lawrence Grading System:**
- Grade 0: No radiographic features of osteoarthritis
- Grade I: Possible joint space narrowing and osteophyte formation
- Grade II: Definite osteophyte formation with possible joint space narrowing
- Grade III: Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour \( \text{some sclerosis and cyst formation and deformity of femoral head and acetabulum} \)
- Grade IV: Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour \( \text{increased deformity of the femoral head and acetabulum} \)

***Tönnis Classification of Osteoarthritis by Radiographic Changes***
- 0: No signs of osteoarthritis
- 1: Mild: Increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity
2 Moderate: Small cysts, moderate narrowing of the joint space, moderate loss of head sphericity
3 Severe: Large cysts, severe narrowing or obliteration of the joint space, severe deformity of the head

Hip Resurfacing Arthroplasty:

**Hip resurfacing procedures will be reviewed on a case by case basis.**

Hip resurfacing arthroplasty may be considered medically necessary when the following criteria are met:

- Pain and documented loss of function (deviation from normal hip function which may include painful weight bearing; painful or inadequate range of motion to accomplish activities of daily living (ADLs) and/or employment; and mechanical catching, locking, popping); are present for at least 6 months; AND
- 6 months of non-operative treatment* have failed to improve symptoms; AND
- Physical exam has typical findings of hip pathology as evidenced by one or more of the following:
  - Painful, limited range of motion or antalgic gait, or
  - Contracture, or
  - Crepitus, or
  - Leg length difference; AND
- Imaging demonstrates advanced hip joint pathology of at least **Kellgren-Lawrence grade 3-4 or ***Tönnis grade 2 or 3 or avascular necrosis involving less than 50% of the femoral head; AND
- Male patient is less than 65 years old, or female patient is less than 55 years old; AND
- BMI less than 40; AND
- Patient does not have evidence of any of the following contraindications:
  - 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
  - Current or recent 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

- Relative Contraindications:
  - Osteoporosis or osteopenia (DEXA scan bone mineral density evaluation)
- Absolute Contraindications:
  - Local or remove active infection
Female of child-bearing age (due to metal ions circulating in blood with potential risk to fetus)

**Kellgren-Lawrence Grading System:**
- Grade 0: No radiographic features of osteoarthritis
- Grade I: Possible joint space narrowing and osteophyte formation
- Grade II: Definite osteophyte formation with possible joint space narrowing
- Grade III: Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour (*some sclerosis and cyst formation and deformity of femoral head and acetabulum*)
- Grade IV: Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour (*increased deformity of the femoral head and acetabulum*)

***Tönnis Classification of Osteoarthritis by Radiographic Changes***
- 0: No signs of osteoarthritis
- 1: Mild: Increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity
- 2: Moderate: Small cysts, moderate narrowing of the joint space, moderate loss of head sphericity
- 3: Severe: Large cysts, severe narrowing or obliteration of the joint space, severe deformity of the head

B. Hip Revision/Conversion Arthroplasty

Hip Revision/Conversion Arthroplasty may be considered medically necessary when a previous hip reconstruction meets the following criteria:
- Extensive disease or damage due to fracture, malignancy, osteolysis, or other bone or soft-tissue reactive or destructive process confirmed by MRI or other advanced imaging. *NOTE*: *MRI is used less often in these circumstances unless it is a metal-on-metal and looking for soft-tissue lesions: x-ray, CT, nuclear studies are used more frequently; OR*
- Infected joint confirmed by synovial fluid aspiration (cell count and/or culture); OR
- When all of the following are present:
  - Symptomatic hip arthroplasty where patient has persistent, severe disabling pain and loss of function for > 6 months: AND
  - Unstable joint upon physical exam: AND
  - Aseptic loosening, osteolysis, other bone or soft-tissue reactive or destructive process, inappropriate positioning of components, or other failure of fixation of components confirmed on imaging

Additional Information:

*Non-operative management may include one or more of the following modalities:*
- Rest or activity modifications/limitations:
- Weight reduction for patient with elevated BMI:
- Protected weight-bearing with cane, walker or crutches:
- Physical therapy modalities:
- Supervised home exercise:
- Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics:
- Injections: cortisone, viscosupplementation, PRP (platelet-rich plasma)
REFERENCES


Hawker, Gillian A., et al. "Which patients are most likely to benefit from total joint arthroplasty?." *Arthritis & Rheumatism* 65.5 (2013): 1243-1252.


INTRODUCTION:

This guideline describes the indications for, and surgical uses of arthroscopy in the hip as well as open, non-arthroplasty hip repair procedures. Arthroscopy introduces a fiberoptic camera into the hip joint (arthroscopy) and surrounding extra-articular areas (endoscopy) through a small incision for diagnostic purposes. Other tools may then be introduced to remove, repair, or reconstruct intra-articular and extra-articular pathology. 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.

This guideline is structured with clinical indications outlined for each of the following applications:

Arthroscopic:

d) Diagnostic arthroscopy

e) Femoroacetabular Impingement (FAI)
   • Labral Repair Only
   • CAM, Pincer, CAM & Pincer combined

f) Synovectomy, Biopsy, or Removal of Loose or Foreign Body

g) Chondroplasty or abrasion for Chondral injuries, chondromalacia

h) Extra-articular (Endoscopic) Hip Surgery

CLINICAL INDICATIONS:

C. Diagnostic Hip Arthroscopy

All requests for diagnostic hip arthroscopy will be considered and decided on a case-by-case basis.

D. Femoroacetabular Impingement (FAI)

FAI is a condition characterized by a mechanical conflict between the femur (cam) and/or 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. Thus, “isolated” labral tears are very uncommon. Labral tears are infrequently traumatic (<5%). There is no evidence to support hip arthroscopy for FAI and/or labral tear in an asymptomatic subject.

Labral Repair

Arthroscopic labral repair may be medically necessary when ALL of the following criteria are met:

- Hip or groin pain in positions of flexion and rotation that may be associated with mechanical symptoms of locking, popping, or catching; AND
- Positive provocative test on physical exam with pain at the hip joint with flexion, adduction, and internal rotation; AND
- Acetabular labral tear by MRI, with or without intra-articular contrast; AND
- Symptoms not improved with at least 6 weeks of conservative, non-operative care*, AND
• 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; AND
• Patient is less than age 50.

NOTE: Arthroscopy of the hip for acetabular labral or repair is considered not medically necessary in the presence of significant hip joint arthritis (Tönnis grade II or greater)**, dysplasia*** or other structural abnormality that would require skeletal correction.

***Dysplasia defined as:
  o Lateral center edge angle <20 degrees; OR
  o Anterior center edge angle <20 degrees; OR
  o Tönnis angle >15 degrees; OR
  o Femoral head extrusion index >25%

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:
• Positional hip pain for at least 6 weeks not improved with conservative, non-operative care*; AND
• Positive impingement sign on physical exam (hip or groin pain with flexion, adduction and internal rotation; or extension and external rotation); AND
• One of the following radiograph, CT and/or MRI findings of FAI:
  o Nonspherical femoral head or prominent head-neck junction (pistol-grip deformity) with alpha angle >55 degrees indicating CAM impingement; OR
  o 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; OR
  o Combination of CAM and pincer criteria; AND
• No evidence of significant hip joint arthritis; AND
• Skeletally mature patient, AND
• Under age < 50 years old; AND
• BMI < 40; AND
• Radiographic images show no evidence of ANY of the following indicators for hip dysplasia:
  o Lateral center edge angle <20°; OR
  o Anterior center edge angle <20°; OR
  o Tönnis angle >15°; OR
  o Femoral head extrusion index >25%

NOTE: arthroscopy of the hip for FAI is considered not medically necessary or contraindicated in the presence of significant hip joint arthritis (Tönnis grade II or greater)**, the skeletally immature patient (open proximal femoral physis), age > 50 years, or BMI >40. Requests meeting any of these criteria will be reviewed on a case by case basis.

E. 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:

- Radiographic evidence of acute post-traumatic intra-articular foreign body or displaced fracture fragment;

**OR**

- When ALL of the following criteria are met:
  - Hip pain associated with grinding, catching, locking, or popping for at least 12 weeks not improved with conservative, non-operative care*; AND
  - Physical exam finding confirms painful hip with limited range of hip motion; AND
  - Radiographs, CT and/or MRI with synovial proliferation, calcifications, nodularity, inflammation, pannus, loose body

**F. 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.

All requests will be considered and decided on a case-by-case basis.

**G. 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.

Use of this technology for these applications will be decided on a case-by-case basis.

Extra-articular hip applications may be used to minimize symptoms of internal snapping hip (internal coxa saltans, iliopsoas tendonitis, snapping iliopsoas), iliopsoas tendon at iliopectineal eminence or anterior inferior iliak 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 iliak spine (subspine) decompression for subspine impingement (3 types of anterior inferior iliak 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.

*Type 3 should have surgical decompression. Most type 2 should have surgical decompression. Type 1 should never need surgical decompression.*

- 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**

- 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; AND
• At least 6 months of non-operative care* that may include activity modification, supervised physical therapy, NSAIDS, and/or corticosteroid injection: AND
• Physical exam findings align with patient symptoms and have at least one or more of the following:
  o Limp or painful ambulation
  o Tenderness and/or crepitus to palpation
  o Visible, audible, or palpable snapping at the greater trochanter or pelvic brim
  o Pain and/or weakness with active or resisted motion of the hip
  o Pain relief with diagnostic local anesthetic injection

Additional Information:

*Non-Operative Treatment:
Throughout this document, conservative, non-operative care* is defined as a combination of two or more of the following:
• Rest or activity modifications/limitations;
• Ice/heat;
• Protected weight bearing;
• Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics;
• Brace/orthosis;
• Physical therapy modalities;
• Supervised home exercise;
• Weight optimization;
• Injections: cortisone/viscosupplementation/PRP (Platelet-rich plasma)

**Tönnis Classification of Osteoarthritis by Radiographic Changes
Grade 0  No signs of osteoarthritis
Grade 1  Mild: Increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity
Grade 2  Moderate: Small cysts, moderate narrowing of the joint space, moderate loss of head sphericity
Grade 3  Severe: Large cysts, severe narrowing or obliteration of the joint space, severe deformity of the head

Additional Notes:
• A very high prevalence of abnormal radiographs is found in asymptomatic patients.
  o 33% of asymptomatic hips have a cam
  o 66% of asymptomatic hips have a pincer
  o 68% of asymptomatic hips have a labral tear
• FAI and labral tears are precursors to hip arthritis
• Dysplasia is precursor to hip arthritis
• Arthroscopy is never indicated for treatment of osteoarthritis within the hip
• Rarely (if ever) arthroscopy for dysplasia

REFERENCES


Mascarenhas, Randy; Frank, Rachel M.; Lee, Simon; Salata, Michael J.; Bush-Joseph, Charles; Nho, Shane J. "Endoscopic Treatment of Greater Trochanteric Pain Syndrome of the Hip." *JBJS REVIEWS* 2014;2(12):e2 · http://dx.doi.org/10.2106/JBJS.RVW.N.00026 1


CPT Codes: 27446, 27447, 27486, 27487, 27488, 27438

INTRODUCTION:

Arthroplasty describes the surgical replacement or reconstruction of a joint with implanted devices when the joint has been damaged by an arthritic or traumatic process. This guideline outlines the clinical indications for three types of knee arthroplasty procedures: total, partial/unicompartmental, and revision arthroplasty.

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.

This guideline is structured with clinical indications outlined for each of the following applications: Total Knee Arthroplasty (TKA), Unilateral Knee Arthroplasty (UKA), and Revision Arthroplasty.

A. Total Knee Arthroplasty (TKA)

Total Knee Arthroplasty (TKA) describes reconstruction of all articulating joint surfaces. TKA may be considered medically necessary for treatment of the following knee joint pathology:

- Extensive disease or damage due to rheumatoid arthritis, fracture, or avascular necrosis confirmed by imaging (radiographs, MRI or other advanced imaging); AND
- Patient has pain and documented loss of function (no indication to perform TKA in patient with severe disease and no symptoms);

OR

When ALL of the following criteria are met:

- Pain 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; AND
- At least 6 months of non-operative care* that has failed to improve symptoms. Non-operative care should include at least two or more 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) Supervised home exercise;
  f) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics;
  g) Brace/orthosis;
  h) Injections: cortisone/viscosupplementation/PRP (platelet rich plasma); AND
- 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: AND
• Radiographic findings show evidence of bicompartmental or tricompartmental advanced arthritic changes, documented by weight-bearing radiographs described as Kellgren-Lawrence (K-L)** stage III or stage IV degeneration

NOTE:
• All requests for simultaneous bilateral total knee replacements will be reviewed on a case by case basis.
• All requests for TKA in patients with chronic, *painless* effusion and extensive radiographic arthritis will be evaluated on a case-by-case basis.

**Kellgren-Lawrence Grading System:**
Grade 0: No radiographic features of osteoarthritis
Grade I: Possible joint space narrowing and osteophyte formation
Grade II: Definite osteophyte formation with possible joint space narrowing
Grade III: Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour
Grade IV: Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour;

Contraindications:
• Absolute contraindication:
  o Active infection (local or remote)

• Relative contraindication: Any of the following:
  o 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.
  o Extreme morbid obesity (BMI > 40)
  o Extensor mechanism deficiency
  o Neuropathic joint
  o Severe peripheral vascular disease
  o Compromised soft tissue envelope
  o Uncontrolled comorbidities

B. **Unicompartmental Knee Arthroplasty (UKA)/Partial Knee Replacement (PKA)**
Unicompartmental knee arthroplasty (UKA) is also called partial, hemi- or unicompartmental knee, bicondylar knee arthroplasty, and involves reconstruction of either the medial (more common than lateral) or lateral weight bearing compartment of the knee and/or patellofemoral joint

UKA/PKA may be medically necessary when ALL of the following criteria are met:
• Pain localized to the medial or lateral compartment is present for at least 6 months; AND
• At least 6 months of non-operative care that has failed to improve symptoms. *Non-operative care should include at least two or more of the following:
  a) Rest or activity modifications/limitations;
  b) Weight optimization;
  c) Protected weight-bearing with cane, walker or crutches;
  d) Physical therapy modalities;
  e) Supervised home exercise;
  f) Pharmacologic treatment: oral/topical NSAIDS, acetaminophen, analgesics;
  g) Brace/orthosis;
h) Injections: cortisone/viscosupplementation/PRP (platelet rich plasma); AND

- Total arc of motion (goniometer) > 90 degrees; AND
- Normal ACL or stable reconstructed ACL per physical exam test; AND
- Age > 50 years; AND
- Radiographic findings demonstrate only unicompartmental disease (with or without patellofemoral involvement) with evidence of degeneration equal to K-L* Grade 3 or 4; AND
- Contracture < 5-10 degrees upon physical exam (goniometer); AND
- Angular deformity < 10 passively correctable to neutral upon physical exam (goniometer); AND
- BMI < 40

NOTE:
- All requests for UKA in patients with chronic, painless effusion and extensive radiographic arthritis will be evaluated on a case-by-case basis.

**Kellgren-Lawrence Grading System:**

Grade 0: No radiographic features of osteoarthritis
Grade I: Possible joint space narrowing and osteophyte formation
Grade II: Definite osteophyte formation with possible joint space narrowing
Grade III: Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour
Grade IV: Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour

Outerbridge Arthroscopic Grading System

Grade 0 Normal cartilage
Grade I Softening and swelling
Grade II Partial thickness defect, fissures < 1.5cm diameter
Grade III Fissures down to subchondral bone, diameter > 1.5cm
Grade IV Exposed subchondral bone

Contraindications:
- Local or systemic active infection
- Inflammatory arthritis
- Angular deformity or contracture greater than indicated range
- Significant arthritic involvement of other knee compartments
- Ligamentous instability (at least ACL [anterior cruciate ligament])
- Poor bone quality or significant osteoporosis or osteopenia
- Meniscectomy of the opposite compartment
- Stiffness greater than indicated range of motion

C. 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:

- Previous UKA/PKA or TKA joint; AND
- Infection ruled out by synovial fluid aspiration/biopsy (cell count and/or culture) AND off antibiotics; OR
- When ALL of the following criteria are met:
  - Symptomatic UKA/PKA or TKA as evidence by persistent, severe disabling pain and loss of function; AND
Any of the following 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 associated with reproducible pain; AND

- Aseptic loosening, osteolysis confirmed on radiographic or advanced imaging (nuclear medicine bone scan, CT scan, MRI)

**Contraindications:**
- Absolute contraindication:
  - Local or systemic active infection
- Relative contraindication: Any of the following:
  - 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:
- Procedures utilizing computer-navigated or patient-specific or gender-specific instrumentation
- Bicompartmental arthroplasty (investigational at this time)
- Robot-assisted TKA (Makoplasty)

**Other issues:**
- Manipulation following total knee arthroplasty:
  - Nonsurgical treatment is initial treatment
  - However, manipulation is indicated if within 3 months from time of primary arthroplasty if physical therapy is unable to improve motion to satisfactory degree
    - If cause of arthrofibrosis/stiffness is due to technical error (component malpositioning or inappropriate sizing), then surgical revision arthroplasty is indicated
    - If cause of arthrofibrosis/stiffness is due to adhesions/capsular contraction, then either arthroscopic or open lysis of adhesions is indicated

- 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.

**REFERENCES**


CPT Codes: 27332, 27333, 27403, 29868, 29880, 29881, 29882, 29883, 29885, 29886, 29887, 29888, 29889, 27412, 27415, 27416, 27418, 27420, 27422, 27424, 27425, 29866, 29867, 29870, 29873, 29874, 29875, 29876, 29877, 29879, G0289, 27570, 29884

INTRODUCTION:

This guideline describes surgical indications of both arthroscopy as well as open, non-arthroplasty knee surgery. Also included are indications for knee manipulation. 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 and surgeon skill/experience.

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.

This guideline is structured with clinical indications outlined for each of the following applications: Arthroscopic; Open, non-arthroplasty; Manipulation:

d) Diagnostic knee arthroscopy
e) Debridement with or without chondroplasty
f) Meniscectomy/meniscal repair
g) Ligament reconstruction/repair
   i. Anterior cruciate ligament (ACL) reconstruction
   ii. Posterior cruciate ligament (PCL) reconstruction
   iii. Collateral ligament repair
h) Articular cartilage restoration/repair:
   i. Marrow stimulating techniques (microfracture, drilling, abrasion chondroplasty, augmented marrow-stimulation [BioCartilage])
   ii. Restorative techniques (osteochondral autograft transfer system (OATS), mosaicplasty, autologous chondrocyte implantation (ACI), osteochondral allograft implantation, minced articular cartilage allograft transplantation [DeNovo NT])
i) Synovectomy (major [2+ compartments], minor [1 compartment])
j) Loose body removal
k) Lateral release \patellar realignment
l) Manipulation under anesthesia (MUA)
m) Lysis of adhesions for arthrofibrosis of the knee

*Non-operative Treatment:
Throughout this document non-operative care* is defined as a combination of two or more 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:
- Injections: cortisone, viscosupplementation, platelet rich plasma (PRP)

**Kellgren-Lawrence Grading System:**
- Grade 0: No radiographic features of osteoarthritis
- Grade I: Doubtful joint space narrowing and possible osteophytic lipping
- Grade II: Definite osteophyte formation with possible joint space narrowing on anteroposterior weight-bearing radiograph
- Grade III: Multiple osteophytes, definite narrowing of joint space, some sclerosis and possible bony deformity
- Grade IV: Large osteophytes, marked narrowing of joint space, severe sclerosis and definite bony deformity

***Outerbridge Arthroscopic Grading System***
- Grade 0: Normal cartilage
- Grade I: Softening and swelling/blistering
- Grade II: Partial thickness defect, fissures < 1.5cm diameter/wide
- Grade III: Fissures /defects down to subchondral bone with intact calcified cartilage layer, diameter > 1.5cm
- Grade IV: Exposed subchondral bone

****The International Cartilage Research Society (ICRS)****
- Grade 0: Normal cartilage
- Grade I: Nearly normal. Superficial lesions.
  - A. Soft indentation
  - B. And/or superficial fissures and cracks
- Grade II: Abnormal. Lesions extending down to <50% of cartilage depth
- Grade III: Severely abnormal
  - A. Cartilage defects extending down >50% of cartilage depth
  - B. And down to calcified layer
  - C. And down to, but not through the subchondral bone
  - D. And blisters
- Grade IV: Severely abnormal (through the subchondral bone)
  - A. Penetration of subchondral bone but not across entire diameter of defect
  - B. Penetration of subchondral bone across the full diameter of the defect

**CLINICAL INDICATIONS:**

A. **Diagnostic Knee Arthroscopy**
   Diagnostic knee arthroscopy may be medically necessary when ALL of the following criteria are met:
   - At least 3 months of 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 <90 degrees flexion or both) to accomplish activities of daily living (ADLs), recreational activity, and/or employment (documentation of missed days of work or modifications of work status due to injury/pain)); AND
• At least 12 weeks of non-operative care* that has failed to improve symptoms; AND
• Clinical documentation of painful weight bearing, joint line tenderness, effusion and/or limited motion compared to presymptomatic joint range; AND
• Indeterminate radiographs AND MRI findings.

B. **Debridement with or without Chondroplasty**
Debridement may be medically necessary when ALL of the following criteria are met:
• 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 <90 degrees flexion or both) to accomplish activities of daily living (ADLs) and/or employment (documentation of missed days of work or modifications of work status due to injury/pain)); AND
• At least 12 weeks of non-operative care* that has failed to improve symptoms; AND
• MRI results showing evidence of unstable chondral flap; AND
• Recurrent (more than 2) or persistent effusion(s)

**OR**
• 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*; AND
• At least 6 weeks of supervised or self-directed physical therapy that has failed to improve symptoms.

**OR**
• Debridement chondroplasty for patellofemoral chondrosis when ALL of the following criteria are met:
  o Anterior knee pain and loss of function (deviation from normal pain-free weight bearing, stable articulation, and/or range of motion to accomplish activities of daily living (ADLs) and/or employment); AND
  o Other extra-articular or intra-articular sources of pain or dysfunction have been excluded (referred pain, radicular pain, tendinitis, bursitis, neuroma); AND
  o 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); AND
  o Imaging (radiographs, MRI, or CT to measure tibial tubercle—trochlear groove distance)
  o At least 12 weeks of non-operative care has failed to improve symptoms; AND
  o No evidence of osteoarthritis (Kellgren-Lawrence** Grade 3-4 based on standing or weight-bearing radiographs and patellofemoral views))

*NOTE: arthroscopic debridement with or without chondroplasty for osteoarthritis of the knee is considered NOT MEDICALLY NECESSARY unless above criteria noted.*

C. **Meniscectomy/Meniscal Repair**
Meniscectomy and/or meniscal repair may be medically necessary when the following criteria are met:
• Symptomatic meniscal tear confirmed by MRI results that show a peripheral longitudinal tear in a vascular zone, associated with pain and mechanical symptoms upon physical exam:
Pediatric or adolescent patient has pain and mechanical symptoms upon physical exam; AND MRI results show unstable tear;

OR

When at least 3 of the following 5 criteria are met:
1. History of "catching" or "locking" as reported by the patient;
2. Knee joint line pain with forced hyperextension upon physical exam;
3. Knee joint line pain with maximum flexion upon physical exam;
4. Knee pain or an audible click with McMurray’s maneuver upon physical exam;
5. Joint line tenderness to palpation upon physical exam; AND

At least 6 weeks of non-operative care* that has failed to improve symptoms; AND

One of the following radiographic findings:
- Radiographic findings without moderate or severe osteoarthritic changes; OR
- MRI results confirm meniscal tear in patients < 30 years of age; OR
- MRI results confirm displaced tear (any age);

OR

Meniscus tear encountered during other medically necessary arthroscopic procedure

**Absolute Contraindications**
- Arthroscopic meniscectomy or meniscal repair is never medically necessary in the presence of Kellgren-Lawrence Grade 4 osteoarthritis.

**Relative Contraindications**
- Meniscectomy or repair is considered NOT MEDICALLY NECESSARY in the presence of Kellgren-Lawrence Grade 3 osteoarthritis 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

**D. 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 are met:
- 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, or Pivot Shift, instrumented (KT-1000 or KT-2000) laxity of greater than 3 mm side-side difference; AND
- MRI results confirm complete ACL tear; AND
- Patient has no evidence of severe arthritis (Kellgren-Lawrence** Grade 3 or 4)

OR

When ONE of the following criteria are met:
o MRI results confirm ACL tear associated with other ligamentous instability or repairable meniscus; OR
o MRI results confirm partial or complete ACL tear AND patient has persistent symptoms despite at least 12 weeks of non-operative care*; OR
o 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)); AND
o Patient has no evidence of severe arthritis (Kellgren-Lawrence** Grade 3 or 4)

• 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 ALL of the following criteria are met:
• 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; AND
• MRI results confirm complete PCL tear; AND
• Failed non-operative care (bracing in full extension successful in acute PCL tears); AND
• Absence of medial and patellofemoral K-L grade 3-4 changes in chronic tears;
  OR
• The following clinical scenarios will be considered and decided on a case-by-case basis:
  o pediatric and adolescent tears in patients with open physes or open growth plates
  o symptomatic partial tears with persistent instability despite non-operative care
  o incidental Kellgren-Lawrence Grade 2-3 osteoarthritis in acute/subacute tears with unstable joint

• Tears in patients less than age 13 will be reviewed on a case by case basis.

Collateral Ligament Repair or Reconstruction:
Collateral ligament repair or reconstruction should rarely occur independent of additional repair or reconstruction surgery. All non-traumatic collateral ligament repair/reconstruction requests will be reviewed on a case by case basis.

E. Articular Cartilage Restoration/Repair
Skeletally Immature Indications:
• When ALL of the following criteria are met:
  o Skeletally immature patient; AND
  o Patient is symptomatic (pain, swelling, mechanical symptoms of popping, locking, catching, or limited range of motion); AND
  o radiographic findings (any radiograph and MRI) of a displaced lesion:
  OR
• When ALL of the following criteria are met:
  o Skeletally immature patient; AND
  o Patient is symptomatic (pain, swelling, mechanical symptoms of popping, locking, catching, or limited range of motion); AND
  o At least 12 weeks of non-operative care* has failed to improve symptoms; AND
Radiographic findings (any radiograph and MRI) results finding of a stable osteochondral lesion

OR

- When ALL of the following criteria are met:
  - Skeletally immature: AND
  - Asymptomatic: AND
  - At least 12 weeks of non-operative care has failed to improve lesion stability or size; AND
  - Radiographic findings (any radiograph and MRI) results finding of an unstable osteochondral lesion

AND

- 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 techniques (microfracture & drilling. Abrasion arthroplasty is including in coding but is not indicated) may be medically necessary when ALL of the following criteria are met:
  - Skeletally mature adult; AND
  - MRI confirms a full-thickness weight-bearing lesion that is < 2.5 sq.cm; AND
  - Patient is symptomatic (pain, swelling, mechanical symptoms of popping, locking, catching, or limited range of motion); AND
  - Patient is less than 50 years of age; AND
  - BMI < 35 (optimal outcomes if patient BMI <30); AND
  - Physical exam findings and/or (imaging) results confirm knee has stable ligaments; AND
  - No evidence of prior meniscectomy in same compartment (medial femoral condyle full thickness lesion and prior medial meniscectomy) unless concurrent meniscal transplant performed.

OR

- Restorative techniques (abrasion arthroplasty, osteochondral autograft transfer or transplantation (OATS), mosaicplasty, 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:
  - Skeletally mature adult; AND
  - MRI results confirm a full thickness chondral or osteochondral lesion of the femoral condyles or trochlea > 2.5 cm; AND
  - Patient is less than 50 years of age; AND
  - Patient has been symptomatic (pain, swelling, mechanical symptoms of popping, locking, catching, or limited range of motion) for at least 6 months; AND
  - At least 6 months of non-operative care* has failed to improve symptoms; AND
  - 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); AND
  - BMI < 35 (optimal outcomes if patient BMI <30): AND
MRI shows no evidence of significant osteoarthritis (greater than Kellgren-Lawrence Grade 2); AND

No prior meniscectomy in same compartment (unless concurrent or staged meniscal transplant performed)

OR

- 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:
  - Anterior knee pain and 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 <90 degrees flexion or both) to accomplish activities of daily living (ADLs), recreational activity, and/or employment (documentation of missed days of work or modifications of work status due to injury/pain)); AND
  - Other extra-articular or intra-articular sources of pain or dysfunction have been excluded (referred pain, radicular pain, tendinitis, bursitis, neuroma); AND
  - 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); AND
  - Radiologic imaging shows patellofemoral chondrosis graded 3 or 4 by the Outerbridge Classification*** or ICRS**** (grade 3-4) classification
  - At least 6 months of non-operative care has failed to improve symptoms; AND
  - No evidence of osteoarthritis (Kellgren-Lawrence** Grade 3-4 based on standing or weight-bearing radiographs) in the medial/lateral compartments

F. Synovectomy (major [2+ compartments], minor [1 compartment])

Synovectomy may be medically necessary when ALL of the following criteria are met:

- Proliferative rheumatoid synovium (in patients with established rheumatoid arthritis according to the American College of Rheumatology Guidelines); AND
- Not responsive to disease modifying drug (DMARD) therapy for at least 6 months and at least 6 weeks of non-operative care that has failed to improve symptoms; AND
- At least one instance of aspiration of joint effusion and cortisone injection (if no evidence of infection):

  OR

- Hemarthrosis from injury, coagulopathy or bleeding disorder confirmed by physical exam, joint aspiration, and/or MRI:

  OR

- Proliferative pigmented villonodular synovitis, synovial chondromatosis, sarcoid synovitis, or similar proliferative synovial disease, traumatic hypertrophic synovitis confirmed by history, MRI or biopsy; AND
- At least 6 weeks of non-operative care* that has failed to improve symptoms; AND
- At least one instance of aspiration of joint effusion and injection of cortisone (if no evidence of infection):

  OR
• Detection of painful plica confirmed by physical exam and MRI findings; AND
• At least 12 weeks of non-operative care* that has failed to improve symptoms.
• At least one instance of aspiration of joint effusion OR single injection of cortisone (effusion may not be present with symptomatic plica);

G. Loose Body Removal
Loose body removal may be medically necessary when the following criteria are met:
• Removal of loose body or foreign object that causes limitation or 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 <90 degrees flexion or both) to accomplish activities of daily living (ADLs), recreational activity, and/or employment (documentation of missed days of work or modifications of work status due to injury/pain)).

H. 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. Surgical indications are based on relevant clinical symptoms, physical exam, radiologic findings, and response to non-operative management when medically appropriate.

Surgical intervention for the treatment of lateral patellar compression syndrome is indicated when the following criteria are met:
- Evidence of lateral patellar tilt from radiologic images (patellofemoral view: mercer merchant (45-60 degrees flexion); skyline (60-90 degrees flexion); sunrise (60-90 degrees flexion); AND
- Associated lateral patella facet K-L changes grade 1, 2, or 3; AND
- Reproducible isolated lateral patellofemoral pain with patellar tile test; AND
- At least 6 months of non-operative care* has failed to improve symptoms including appropriate hamstring/IT band stretching and patellar mobilization techniques; AND
- No evidence of patellar dislocation without documented patellar tilt; AND
- No evidence of medial patellofemoral changes (Kellgren-Lawrence Grade 2 osteoarthritis or higher);

Surgical intervention for the treatment of patellar malalignment and/or patellar instability is indicated when the following criteria are met:
- 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
- Repeat (greater than 2) patellar dislocations or subluxations have occurred despite 6 months of non-operative care* with radiologic confirmation of MPFL (medial patellofemoral ligament) deficiency; OR
- Physical exam has patellofemoral tenderness and abnormal articulation of the patella in the femoral trochlear groove (patellar apprehension with positive J sign); AND
- Radiologic images rule out fracture or loose body, and show abnormal articulation, trochlear dysplasia, or other abnormality related to malalignment; AND
CT scan or MRI rules out other abnormality to malalignment (tibial tubercle-trochlear groove (TT-TG) distance > 20 millimeters); AND
At least 6 months of non-operative care* has failed to improve symptoms

I. Manipulation under Anesthesia (MUA)
Manipulation under anesthesia (MUA) may be indicated when the following criteria are met:
• Physical exam findings demonstrate inadequate range of motion of the knee defined as less than 105 degrees of flexion; AND
• Failure to improve range of motion of the knee despite 6 weeks (12 visits) of documented physical therapy; AND
• Patient is less than 12 weeks after ligamentous or joint reconstruction.

J. 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.

• Physical exam findings demonstrate inadequate range of motion of the knee, defined as less than 105 degrees of flexion; AND
• Failure to improve range of motion of the knee despite 6 weeks (12 visits) of documented physical therapy; AND
• Patient is more than 12 weeks after ligamentous or joint reconstruction, or resolved infection; OR
• Patient is more than 12 weeks after trauma, or resolved infection; AND
• Patient has native knee; AND
• Manipulation under anesthesia is also performed

REFERENCES


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.

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.

This guideline outlines several methods suitable for the employment of radiation therapy in conjunction with bone metastasis treatment. The following indications serve as guidelines only, and are based on both the ACR Appropriateness Criteria and the ASTRO Evidence Based Guideline. The use of extended fraction (>10) and/or the use of IMRT/SBRT/protons are not considered to be the standard of care, with relatively limited data to support its use. The ASTRO Task Force suggests that “SBRT be reserved for patients who fit specific inclusion and exclusion criteria, who are treated in centers with sufficient training and experience, and preferably within the confines of a radiotherapeutic trial.” Furthermore, the Task Force states that “SBRT should not be the primary treatment of vertebral bone lesions causing spinal cord compression.”

Finally, 2 dimensional planning, one or two fields, and limited if any blocking would be usual and customary. The use of daily IGRT, multiple fields with complex blocking are generally inappropriate for the treatment of bone metastasis.

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 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.

**REFERENCES**


(Low Dose Radiation (LDR), High Dose Radiation (HDR), Selective Internal Radiation Therapy (SIRT, Electronic Brachytherapy)

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 know 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


radioembolization brachytherapy oncology consortium.  

https://www.americanbrachytherapy.org/guidelines/Guidelines_Carcinoma_Cervix_PartIII.pdf


http://www.cancernetwork.com/review-article/brachytherapy-carcinoma-lung


http://www.americanbrachytherapy.org/guidelines/plaque_brachytherapy_melanoma_retinoblastoma.pdf


https://www.americanbrachytherapy.org/guidelines/Guidelines_Carcinoma_Cervix_PartII.pdf

http://www.americanbrachytherapy.org/guidelines/Guidelines_High-Dose-Rate_Prostate.pdf

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 US 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 histo-pathological 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 for Stage
(T1-2N0) or DCIS with negative margins. 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 any 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.

**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 30 fx)
- Recurrence – Low Grade
  - 3D-CRT/IMRT – (max 30 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 30 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)
  o Whole Brain Radiation Therapy (WBRT) 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)
  o WBRT 2D/3D-CRT + 3D/IMRT boost
  o WBRT 2D/3D-CRT 20-45Gy (maximum 20 fractions) + SRS/SBRT boost 15-24 Gy, maximum 5 fractions
  o 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)
  o 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 – 15-40 Gy (maximum 15 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 metastatic central nervous system tumors in a pediatric patient (less than 21 years of age)

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)
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:

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.
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 30 fx)
- Recurrence – Low Grade
  - 3D-CRT/IMRT – (max 30 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 30 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)
  o Whole Brain Radiation Therapy (WBRT) 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)
  o WBRT 2D/3D-CRT + 3D/IMRT boost
  o WBRT 2D/3D-CRT 20-45Gy (maximum 20 fractions) + SRS/SBRT boost 15-24 Gy, maximum 5 fractions
  o 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)
  o 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 – 15-40 Gy (maximum 15 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 metastatic central nervous system tumors in a pediatric patient (less than 21 years of age)

  *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)**

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 post operative/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 un-resectable 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.

**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


Garofalo M et al: RTOG 0822: A Phase II Study of Preoperative (preop) Chemoradiotherapy (CRT) Utilizing IMRT in Combination with Capecitabine (C) and Oxaliplatin (O) for Patients (pts) with Locally Advanced Rectal Cancer. Abstract presented at ASTRO 2011.


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 cirrus, 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 iridium 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 (PCR) 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
- 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)

Stage IV

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.

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
- Primary Therapy (Unresectable/Medically Unfit) Any N, AnyT,M0
- Postoperative -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
  - T1-2, N0
  - 2D/3D/IMRT – up to 42 fractions T1N1, T2N0-1
    - Conventional and accelerated fractionation · 66-74 Gy (up to 37 fractions)
- Hyperfractionation - 81.6 Gy, 1.2 Gy per fraction BID (up to 68 fractions)
- Concomitant boost 72 Gy, 1.8 with 1.5 Gy boost delivered as a second daily fraction the last twelve treatments (up to 41 fractions)
  - T2-4aN0-3
- Concurrent chemoradiation – (up to 42 fractions)
- Post-operative radiation therapy
  - Presence of adverse factors
    - pT3 or pT4 primary tumors
    - N2-3
    - Perineural invasion
    - Vascular tumor embolism
    - Extracapsular spread
    - Positive surgical margin
  - +/- chemotherapy – (up to 40 fractions)
  - Palliative radiation therapy if symptomatic up to 20 fractions
  - Re-treatment may be indicated if no metastatic disease present

**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**


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 17 fractions

Stage IB-IIB (nonbulky disease)
- Chemotherapy + radiation therapy (30 Gy) up to 17 fractions

Stage I-IV (bulky disease)
- Chemotherapy + radiation therapy (30-36 Gy) up to 20 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.

**REFERENCES**


Engert, A., Franklin, J., Eich, H.T., Brillant, C., Sehlen, S., Cartoni, C., ... Diehl, V. (2007). Two cycles of doxorubicin, bleomycin, vinblastine, and dacarbazine plus extended-field radiotherapy is superior to


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.
- 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


Nutting, C.M., Convery, D.J., Cosgrove, V.P., et al. (2001). Improvements in target coverage and reduced spinal cord irradiation using intensity-modulated radiotherapy in patients with carcinoma of the


TOC

**Intraoperative Radiation Therapy (IORT)**

**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.

**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.

**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.

**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.

**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:

- 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**


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 Magellan Healthcare clinical guideline for Central Nervous System (CNS).

**BONE:** For metastasis to bone, refer to the Magellan Healthcare 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

http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/RMBD.pdf


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.
- 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-Hodgkins lymphoma originates in B-lymphocytes (80-85%) with T-lymphocytes comprising 15-20%. Natural killer cell lymphomas are very rare. The classification of non-Hodgkins 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.

Radiation dose is typically 24-36 Gy in standard fractionation. The following include radiation dose guidelines for the following lymphomas:

- Follicular lymphoma (24-30 Gy, or 36 Gy if bulky) up to 20 fractions
- Mantle cell lymphoma (30-36 Gy) up to 20 fractions
- MALT lymphoma – Marginal Zone (24-30 Gy) up to 17 fractions
- Diffuse large B cell lymphoma (30-36 Gy for CR, 40-50 Gy for PR following chemotherapy) up to 28 fractions
- Primary cutaneous anaplastic large cell lymphoma: 30-36 Gy up to 20 fractions
- NK/T Lymphoma
  - primary treatment: 50-65 Gy up to 36 fractions
  - combined modality: 45-60 Gy up to 33 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 1.8 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 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.

**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
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)
  - 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 hemoptysis 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.

**REFERENCES:**


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3968555/


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 Magellan Healthcare 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 disease

- 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

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**


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

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
  o Highly conformal radiation therapy technique (3D-CRT/IMRT) – doses 75 – 79.2 Gy (up to 44 fractions) with IGRT
- 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
  o Highly conformal radiation therapy technique (3D-CRT/IMRT) – doses 75 – 79.2 Gy (up to 44 fractions) with IGRT
  o 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
  o Highly conformal radiation therapy technique (3D-CRT/IMRT) – doses 75 – 81 Gy (up to 45 fractions)
  o 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
- Highly conformal radiation therapy technique (3D-CRT/IMRT) – doses up to 81 Gy (up to 45 fractions) with IGRT
- 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
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) – doses up to 81 Gy (up to 45 fractions) with IGRT
- 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
  - Highly conformal radiation therapy technique (3D-CRT/IMRT) – Doses up to 81 Gy (up to 45 fractions) with IGRT

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 multiple 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. 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.
REFERENCES


http://www.astro.org/uploadedFiles/Main_Site/Practice_Management/Reimbursement/ASTRO%20PBT%20Model%20Policy%20FINAL.pdf


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:

- 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 as the base of skull (chordoma, chondrosarcomas)
- Intraocular melanomas or other ocular tumors

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

- Central nervous system lesions adjacent to the brain stem, spinal cord, or optic nerve. 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.


Zietman AL, Bae K, Slater JD, et al. Randomized trial comparing conventional-dose with highdose conformal radiation therapy in early-stage adenocarcinoma of the prostate: long-term results from
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

- 35 - 66 Gy to up to 33 fractions

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 35 fractions.

**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.

**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-operative spinal tumor (primary, recurrent or metastatic) that is causing compression or intractable pain.
- Trigeminal neuralgia that has not responded to other, more conservative, treatments.
- Uveal tract melanoma (melanoma of the iris, ciliary body and choroid).
- 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 considered not medically necessary for 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


INTRODUCTION:

Thyroid, parathyroid and lymph nodes are the most commonly imaged areas of the head and neck region and ultrasound is the most appropriate imaging modality. Along with imaging minimally invasive procedures (fine needle aspiration) are performed on thyroid nodules clinically relevant lymph nodes and parathyroid. Besides the thyroid, parathyroid and lymph nodes, the salivary glands can be imaged.

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.
- As a diagnostic tool for individuals with:
  - Thyroid nodules identified via palpation
  - Unexplained cervical adenopathy
  - Past history of radiation in the cervical region (annually)
  - Family history of carcinoma of the thyroid gland (annually)
- Evaluation of abnormalities detected by other imaging examinations.
- Staging tumors of the thyroid.
- Monitoring the thyroid bed and cervical nodal compartments after thyroidectomy.

Parathyroid Gland:
- To localize adenomas in preparation for surgery.

Salivary Gland:
- To localize and identify lesions within the submandibular salivary gland or superficial lobes of the parotid.
- To determine benign vs. malignant tumors.
- Sialolithiasis
- For suspected abscess

Cervical Lymph Nodes:
- To identify the size and complexity of cervical lymph nodes
- To differentiate benign vs. malignant nodes, although additional cytology may be needed to identify histological origin

Mass
- Evaluation of undiagnosed mass.
Other Indication:
- Follow up of an abnormality seen on prior imaging

ADDITIONAL INFORMATION RELATED TO HEAD AND NECK ULTRASOUND

Thyroid Gland
Ultrasound (US) of the thyroid gland is indicated to identify thyrotoxicosis, decipher between a benign versus malignant nodule present in or around the gland, and monitor disease progression or response to treatment.

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.

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. US is also used to stage Sjogren's disease.

Masses of unknown origin
In diagnosing head and neck masses or swellings of unknown origin, US can assist in making the initial diagnosis.

REFERENCES


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 a specific section of the abdomen (e.g., upper quadrant, retroperitoneal or 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 IN AN ADULT:

Suspected appendicitis:
- Right-sided mid or lower abdominal pain with at least one of the following:
  - Fever
  - Elevated WBC
  - Nausea
  - Guarding and/or rebound

Non-hepatic or non-pulsatile mass/lesion(s):
- Abdominal mass of undetermined cause found on physical examination.
- Follow-up of diagnosed masses under surveillance or treatment at intervals ≥ 6 months.

Gallbladder Disease:
- Symptoms suggestive of gallbladder disease including:
  - Right quadrant pain
  - Fever
  - Elevated WBC
  - Murphy’s sign
  - Jaundice
  - History of biliary surgery
  - Known cholelithiasis
  - New onset of jaundice in patient without pain.

Hepatic Disease

Inflammatory:
- Suspected inflammatory or infectious process involving the liver
- Follow-up of infectious lesion(s) 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.
Mass Lesions:
- To determine if lesion identified on other imaging is cystic, solid or vascular
- To evaluate for liver metastases when elevated liver functions and known primary tumor
- To follow known liver masses after anti-tumor treatment (≥ 6 month interval) or antibiotic treatment (interval depends on organisms).

Suspected Ascites

Renal Disease:

Hematuria:
- Hematuria (except young females with cystitis)
- Known or Suspected Kidney Stones
- Flank pain

Acute Pyelonephritis:
- Suspected acute pyelonephritis in adults presenting with:
  - Flank pain
  - Nausea and vomiting
  - Fever* (>38°C, 100.4°F) or
  - Costovertebral angle tenderness
  - Fever may be absent in frail, older persons or in immunocompromised persons.

Chronic Kidney Disease:
- Newly diagnosed
- Progressive kidney disease or sudden change in kidney function
- eGFR (estimated glomerular filtration rate)
- Symptoms of urinary tract obstruction

Family History of Polycystic Kidney Disease:
- Screening ultrasound after age 20

Kidney Transplant:
- Increase in the serum creatinine levels
- Acute signs, symptoms of inflammatory process or infection in transplanted organ.
- Post operative/procedural
- 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. Follow-up of a kidney abnormality seen on prior imaging

Pancreas Disease:

Suspected Acute Pancreatitis:
- Epigastric/upper abdominal pain of unknown etiology with acute onset that is rapidly increasing in severity, and is persistent without relief AND
- Elevated serum amylase and/or lipase level

Chronic Pancreatitis:
• One or more of the following symptoms:
  o Epigastric pain that often radiates to the back, worsens after eating and may be relieved by sitting or standing upright or leaning forward
  o Steatorrhea or floating stools
  o Vitamin deficiency (fat-soluble vitamins)
  o History of heavy alcohol use
  o History of previous acute episodes of pancreatitis

Other Pancreatic Lesions:
• Suspected pancreatic necrosis
• Suspected pancreatic abscess
• Suspected pancreatic pseudocysts

Splenic Disease

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, port hypertension) OR
  o Palpable spleen OR
  o Pain on the upper left side of the abdomen AND
  o Fatigue with shortness of breath OR
  o Frequent hiccups OR inability to eat a large meal

Other Splenic Disease:
• Suspected splenic infarction.
• Splenic and renal echogenicity comparison is indicated (usually appropriate) when examining left native or transplanted kidney.

Other:
• Follow up of an abnormality seen on prior imaging.

Screening for an Abdominal Aortic Aneurysm:
• One screening study for men 65 to 75 years old who currently or have a history of smoking.

Non-screening studies for Abdominal Aortic Aneurysm:

<table>
<thead>
<tr>
<th>Indications</th>
<th>Appropriate Use Score (4-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal Aortic Disease: Signs and/or Symptoms</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Lower extremity claudication</td>
</tr>
<tr>
<td>2</td>
<td>New onset abdominal or back pain</td>
</tr>
<tr>
<td>3</td>
<td>Aneurysmal femoral or popliteal pulse</td>
</tr>
<tr>
<td>4</td>
<td>Pulsatile abdominal mass</td>
</tr>
<tr>
<td>5</td>
<td>Decreased or absent femoral pulse</td>
</tr>
<tr>
<td></td>
<td>• Abdominal or femoral bruit</td>
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<td>---</td>
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</tr>
<tr>
<td>7</td>
<td>• Evidence of atheroemboli in the lower extremities, including ischemic toes</td>
</tr>
<tr>
<td>8</td>
<td>• Erectile dysfunction</td>
</tr>
<tr>
<td>9</td>
<td>• Abnormal physiologic testing indicating aortoiliac occlusive disease</td>
</tr>
<tr>
<td>10</td>
<td>• Abnormal abdominal x-ray suggestive of aneurysm</td>
</tr>
<tr>
<td>11</td>
<td>• Presence of a lower extremity arterial aneurysm (e.g., femoral or popliteal)</td>
</tr>
<tr>
<td>12</td>
<td>• Presence of a thoracic aortic aneurysm</td>
</tr>
</tbody>
</table>

### New or Worsening Symptoms

|   | • Known abdominal aortic aneurysm (any size) | A (9) |

#### 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>14</td>
<td>Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>n/a</td>
<td>U (4)</td>
</tr>
<tr>
<td>15</td>
<td>Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>n/a</td>
<td>U (4)</td>
</tr>
<tr>
<td>16</td>
<td>Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>U (4)</td>
<td>A (7)</td>
</tr>
<tr>
<td>17</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>18</td>
<td>Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>n/a</td>
<td>A (7)</td>
</tr>
<tr>
<td>19</td>
<td>Women, aneurysm 3.0 to 3.9 cm in diameter</td>
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<td>A (7)</td>
</tr>
<tr>
<td>20</td>
<td>Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>U (5)</td>
<td>A (7)</td>
</tr>
<tr>
<td>21</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>22</td>
<td>Men, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>A (7)</td>
<td>A (7)</td>
</tr>
<tr>
<td>23</td>
<td>Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>A (8)</td>
<td>A (7)</td>
</tr>
<tr>
<td>24</td>
<td>Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>A (8)</td>
<td>A (7)</td>
</tr>
<tr>
<td>25</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)

<table>
<thead>
<tr>
<th></th>
<th>• Aortic or iliac endograft</th>
<th>A (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>26</td>
<td>Aortic and iliac artery stents</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

### New or Worsening Lower Extremity Symptoms After Baseline Exam

<table>
<thead>
<tr>
<th></th>
<th>• Aortic or iliac endograft</th>
<th>A (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>28</td>
<td>Aortic and iliac artery stents</td>
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</tbody>
</table>

### Asymptomatic or Stable Symptom After Baseline

<table>
<thead>
<tr>
<th></th>
<th>At 3 to 5</th>
<th>At 6 to 8</th>
<th>At 9 to 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>26</td>
<td>Aortic or iliac endograft</td>
<td>A (8)</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>Aortic and iliac artery stents</td>
<td>A (7)</td>
<td></td>
</tr>
</tbody>
</table>

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Proprietary

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<table>
<thead>
<tr>
<th>Study, Surveillance Frequency During First Year.</th>
<th>months</th>
<th>months</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Aortic endograft without endoleak stable and/or decreasing residual aneurysm sac size</td>
<td>n/a</td>
<td>U (5)</td>
</tr>
<tr>
<td>31 Aortic endograft with endoleak and/or increasing residual aneurysm sac size</td>
<td>U (6)</td>
<td>A (8)</td>
</tr>
<tr>
<td>32 Aortic or iliac artery stents</td>
<td>n/a</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study, Surveillance Frequency After the 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>33 Aortic endograft without endoleak stable and/or decreasing residual aneurysm sac size</td>
<td>n/a</td>
<td>A (7)</td>
<td>U (5)</td>
</tr>
<tr>
<td>34 Aortic endograft with endoleak and/or increasing residual aneurysm sac size</td>
<td>A (8)</td>
<td>A (7)</td>
<td>U (5)</td>
</tr>
<tr>
<td>35 Aortic or iliac artery stents</td>
<td>n/a</td>
<td>U (5)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

**INDICATIONS FOR AN ABDOMEN ULTRASOUND IN CHILDREN:**

**Suspected appendicitis:**
- Right-sided mid or lower abdominal pain with at least one of the following:
  - Fever
  - Elevated WBC
  - Nausea
  - Guarding and/or rebound

**Gallbladder Disease:**
- Symptoms suggestive of gallbladder disease including:
  - Right upper quadrant pain
  - Fever
  - Elevated WBC
  - Murphy's sign
  - Jaundice
  - History of biliary surgery
  - Known cholelithiasis
  - New onset of jaundice in patient without pain.

**Hepatic Disease**

**Inflammatory**
- Suspected inflammatory or infectious process involving the liver
- Follow-up of infectious lesion(s) 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.

**Mass Lesions:**
- To determine if lesion identified on other imaging is cystic, solid or vascular
• To evaluate for liver metastases when elevated liver functions and known primary tumor
• To follow known liver masses after anti-tumor treatment (≥ 6 month interval) or antibiotic treatment (interval depends on organisms).

Renal Disease:

Hematuria:
• Hematuria (Note: CT or MRI is procedure of choice in macroscopic hematuria and traumatic setting).

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:
  o Poor response to antibiotics within 48 hours
  o Sepsis
  o Urinary retention
  o Poor urine stream
  o Increased serum creatinine
  o Non-E. Coli organism
  o 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

Acute Pyelonephritis:
• Suspected acute pyelonephritis in presenting with:
  • Flank pain
  • Nausea and vomiting
  • Fever* (>38°, 100.4°F) or
  • Costovertebral angle tenderness
  • Fever may be absent in immunocompromised persons.

Chronic Kidney Disease:
• Newly diagnosed
• 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
• Symptoms of urinary tract obstruction

Kidney Transplant:
• Increase in the serum creatinine levels
• Acute signs, symptoms of inflammatory process or infection in transplanted organ.
• Post operative/procedural
• 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. Follow-up of a kidney abnormality seen on prior imaging

**Pancreas Disease:**

**Suspected Acute Pancreatitis:**
• Epigastric/upper abdominal pain of unknown etiology with acute onset that is rapidly increasing in severity, and is persistent without relief AND
• Elevated serum amylase and/or lipase level

**Chronic Pancreatitis:**
• One or more of the following symptoms:
  o Epigastric pain that often radiates to the back, worsens after eating and may be relieved by sitting or standing upright or leaning forward
  o Steatorrhea or floating stools
  o Vitamin deficiency (fat-soluble vitamins)
  o History of heavy alcohol use
  o History of previous acute episodes of pancreatitis

**Other Pancreatic Lesions:**
• Suspected pancreatic necrosis
• Suspected pancreatic abscess
• Suspected pancreatic pseudocysts

**Splenic Disease**

**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, port hypertension) OR
  o Palpable spleen OR
  o Pain on the upper left side of the abdomen AND
  o Fatigue with shortness of breath OR
  o Frequent hiccups OR inability to eat a large meal

**Other Splenic Disease:**
• Suspected splenic infarction.
• Splenic and renal echogenicity comparison is indicated (usually appropriate) when examining left native or transplanted kidney.

**Spine**

**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
  • Skin discolorations
  • Skin tags
  • Hair tufts
  • Hemangiomas
  • Pinpoint midline dimples
  • Paramedian deep dimples

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:
• Follow up of an abnormality seen on prior imaging

REFERENCES


Hepatic Ultrasound


**Renal – Kidney and Adrenal References**


**Aorta - Diaphragm – Spine References**


**Gallbladder and Bile Duct References:**


Pancreas and Spleen References:


CPT Codes: 76856, 76857

INTRODUCTION:

Ultrasound is safe and painless, and produces pictures of the inside of the body using sound waves. Ultrasound imaging, also called ultrasound scanning or sonography, involves the use of a small transducer (probe) and ultrasound gel placed directly on the skin. High-frequency sound waves are transmitted from the probe through the gel into the body. The transducer collects the sounds that bounce back and a computer then uses those sound waves to create an image. Ultrasound examinations do not use ionizing radiation (as used in x-rays), thus there is no radiation exposure to the patient. Because ultrasound images are captured in real-time, they can show the structure and movement of the body's internal organs, as well as blood flowing through blood vessels.

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:
- Signs and symptoms of suspected kidney stones
- Urinary incontinence
- Signs and symptoms of bladder function abnormality

Pain:
- Pelvic pain, etiology unknown

Menstrual abnormality:
- Dysmenorrhea (painful menses)
- Amenorrhea
- Menorrhagia
- Menometrorrhagia
- Metrorrhagia (irregular uterine bleeding)
- Delayed menses
- Vaginal bleeding in a prepubertal child
- Postmenopausal bleeding
- Imperforate hymen

Known or suspected infection or inflammation of the pelvis:
- Signs or symptoms of pelvic infection, inflammation, or abscess.
- Excessive bleeding, pain, or signs of infection after pelvic surgery, delivery, or abortion.

Other Indications:
- Pre-pubertal child
- Precocious puberty
- Localization of an intrauterine contraceptive device.
- Screening for malignancy in patients at increased risk.
• Pelvic organ prolapse.
• Follow-up of a previously detected abnormality.
• Evaluation, monitoring, and/or treatment of infertility patients
• Abnormal or technically limited physical-pelvic examination
• Congenital anomalies
• Foreign body localization
• Evaluation of ovarian, adnexal, or uterine abnormalities
• Evaluation of a hernia
• Guidance for interventional or surgical procedures.
• Follow up of a pelvic abnormality seen on prior imaging
• Obstructive urinary symptoms.
• Ureteral displacement or obstruction.
• Known or suspected tumor or mass.

Infertility:
• Evaluation of infertility/seminal vesicles patients.

ADDITIONAL INFORMATION:
• 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.

• Pelvic ultrasound may be used in adolescents to track developmental changes in uterine and ovarian morphology as a function of weight gain. The use of pelvic U/S allows for more objective estimates of weight gain requirements that are reliably linked to increasing reproductive maturity.

• 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:
  o blockages to blood flow (such as clots)
  o narrowing of vessels (which may be caused by plaque)
  o tumors and congenital malformation

• Transabdominal ultrasound (TAUS) – TAUS imaging has been evaluated to train the strength and endurance of the pelvic floor muscles (PFMs). Use of TAUS imaging is a helpful assessment and biofeedback tool for re-education and rehabilitation of the PFMs for the patient.

• 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:

- Abnormality noted on other imaging studies (e.g., computed tomography, magnetic resonance imaging, positron emission tomography)
- Intersex conditions*
- Infertility
- Occult primary tumor detection in patients with metastatic germ cell tumor
- Palpable inguinal or scrotal mass
- Potential scrotal hernia
- Suspected testicular torsion (when real time, pulse wave and color doppler ultrasound imaging are used in conjunction)
- Follow up of previous indeterminate scrotal ultrasound
- Undescended testes
- Scrotal asymmetry, swelling, or enlargement
- Scrotal pain
- Varicocele
- Trauma

INDICATIONS FOR SURVEILLANCE:

- Prior primary testicular neoplasms, leukemia, or lymphoma

ADDITIONAL INFORMATION RELATED TO ULTRASOUND OF THE SCROTUM

Scrotal abnormalities may be the result of disease, injury, or a physiologic anomaly. Abnormalities within the reproductive tract may appear as scrotal masses or as intersex conditions. Masses may be of little significance or may represent life-threatening illnesses. Examples of these include inguinal or scrotal hernias, tumors, varicocele, acute epididymitis or epididymoorchitis, a torsioned spermatic cord or testicular appendage. Physical examination in combination with appropriate imaging of these tissues is important, as a surgical versus nonsurgical diagnosis must be clearly identified, especially in patients experiencing acute pain without having a history of trauma or previous scrotal mass.

An inguinal or scrotal hernia occurs when intestinal loops and/or omentum passes through thin or weakened spots in the groin muscle, resulting in a bulge in the groin or scrotal area. A scrotal mass may be an accumulation of fluids; abnormal tissue growth; or the swelling, inflammation, or hardening of the normal contents of the scrotum. A mass may be cancerous or caused by another condition.
A varicocele is the result of valvular dysfunction of the veins along the spermatic cord, which prevents the proper flow of blood and swelling or widening of the veins.

Epididymitis is inflammation of the epididymis, the tube that connects the testicle with the vas deferens. Infertility may be affected by testicular abnormalities such as microcirculation impairment, ischemia, or disease pathology.

Testicular torsion occurs when a testicle rotates, twisting the spermatic cord that brings blood to the scrotum. The reduced blood flow causes sudden, and often severe, pain and swelling.

Undescended testicles are the failure of the testicles to descend through the inguinal canal into the scrotum before birth. US has not been shown to be effective in the localization of undescended testes.

Testicular injuries can be divided into 3 broad categories based on the mechanism of injury. These categories include (1) blunt trauma, (2) penetrating trauma, and (3) degloving trauma. Such injuries are typically seen in patients aged 15-40 years. Scrotal ultrasonography with Doppler flow evaluation is particularly helpful in determining the nature and extent of injury. This is especially true in blunt trauma cases, given the difficulty of scrotal examination and the repercussions of missing a testicular rupture.

*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


The Intersex Society of North America (ISNA) http://www.isna.org/


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 relatively 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.

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 (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>
<tr>
<td>1.</td>
<td>• 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</td>
<td>A (9)</td>
</tr>
<tr>
<td>2.</td>
<td>• Hollenhorst plaque visualized on retinal examination</td>
<td>A (8)</td>
</tr>
<tr>
<td>3.</td>
<td>• Lightheadedness or impaired vision in the setting of upper extremity exertion • Evaluation for subclavian–vertebral steal phenomenon</td>
<td>A (7)</td>
</tr>
<tr>
<td>4.</td>
<td>• Syncope of uncertain cause after initial cardiovascular</td>
<td>U (5)</td>
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<tr>
<td>5.</td>
<td>• Suspected symptomatic vertebrobasilar occlusive disease in the symptomatic patient (e.g., vertigo, ataxia, diplopia, dysphagia, dysarthria) A (7)</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>• Evaluation for suspected carotid artery dissection (b) A (8)</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>• Pulsatile neck mass A (8)</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>• Cervical bruit   • No prior carotid artery assessment A (7)</td>
<td></td>
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</tbody>
</table>

**Evaluation for Cerebrovascular Disease—Asymptomatic With Comorbidities or Risk Factors for Carotid Artery Stenosis**

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<table>
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<tbody>
<tr>
<td>9.</td>
<td>• No cervical bruit   • Atherosclerotic disease in other vascular beds (e.g., lower extremity PAD, coronary artery disease, abdominal aortic aneurysm) (c) A (7)</td>
</tr>
<tr>
<td>10.</td>
<td>• No cervical bruit   • History of neck irradiation ≥10 years ago U (5)</td>
</tr>
<tr>
<td>11.</td>
<td>• Known renal fibromuscular dysplasia U (5)</td>
</tr>
</tbody>
</table>

**Prior to Open Heart Surgery**

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<tbody>
<tr>
<td>12.</td>
<td>• Planned coronary artery bypass grafting (CABG) (c) U (6)</td>
</tr>
<tr>
<td>13.</td>
<td>• 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)</td>
</tr>
<tr>
<td>14.</td>
<td>• Atherosclerotic risk factors present   • Planned valve repair/replacement surgery (without CABG) (c) U (6)</td>
</tr>
<tr>
<td>15.</td>
<td>• No atherosclerotic risk factors   • Planned valve repair/replacement surgery (without CABG) (c) U (4)</td>
</tr>
</tbody>
</table>

**Follow-Up or Surveillance for Carotid Artery Stenosis—Asymptomatic***

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<table>
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<tbody>
<tr>
<td>16.</td>
<td>• Normal prior examination (no plaque, no stenosis) (c) (e) I (1)</td>
</tr>
</tbody>
</table>

**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>17.</td>
<td>• Plaque without significant stenosis of the ICA (plaque, normal ICA velocity) (e) I (1)</td>
<td>I (1)</td>
<td>I (1)</td>
</tr>
</tbody>
</table>
18. •Mild ICA stenosis (e.g., <50%) (e) & I (1) & I (1) & I (1)
19. •Moderate ICA stenosis (e.g., 50% to 69%) (e) & I (2) & U (6) & U (6)
20. •Severe ICA stenosis (e.g., 70% to 99%) (e) & U (5) & A (7) & U (6)

<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>21. •Plaque without significant stenosis of the ICA (plaque, normal ICA velocity) (e)</td>
<td>I (1)</td>
<td>I (3)</td>
<td>I (1)</td>
</tr>
<tr>
<td>22. •Mild ICA stenosis (e.g., &lt;50%) (e)</td>
<td>I (2)</td>
<td>U (5)</td>
<td>U (6)</td>
</tr>
<tr>
<td>23. •Moderate ICA stenosis (e.g., 50% to 69%) (e)</td>
<td>I (3)</td>
<td>A (7)</td>
<td>U (6)</td>
</tr>
<tr>
<td>24. •Severe ICA stenosis (e.g., 70% to 99%) (e)</td>
<td>A (7)</td>
<td>A (7)</td>
<td>U (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Surveillance After Carotid Artery Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>25. • Baseline (within 1 month) after carotid intervention</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year</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>26. • Following normal ipsilateral 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>

<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 ipsilateral 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>

*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 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 9 month.
3) Emergent or urgent requests in the immediate postoperative or postprocedural period.

ADDITIONAL CONSIDERATIONS

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

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
REFERENCES:


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)
- Management of infants of less than 30 days gestation and very low birth weight preterm infants

TCD is not specifically indicated or is superseded by more relevant modalities (such as MRA, CTA or Angiography):

- Assessing collateral blood flow and embolization during carotid endarterectomy; or
- Assessing patterns and extent of collateral circulation in persons with known regions of severe stenosis or occlusion, including persons with Moyamoya syndrome; or
- Assessing persons suspected of having patent foramen ovale/paradoxical embolism (symptoms include visual disturbance, weakness, hemiplegia, or slurred speech); or
- Assessing persons with suspected brain death; or
- Detecting arterio-venous malformations (AVMs) and studying their supply arteries and flow patterns; or
- Detecting microemboli in cerebral artery embolism; or
- Detecting severe stenosis in the major basal intra-cranial arteries for members who have neurological signs or symptoms or carotid bruits; or
- Diagnosing dissection of vertebral artery; or
- Evaluating and following persons with vasoconstriction of any cause, especially after subarachnoid hemorrhage; or
**TCD is not indicated for the following scenarios:**

- Assessing autoregulation, physiologic, and pharmacologic responses of cerebral arteries; or
- Brain tumors; or
- Diagnosing cerebral vein and sinus thrombosis and other conditions that involve venous pathology; or
- Diagnosing or monitoring response to anti-thrombotic therapy in ischemic cerebrovascular disease; or
- Epilepsy; or
- Evaluating adults with sickle cell anemia; or
- Evaluating ataxia, head trauma/skull fracture; or
- Evaluating children with neurofibromatosis; or
- Evaluating persons with dilated vasculopathies such as fusiform aneurysms; or
- Familial and degenerative diseases of the cerebrum, brainstem, cerebellum, basal ganglia and motor neurons (e.g., Parkinson’s disease); or
- Following placement of an intra-cerebral arterial stent; or
- Infectious and inflammatory conditions of the brain; or
- Migraine headaches; or
- Monitoring during cardiopulmonary bypass and other cerebrovascular and cardiovascular interventions, and surgical procedures other than carotid endarterectomy; or
- Predicting hemorrhagic transformation of ischemic infarction; or
- Predicting outcome in vertebrobasilar distribution stroke; or
- Psychiatric disorders; or
- Screening for carotid artery stenosis in asymptomatic adults; or
- Screening for stenosis of cerebral arteries in persons with fibromuscular dysplasia.

**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 relatively 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.

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.

**ACCF/ACR/AIUM/ASE/ASN/ICAVL/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><strong>Lower Extremity Artery Testing Using Multilevel Physiological Testing Alone or Duplex Ultrasound With Single-Level ABI and PVR</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Evaluation for Lower Extremity Atherosclerotic Disease – Potential Signs and/or Symptoms</strong></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>
<td>109.</td>
<td>Suspected acute limb ischemia (e.g., cold, painful limb with pallor, pulselessness, paresthesia)</td>
<td>A (9)</td>
</tr>
<tr>
<td>110.</td>
<td>Nocturnal leg cramps</td>
<td>I (2)</td>
</tr>
<tr>
<td></td>
<td>Normal pulses</td>
<td></td>
</tr>
</tbody>
</table>
| 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**

| 115. | • Normal Baseline Study | A (7) |
| 116. | • Abnormal baseline ABI (i.e., ABI ≤ 0.90) | A (8) |

**No Change in Symptom Status (No revascularization)**

<table>
<thead>
<tr>
<th>Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year</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>117.</td>
<td>• Normal baseline ABI (no stenosis)</td>
<td>I (1)</td>
<td>I (1)</td>
</tr>
<tr>
<td>118.</td>
<td>• Mild or moderate disease (e.g., ABI &gt;0.4)</td>
<td>I (2)</td>
<td>I (2)</td>
</tr>
<tr>
<td>119.</td>
<td>• Severe (e.g., ABI &lt;0.4)</td>
<td>I (3)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptomatic 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>120.</td>
<td>• Normal baseline ABI (no stenosis)</td>
<td>I (1)</td>
<td>I (1)</td>
</tr>
<tr>
<td>121.</td>
<td>• Mild or moderate disease (e.g., ABI &gt;0.4)</td>
<td>I (2)</td>
<td>I (2)</td>
</tr>
<tr>
<td>122.</td>
<td>• Severe (e.g., ABI &lt;0.4)</td>
<td>U (4)</td>
<td>U (4)</td>
</tr>
</tbody>
</table>

**Surveillance of Lower Extremity PAD After Revascularization (Duplex/ABI)**

| 123. | • Baseline surveillance (within 1 month) | A (8) |

**New or Worsening Symptoms**

| 124. | • After revascularization (angioplasty ± stent or bypass) | A (9) |

**Asymptomatic or Stable Symptoms**

<table>
<thead>
<tr>
<th>Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year</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>125.</td>
<td>• After angioplasty ± stent placement</td>
<td>I (2)</td>
<td>U (6)</td>
</tr>
<tr>
<td>126.</td>
<td>• After vein bypass graft</td>
<td>U (6)</td>
<td>A (8)</td>
</tr>
<tr>
<td></td>
<td>After prosthetic bypass graft</td>
<td>U (5)</td>
<td>A (7)</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency After First Year</td>
<td>Every 6 months</td>
<td>Every 12 months</td>
<td>Every 24 months or greater</td>
</tr>
<tr>
<td>128.</td>
<td>After angioplasty ± stent placement</td>
<td>I (3)</td>
<td>A (7)</td>
</tr>
<tr>
<td>129.</td>
<td>After vein bypass graft</td>
<td>U (5)</td>
<td>A (7)</td>
</tr>
<tr>
<td>130.</td>
<td>After prosthetic bypass graft</td>
<td>I (3)</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**Lower Extremity Artery Testing With ABI Only**

**Screening for Lower Extremity Atherosclerotic Disease - Potential Signs**

<table>
<thead>
<tr>
<th></th>
<th>Diminished pulses</th>
<th>A (7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>131.</td>
<td>Femoral Bruit</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**Screening for Lower Extremity Atherosclerotic Disease – Asymptomatic With Comorbidities**

<table>
<thead>
<tr>
<th></th>
<th>Age &gt;50 years</th>
<th>A (7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>133.</td>
<td>With diabetes</td>
<td></td>
</tr>
<tr>
<td>134.</td>
<td>Age &lt;50 years</td>
<td></td>
</tr>
<tr>
<td>135.</td>
<td>With diabetes</td>
<td></td>
</tr>
<tr>
<td>135.</td>
<td>Age &lt;50 years</td>
<td></td>
</tr>
<tr>
<td>136.</td>
<td>Cigarette smoking (current or past)</td>
<td>A (7)</td>
</tr>
<tr>
<td>136.</td>
<td>Age &gt;70 years</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**Lower Extremity Artery Testing With Duplex Ultrasound Only**

**Evaluation for Groin Complication After Femoral Access**

<table>
<thead>
<tr>
<th></th>
<th>Pulsatile groin mass</th>
<th>A (9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>137.</td>
<td>Bruit or thrill over the groin</td>
<td>A (8)</td>
</tr>
<tr>
<td>138.</td>
<td>Ecchymosis</td>
<td>U (4)</td>
</tr>
<tr>
<td>139.</td>
<td>Significant hematoma</td>
<td>A (7)</td>
</tr>
<tr>
<td>140.</td>
<td>Severe pain within groin post procedure</td>
<td>A (&amp;)</td>
</tr>
</tbody>
</table>

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.
- Routine surveillance after femoral-popliteal or femoral-tibial-pedal bypass with a venous conduit. Minimal surveillance intervals are 3, 6 and 12 months then yearly.
- 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.
- 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:

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 regimens 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, ICAVL or American College of Radiology, ACR). Interpretation of studies is 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. 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


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 relatively 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 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.

<table>
<thead>
<tr>
<th>ACCF/ACR/AIUM/ASE/ASN/ICAVAL/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>A _ appropriate; I _ inappropriate; U _ uncertain</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Upper Extremity Arterial Testing – Physiological Testing or Duplex Ultrasound Study</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Evaluation for Upper Extremity PAD – Potential Signs and/or Symptoms</strong></td>
<td></td>
<td></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></td>
<td>Periclavicular bruit</td>
<td>U (5)</td>
</tr>
<tr>
<td>---</td>
<td>----------------------</td>
<td>-------</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>
</tbody>
</table>

**Surveillance of Upper Extremity PAD After Revascularization**

<table>
<thead>
<tr>
<th></th>
<th>Baseline (within 1 month)</th>
<th>A (8)</th>
</tr>
</thead>
</table>

**New or Worsening Symptoms**

<table>
<thead>
<tr>
<th></th>
<th>After revascularization (stent or bypass)</th>
<th>A (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>155.</td>
<td>Post trauma</td>
<td>A (8)</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>156.</td>
<td>After vein bypass graft</td>
<td>U (6)</td>
<td>A (7)</td>
</tr>
<tr>
<td>157.</td>
<td>After prosthetic bypass graft</td>
<td>I (3)</td>
<td>U (6)</td>
</tr>
</tbody>
</table>

**Asymptomatic or Stable Symptoms After Baseline Study, 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>158.</td>
<td>After vein bypass graft</td>
<td>U (4)</td>
<td>A (7)</td>
</tr>
<tr>
<td>159.</td>
<td>After prosthetic bypass graft</td>
<td>U (4)</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

**ADDITIONAL CONSIDERATIONS:**

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:**

**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.

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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 relatively 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 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.

<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 appropriate; R = rarely appropriate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Venous Duplex of the Upper extremities for Patency and Thrombosis**

**Limb Swelling**

1. • Unilateral – Acute  
   A (9)

2. • Unilateral – chronic, persistent  
   A (7)

3. • Bilateral – acute  
   • Suspected central venous obstruction  
   A (8)

4. • Bilateral—chronic, persistent  
   • No alternative diagnosis identified (e.g., no CHF or CHF)  
   A (7)
anasarca from hypoalbuminemia)  
- Suspected central venous obstruction

<table>
<thead>
<tr>
<th>Limb Pain (without swelling)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Nonarticular pain in the upper extremity (no indwelling upper extremity venous catheter)</td>
</tr>
<tr>
<td>6. Nonarticular pain in the upper extremity with indwelling upper extremity venous catheter</td>
</tr>
<tr>
<td>7. Tender, palpable cord in the upper extremity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shortness of Breath</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Suspected pulmonary embolus (no indwelling upper extremity venous catheter)</td>
</tr>
<tr>
<td>9. Suspected pulmonary embolus with indwelling upper extremity venous catheter</td>
</tr>
<tr>
<td>10. Diagnosed pulmonary embolus (no indwelling upper extremity venous catheter)</td>
</tr>
<tr>
<td>11. Diagnosed pulmonary embolus with indwelling upper extremity venous catheter</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fever</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Fever of unknown origin (no indwelling upper extremity venous catheter)</td>
</tr>
<tr>
<td>13. Fever with indwelling upper extremity venous catheter</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Known Upper Extremity Venous Thrombosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. New upper extremity pain or swelling while on anticoagulation.</td>
</tr>
<tr>
<td>15. New upper extremity pain or swelling not on anticoagulation (i.e., contraindication to anticoagulation)</td>
</tr>
<tr>
<td>16. Before anticipated discontinuation of anticoagulation treatment</td>
</tr>
<tr>
<td>17. Shortness of breath in a patient with known upper extremity DVT</td>
</tr>
<tr>
<td>• Not on anticoagulation, phlebitis location ≤ 5 cm from deep vein junction.</td>
</tr>
<tr>
<td>• Not on anticoagulation, phlebitis location ≥ 5 cm from deep vein junction.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vein Mapping Prior to ByPass Surgery (Coronary or Peripheral)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20. In the absence of adequate leg vein for harvest</td>
</tr>
<tr>
<td>21. In the presence of adequate leg vein for harvest.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screening Examination for Upper Extremity DVT (Screening examination performed in the absence of</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>---</td>
</tr>
<tr>
<td>22</td>
</tr>
<tr>
<td>23</td>
</tr>
<tr>
<td>24</td>
</tr>
<tr>
<td>25</td>
</tr>
<tr>
<td>26</td>
</tr>
<tr>
<td>27</td>
</tr>
</tbody>
</table>

**VENOUS DUPLEX FOR LOWER EXTREMITIES**

**Venous Duplex of the Lower Extremities for Patency and Thrombosis**

**Limb Swelling**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Code</th>
</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)**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Code</th>
</tr>
</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**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Code</th>
</tr>
</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**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Code</th>
</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**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Code</th>
</tr>
</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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>40.</td>
<td>• New lower extremity pain or swelling</td>
<td>A (7)</td>
</tr>
<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:**

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 **Appropriate** study when evidence of venous obstruction exist 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:**

**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**


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 relatively 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.

Renal Artery imaging involves the use of color Doppler to access flow disturbance and the presence of plaque and spectral Doppler to measure flow velocities from the renal artery ostium to the hilum. Doppler spectral waveforms are obtained from the segmental arteries of the renal parenchyma. Kidney length is noted. Multiple renal arteries are noted. Patency of the renal veins and any other abnormalities such as masses or cysts are documented.

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.

### ACCF/ACR/AIUM/ASE/ASN/ICAVAL/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>Renal and Mesenteric Artery Duplex</td>
<td>A _ appropriate; I _ inappropriate; U _ uncertain</td>
<td></td>
</tr>
<tr>
<td>34.</td>
<td>Malignant Hypertension (see Assumptions)</td>
<td>A (8)</td>
</tr>
<tr>
<td>35.</td>
<td>Resistant Hypertension (see Assumptions)</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</td>
<td>A (7)</td>
</tr>
</tbody>
</table>
### 39. Unknown cause of azotemia (e.g., unexplained increase in creatinine)  
A (7)

### 40. Increased creatine (>50% baseline or above normal levels) after the administration of ACE/ARBs.  
A (8)

### 41. Acute renal failure with aortic dissection  
A (8)

### 42. Epigastric bruit  
A (7)

### Heart Failure of Unknown Origin

#### 43. Refractory CHF  
A (7)

#### 44. “Flash” pulmonary edema  
A (8)

### Screening for Renal Artery Stenosis - Asymptomatic

#### 45. Atherosclerotic vascular disease in other beds (e.g., peripheral artery disease) and well-controlled hypertension  
I (3)

#### 46. Unexplained size discrepancy between kidneys (>1.5 cm; in longest dimension) as discovered by CT or ultrasound  
U (4)

### Evaluation for Mesenteric Artery Stenosis – Potential Signs and/or Symptoms

#### Symptomatic

#### 47. Evaluation for acute abdominal pain “out of proportion to exam"  
Leukocytosis, “thumbprinting” pneumatosis or hemoconcentration, and acidosis with or without elevated amylase, alkaline phosphatase, or CPK  
I (3)

#### 48. Postprandial pain or weight loss not otherwise explained  
GI evaluation previously completed  
A (8)

#### 49. Postprandial pain or discomfort  
GI evaluation not yet undertaken  
U (5)

#### 50. Chronic constipation or diarrhea  
GI evaluation not yet undertaken  
I (3)

#### 51. Unexplained or unintended weight loss  
U (5)

#### 52. Abdominal or epigastric bruit  
U (4)

#### Follow-Up Testing for Renal Artery Stenosis - Asymptomatic

#### 53. Prior imaging indicates renal artery stenosis  
Determine hemodynamic significance  
A (7)

#### 54. Surveillance of known renal artery stenosis  
U (6)

### Surveillance After Renal or Mesenteric Artery Revascularization

#### Asymptomatic
### Baseline surveillance (within 1 month) after revascularization

A (8)

### New or Worsening Symptoms After Baseline

56. • After renal or mesenteric artery revascularization

A (8)

### Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency During First Year

<table>
<thead>
<tr>
<th>Frequency</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>57. During first 12 months after endovascular revascularization</td>
<td>I (3)</td>
<td>U (6)</td>
<td>U (6)</td>
</tr>
</tbody>
</table>

### Asymptomatic or Stable Symptoms After Baseline Study, Surveillance Frequency After First Year

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Every 6 months</th>
<th>Every 12 months</th>
<th>Every 23 months or greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>58. After first 12 months after endovascular revascularization</td>
<td>I (3)</td>
<td>A (7)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

### 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>86.</td>
<td>Abnormal liver function tests.</td>
<td>M (6)</td>
</tr>
<tr>
<td></td>
<td>No alternative diagnosis identified (e.g., medication related or infectious hepatitis)</td>
<td></td>
</tr>
<tr>
<td>87.</td>
<td>Cirrhosis with or without ascites</td>
<td>A (7)</td>
</tr>
<tr>
<td>88.</td>
<td>Jaundice</td>
<td>R (3)</td>
</tr>
<tr>
<td></td>
<td>As an initial diagnostic test</td>
<td></td>
</tr>
<tr>
<td>89.</td>
<td>Jaundice</td>
<td>M (6)</td>
</tr>
<tr>
<td></td>
<td>No alternative diagnosis identified after initial evaluation (e.g., no biliary obstruction)</td>
<td></td>
</tr>
<tr>
<td>90.</td>
<td>Hepatomegaly and/or splenomegaly</td>
<td>A (7)</td>
</tr>
<tr>
<td>91.</td>
<td>Portal hypertension</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

### 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)

**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 below. It is **Not Appropriate** 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. Surveillance is **Appropriate** after 12 months from the procedure.

Routine surveillance is **Not Appropriate** in the absence of recurrent or worsening symptoms.

**Duplex evaluation of the Hepatoportal System**
Duplex ultrasound evaluation is **Appropriate** for the evaluation of cirrhosis 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 **Inappropriate** in the initial evaluation of abdominal pain, 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 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 other symptoms compatible with renal vein thrombosis, renal venous duplex scanning may be **Appropriate**.

Renal venous duplex is **Inappropriate** for the evaluation of microscopic hematuria, fever of unknown origin and pulmonary symptoms. Renal venous duplex is **Inappropriate** 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**


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 relatively 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.

An abdominal Aortoiliac duplex examination should examine the native aorta with 2D sonography from the diaphragm to the groins bilaterally. Diameter measurements are made of the suprarenal, juxtarenal and infrarenal segments of the aorta and common and external iliac arteries. The internal iliac arteries are identified if possible. Measurements are made at the point of maximal diameter. Color duplex is used to determine patency. The presence of thrombus, residual lumen, dissection, flaps, pseudoaneurysms, wall defects stenoses and occlusions are documented. Stenosis is confirmed by spectral Doppler waveform analysis.

Evaluation of endovascular stent grafts is somewhat more complex. Using gray scale or B-mode imaging the diameter of the residual aortic aneurysm is measured, the fixation sites are accessed and the residual sac is observed for areas of echolucency or motion/pulsation. Doppler is used to demonstrate patency of renal and mesenteric arteries, graft limbs, and runoff vessels. Color Doppler is used to detect any endoleak. Pulse wave spectral Doppler is used to detect any flow restrictions or turbulence that may indicate a technical problem. Examination of the mesenteric and splanchnic arteries requires obtaining spectral waveforms from the celiac axis, splenic and hepatic arteries, and the superior and inferior mesenteric arteries.

As a screening examination this is by definition a limited study. 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 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.
<table>
<thead>
<tr>
<th>Criteria #</th>
<th>A _ appropriate; I _ inappropriate; U _ uncertain</th>
<th>9)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aortic and Aortoiliac Duplex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Abdominal Aortic Disease - Signs and/or Symptoms</strong></td>
<td></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>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>
<tr>
<td><strong>New or Worsening Symptoms</strong></td>
<td></td>
<td></td>
</tr>
<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>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>
</tr>
<tr>
<td>84.</td>
<td>Women, aneurysm 3.0 to 3.9 cm in diameter</td>
<td>I (1)</td>
</tr>
<tr>
<td>85.</td>
<td>Aneurysm 4.0 to 5.4 cm in diameter</td>
<td>U (4)</td>
</tr>
<tr>
<td>86.</td>
<td>Aneurysm ≥ 5.5 cm in diameter</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>
</tr>
</thead>
<tbody>
<tr>
<td>95.</td>
<td>• Aortic or iliac endograft</td>
</tr>
<tr>
<td>96.</td>
<td>• Aortic and iliac artery stents</td>
</tr>
</tbody>
</table>

### New or Worsening Lower Extremity Symptoms After Baseline Exam

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>97.</td>
<td>• Aortic or iliac endograft</td>
</tr>
<tr>
<td>98.</td>
<td>• Aortic and iliac artery stents</td>
</tr>
</tbody>
</table>

### Asymptomatic or Stable Symptom 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>99.</td>
<td>• Aortic endograft without endoleak stable and/or decreasing residual aneurysm sac size</td>
<td>I (3)</td>
<td>U (5)</td>
</tr>
<tr>
<td>100.</td>
<td>• Aortic endograft with endoleak and/or increasing residual aneurysm sac size</td>
<td>U (6)</td>
<td>A (8)</td>
</tr>
<tr>
<td>101.</td>
<td>• Aortic or iliac artery stents</td>
<td>I (2)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

### Asymptomatic or Stable Symptom After Baseline Study, Surveillance Frequency After the First Year.

<table>
<thead>
<tr>
<th></th>
<th>Every 6 months</th>
<th>Every 12 months</th>
<th>Every 24 months or greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>102.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>102.</td>
<td>• Aortic endograft without endoleak stable and/or decreasing residual aneurysm sac size</td>
<td>I (3)</td>
<td>A (7)</td>
</tr>
<tr>
<td>------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>103.</td>
<td>• Aortic endograft with endoleak and/or increasing residual aneurysm sac size</td>
<td>A (8)</td>
<td>A (7)</td>
</tr>
<tr>
<td>104.</td>
<td>• Aortic or iliac artery stents</td>
<td>I (2)</td>
<td>U (5)</td>
</tr>
</tbody>
</table>

**ACCF/ACR/AIUM/ASE/IAC/SCAI/SCVS/SIR/SVM/SVS/SVU 2013 Appropriate Use Criteria**

**ACCF et al. Criteria #**

<table>
<thead>
<tr>
<th>Indications</th>
<th>Appropriate Use Score (1-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A _ appropriate; M _ maybe appropriate; R _ rarely appropriate</td>
<td></td>
</tr>
</tbody>
</table>

**Duplex of the IVC and Iliac Veins for Patency and Thrombosis**

**Prior to IVC Filter Placement**

| 75. | • Prior to IVC filter placement  
|     | • For procedural access planning | M (6) |

**Evaluation for Suspected Deep Vein Thrombosis**

| 76. | • Lower extremity swelling – unilateral or bilateral as a “stand-alone test” without venous duplex of the lower extremities | R (3) |
| 77. | • Lower extremity swelling – unilateral or bilateral combined routinely with a venous duplex of the lower extremities | M (4) |
| 78. | • Lower extremity swelling – unilateral or bilateral performed selectively – when the lower extremity venous duplex is normal | M (6) |
| 79. | • Lower extremity swelling – unilateral or bilateral performed selectively – when the lower extremity venous duplex is positive for acute proximal DVT | A (7) |
| 80. | • Selectively – when the flow pattern in 1 or both common femoral veins is abnormal | A (8) |

**Evaluation of Other Symptoms or Signs of Abdominal Vascular Disease**

| 81. | • Pulmonary symptoms (suspected pulmonary embolus) as a “stand-alone test” without a venous duplex of the lower extremities | R (2) |
| 82. | • Pulmonary symptoms (suspected pulmonary embolus) – combined routinely with a venous duplex of the lower extremities | M (4) |
ADDITIONAL CONSIDERATIONS:

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 preprocedual planning in patients being considered for placement of a Vena Caval filter.

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 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
**REFERENCES**


CPT Codes:
93980 – Bilateral or Complete
93981 - 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 relatively 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:

- Evaluation of erectile dysfunction, impaired erection or complete impotence.

INDICATIONS FOR PENILE COLOR CODED DUPLEX SONOGRAPHY (CCDS)* or DYNAMIC PENILE COLOR DUPLEX ULTRASOUND (D-PCDU):

- Evaluation of patients with erectile dysfunction unresponsive to oral medications.

* 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


## 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 relatively 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 Magellan Healthcare does not review requests for ultrasound studies to determine appropriate INITIAL placement of an access site; Magellan Healthcare 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.

### ACCF/ACR/AIUM/ASE/IAI/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>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>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>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>
<tr>
<td>112.</td>
<td>Arm swelling</td>
<td>A (8)</td>
</tr>
<tr>
<td>113.</td>
<td>Hand pain, pallor, and/or digital ulceration (i.e., evaluation for</td>
<td>A (8)</td>
</tr>
</tbody>
</table>

---

**CPT Codes:** 93990
**ADDITIONAL CONSIDERATIONS:**

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 months 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:**

Assessment Prior to Access Site Placement CPT Code G0365 (Not managed by Magellan Healthcare)

- Pre-operative mapping study (upper extremity arterial and venous duplex) ≥ 3 months prior to access placement.
- Pre-operative mapping study (upper extremity arterial and venous duplex) < 3 months prior to access placement.

**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 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.

<table>
<thead>
<tr>
<th>Suspected arterial steal syndrome)</th>
<th>R (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>114. Cool extremity</td>
<td></td>
</tr>
<tr>
<td>115. Without pain, pallor, or ulceration</td>
<td>A (8)</td>
</tr>
<tr>
<td>116. Difficult cannulation by multiple personnel on multiple attempts</td>
<td>R (3)</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td></td>
</tr>
<tr>
<td>116. Routine surveillance of a functioning AVF or AVG</td>
<td>R (3)</td>
</tr>
</tbody>
</table>
**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**


CPT Codes: 94660

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 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:

- The patient has been previously diagnosed by a physician with a sleep disorder that would benefit from treatment using a Positive Airway Pressure 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:

CPT Codes: 95805, 95808, 95810, 95811

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.

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 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 degrade the accuracy of portable monitoring:
  - Moderate to severe pulmonary disease (for example, COPD or asthma) (with nocturnal oxygen use or daytime hypercapnea with documented arterial blood gases showing pO2 less than 60 or pCO2 greater than 45)
  - Neuromuscular disease (e.g., Parkinson’s disease, spina bifida, myotonic dystrophy, amyotrophic lateral sclerosis)
  - Stroke with residual respiratory effects
  - Epilepsy
  - Congestive heart failure (NYHA class III or IV or LVEF less than 45%)
  - Super obesity (BMI greater than 45, or pulmonary function studies show obesity hypoventilation syndrome {BMI greater than 35 plus arterial blood gas with PCO2 greater than 45, or BMI greater than 35 plus inability to lie flat in bed});
OR
- One or more of the following co-morbid sleep disorders:
  o Periodic limb movement disorder (involuntary, jerking movements of the legs during sleep causing excessive daytime sleepiness (EDS) due to sleep fragmentation),
  o Parasomnias that are unusual or atypical because of the individual's age at onset, the time, duration or frequency of occurrence of the behavior including, but not limited to: nocturnal seizures, psychogenic dissociative states, REM sleep behavior disorder, sleep talking and/or confusional arousals,
    o narcolepsy,
    o central sleep apnea or complex sleep apnea;

OR
- Negative or technically inadequate portable monitoring results; or
- Low pretest probability of obstructive sleep apnea (BMI less than 30, normal airway, no snoring, and neck circumference less than 17 inches in men and less than 16 inches in women and Epworth Score <10) but with the likelihood of other sleep disorders not identified during unattended studies; or
- Patient lacks the mobility or dexterity to use portable monitoring equipment safely at home.

Indications for evaluating suspected obstructive sleep apnea
- Individuals who present with clinical features suggestive of moderate to severe OSA as follows:
  o Excessive daytime sleepiness (EDS) and ONE of the following:
    ▪ BMI greater than 30; or
    ▪ Excessive sleepiness while driving; or
    ▪ Loud/intense snoring; or
    ▪ Epworth Sleepiness Scale (ESS) score of 10 or greater; 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 above are also met.

Indications for a split night sleep study:
- Where attended PSG is indicated, a split-night study PSG is considered medically necessary, in which the final portion of the PSG is used to titrate continuous positive airway pressure (CPAP) if the Apnea Hypopnea Index (AHI) is greater than 15 in first 2 hours of a diagnostic sleep study.

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
  o 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
  o If patient has AHI between 5 and 15, and significant daytime sleepiness, or
  o 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
  o 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
  o 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:
- Where repeat testing is indicated, attended full-channel nocturnal polysomnography (PSG) (Type I device) performed in a healthcare facility is considered medically necessary for persons who meet criteria for attended PSG above; in all other cases, unattended (home) sleep studies are considered medically necessary.
- Repeat sleep studies are indicated up to twice a year for any of the following indications:
  - To determine whether positive airway pressure treatment continues to be effective for patients who report continuing 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
  - The patient reports intolerance of current device indicating the need to attempt a different type of device, or
  - To determine whether positive airway pressure treatment settings need to be changed; or
  - To determine whether continued treatment with positive airway pressure treatment is necessary, such as following a significant weight loss, or
  - To assess treatment response after upper airway surgical procedures, or initial treatment with oral appliances.

Indications for evaluation of patients with Narcolepsy/Idiopathic CNS Hypersomnia
- 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.
- 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
- 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-relate seizures or paroxysmal arousals) that are unusual or atypical because of:
  - The patient’s age at onset
  - The time, duration or frequency of occurrence
  - Features of the behaviors that are violent or otherwise potentially injurious to the patient or others
  - The specifics of the particular motor patterns in question, (e.g. stereotypical, repetitive or focal)

Indications for the evaluation of patients with periodic limb movement disorder
- 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
INDICATIONS FOR SLEEP STUDY, ATTENDED – PEDIATRIC PATIENTS (<18):

- 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 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 use of abbreviated or screening techniques, such as videotaping, nocturnal pulse oximetry, daytime nap PSG, measurements of circulating adropin concentrations, plasma pentraxin 3 and TREM1 levels, or unattended home PSG, is considered experimental and investigational for diagnosis of OSAS in children because their effectiveness for this indication has not been established.

Indications for repeat sleep studies in pediatric patients

- To assess for residual sleep related breathing disorder
  - To titrate positive pressure therapy
  - After initiation of therapy for OSA in presence of
    - obesity,
    - craniofacial abnormalities
- 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:

Epworth sleepiness scale: The Epworth sleepiness scale can be found at http://www.narcolepsynetwork.org/wp-content/uploads/2010/05/ESS_Form-052210.pdf

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**


Active Procedures in Physical Medicine

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 in properly choosing the correct service/s when indicated for proper overall case management.

Scope
This policy will apply to all participating network practitioners who provide active procedures, data/claims processing, and peer reviewers.

Definition
The following services are considered “active”; meaning the patient themselves takes 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 references indicate 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 basis 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 basis 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 basis 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 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, and 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 any procedure, instruction and/or exercise performed, area of body and muscle groups treated, and time component.

Units billing
Magellan Healthcare 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 Magellan Healthcare requirements.

CPT Code Definitions, Examples, and Requirements

97110 - Therapeutic Procedures/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.

II. Medical research supports the initiation of appropriate therapeutic procedures/exercise as soon as
    the patient is reasonably able to engage in the planned activity. Therefore, the expectation is for
    a patient to perform therapeutic exercises and receive a home exercise program within a
    reasonable timeframe.

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.

IV. 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
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. 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, progressions in specific active home care program, and anticipated term date for the need for skilled in-office services.

97112 · Neuromuscular reeducation

Definition:
Neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and proprioception (defined as the three modalities of joint position: sense, sense of movement and sense of force.) 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.

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), Feldenkrais, 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(ies), lower extremity(ies), 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 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. 97760 cannot be reported with gait training (97116).

97762-Checkout for Orthotic/Prosthetic use, established patient
**Definition**
Intervention that evaluates the effectiveness of an existing orthotic or prosthetic device and makes recommendations for changes.

**Support for this Service**
Documentation must clearly support the skilled need of 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.

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.
97532 - Cognitive Skills Development  
**Definition**  
Development of cognitive skills to improve attention, memory, problem solving (including compensatory training). Cognitive skill development includes mental exercises that assist the patient in such areas as attention, memory, perception, language, reasoning, planning, problem solving and related skills.

**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, house cleaning, 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, these 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 care-giver 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 range of motion (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 used 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 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**
An 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 an 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 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.

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Guidelines


5. APTA Defensible Documentation Module for patient/Client Management


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Experimental, Unproven, or Investigational Services

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 practitioner.

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. Magellan Healthcare and their client health plan 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
- Spinal Diagnostic Ultrasound
- 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)/Grostic 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 and wobble chair/board treatment
- Preventive Care, Maintenance Care, Corrective Care
- Pro-Adjuster
- Sacro Occipital Technique, Neurocranial Restructuring (NCR), Cranial Manipulation
- Sound Assisted Soft Tissue mobilization
- 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.

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 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 (2009), 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. Ay and colleagues (2010), 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. 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. Kadhim-Saleh et al (2013) examined the effectiveness of LLLT in reducing acute and chronic neck pain. 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. Huang et al (2015), found that the best available current evidence does not support the effectiveness of low level laser therapy as a therapy for patients with knee osteoarthritis.

There is insufficient evidence to support the clinical value of the Pettibon System. 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.

Magellan considers high-density surface electromyography (HD-sEMG), surface scanning EMG, paraspinal surface EMG, or macro EMG 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 Magellan Healthcare 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.
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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.

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” (Clark & Gironda, 2002). 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.

**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. After a review of the scientific evidence Magellan Healthcare 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 et al, 2006)
  - SEM Older people with limited mobility: 21 m (Perera et al, 2006)
  - Older people with stroke: 22 m (Perera et al, 2006)
- Activities of Daily Living Scale of the Knee Outcome Survey
  - 10-30% reduction in the global score
- Berg Balance Scale
  - MDC=4.7 points
  - MDC=6.5 points
- Bournemouth – Back Questionnaire
  - A change of 17 points or 47% is considered clinically significant improvement.
- Bournemouth – Neck Questionnaire
  - A change of 13 points or 34% is considered clinically significant improvement.
- Dizziness Handicap Inventory
  - MDC = 17.18 points
- Dynamic Gait Index
  - MDC=2.9 points
  - Score of 19 or less found to be predictive of falls
- Functional Gait Assessment
  - MCID=4 points
- Functional Rating Index
  - A 10% absolute change represents minimal clinically important change
  - MCIC = 8.4%
- 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 et al, 2006)
  - Substantial meaningful change=.10m/sec (Perera et al, 2006)
  - Meaningful change for those with stroke undergoing rehab=.175 m/sec
• Headache Disability Inventory (HDI)  
  o Authors of the index have determined that a decrease of 29 points or more is considered clinical significant

• LEFS  
  o 10% improvement on the global score

• Neck Disability Index  
  o The minimal detectable change is 10% (approximately 5 points). Clinically meaningful change is considered to be 30-50% (approximately 15 points).

• Oswestry Disability Index  
  o The minimal detectable change is 10.5 points. Clinically meaningful change is considered to be 30-50%.

• Pain Disability Index  
  o A decrease of 8.5-9.5 points is considered clinically important

• Patient Specific Functional Scale  
  o Minimum detectable change (90%CI) for average score = 2 points  
  o Minimum detectable change (90%CI) for single activity score = 3 points

• Roland-Morris Disability Questionnaire  
  o Minimal Important Change=5pts  
  o A 30% change in RMQ score is considered meaningful with 50% considered substantial.

• Shoulder Pain and Disability Index  
  o 10-30% reduction on the global score

• Timed Up and Go (TUG)  
  o Cut-off score of 13.5 sec or longer is predictive of falls

• Tinetti (POMA)  
  o MDC= 5 Points

• VAS scores  
  o Minimum of a 2 point change on a 0-10 pain scale

Keele STarT Back Screening Tool

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.

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Tuchin PJ, et al. A Randomized Controlled Trial of Chiropractic Spinal Manipulative Therapy for Migraine. JMPT 2000; 23(2):91-95


Policy Statement
Habilitative Physical and Occupational Therapy may or may not be covered by all Magellan Healthcare clients. 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.

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 when the disorder is so severe that the patient is not able to take part in the other goals for physical, occupational or speech therapy.

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 10th percentile of ≥ 1.5 standard deviations below the normal for the patient’s age and
   b. Below the average functional ability for 12 year olds.

When standard deviation or percentile ranking cannot be completed, age equivalency scores will apply though they are not the preferred because they are not as accurate.

- Chronological age 0-6 months: ≥ 2 month delay;
- Chronological age 7-12 months: ≥ 3 month delay;
- Chronological age 13-18 months: ≥ 4 month delay;
- Chronological age 19-24 months: ≥ 5 month delay;
- Chronological age 25-30 months: ≥ 6 month delay;
- Chronological age 31-36 months: ≥ 9 month delay;
- Chronological age 3-5 years: ≥ 1 year delay
- Chronological age >5 years: ≥ 1.5 year delay

3. Magellan Healthcare 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. 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. 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 requirements. If the patient is not progressing then documentation of a revised treatment plan is necessary.

6. 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.

7. 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.

8. For patients no longer showing functional improvement, a weaning process of three to six months should occur. If the patient shows signs of regression in function then 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 of changes in condition resulting in functional decline.

REFERENCES


Policy Statement
Habilitative Speech Therapy may or may not be covered by all Magellan Healthcare 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
Requirements for Habilitative Speech Therapy.

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

   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. Magellan Healthcare advises that patients be evaluated by and/or be coordinating speech therapy services with other community service agencies and/or school system when available. 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. 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.

6. 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.

7. 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.

8. For patients no longer showing functional improvement, a weaning process of three to six months should occur. If the patient shows signs of regression in function then 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.

REFERENCES

Arkansas Medicaid Website.
https://www.medicaid.state.ar.us/InternetSolution/Provider/docs/therapy.aspx


Policy Statement
Magellan Healthcare 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 practitioners.

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 (97035), paraffin bath (97018) and whirlpool (97022).

   B. Electrical therapy – High volt, low volt, interferential current, 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, 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-basis 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.

A review on non-pharmacological therapies for acute and chronic LBP by the American Pain Society and the American College of Physicians (Chou et al, 2007) 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. 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.

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.

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 OA in the short term. Larger high-quality RCTs are needed to establish the effectiveness of exercise and manual therapies in the medium and long term.
Low quality evidence suggests clinically important long-term improvements in 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.

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 2 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.

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).

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.

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.

A number of pharmacological and 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.

Guidelines on treatment of LBP from the National Collaborating Centre for Primary Care (Savigny et al, 2009) found insufficient evidence for the use of interferential stimulation in LBP and recommended against its use for that indication.

In a systematic review and meta-analysis, Fuentes et al (2010) 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.

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.

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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.

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 physical medicine practitioners with current documentation requirements for a plan of care.

Scope
Participating network practitioners.

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
  - 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.

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Medicare Benefit Policy Manual, Chapter 16, 240.1.2 A- 240.1.3: Documentation Requirements


Recommendations for Chiropractic Documentation, Wisconsin Chiropractic Association.

Treatment Plan for Chiropractic Manipulation Services. WPS Government Health Administrators.

Yeomans SG. The clinical application of outcomes assessment. Appleton & Lange: 2000

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 afore cited 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
Participating network practitioners.

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 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.
GUIDELINES (CHIRO):

I. *New patient* Evaluation and Management (E/M) coding requirements – must have 3 of 3:

<table>
<thead>
<tr>
<th>Code</th>
<th>99201 (10 m)</th>
<th>99202 (20 m)</th>
<th>99203 (30 m)</th>
<th>99204 (45 m)</th>
<th>99205 (60 m)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical History</strong></td>
<td>Problem focused CC</td>
<td>Problem focused CC</td>
<td>Detailed CC</td>
<td>Comprehensive CC</td>
<td>Comprehensive CC</td>
</tr>
<tr>
<td></td>
<td>HPI: 1-3</td>
<td>HPI: 1-3</td>
<td>HPI: ≥ 4</td>
<td>HPI: ≥ 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ROS: none</td>
<td>ROS: related to CC</td>
<td>ROS: 2-9</td>
<td>ROS: 10-14</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFSH: None</td>
<td>PFSH: 1 item any area</td>
<td>PFSH: 1 item each area</td>
<td>PFSH: 1 item each area</td>
<td></td>
</tr>
<tr>
<td><strong>Physical Exam</strong></td>
<td>Affected body area</td>
<td>Affected body area and 2-4 related organ systems</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>

II. *Established patient* E/M coding requirements – must have 2 of 3:

<table>
<thead>
<tr>
<th>Code</th>
<th>99211</th>
<th>99212 (10 m)</th>
<th>99213 (15 m)</th>
<th>99214 (25 m)</th>
<th>99215 (40 m)</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 CC</td>
<td>Comprehensive CC</td>
</tr>
<tr>
<td></td>
<td>HPI: 1</td>
<td>HPI: 1-3</td>
<td>HPI: ≥ 4</td>
<td>HPI: ≥ 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ROS: none</td>
<td>ROS: related to CC</td>
<td>ROS: 2-9</td>
<td>ROS: 10-14</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFSH: None</td>
<td>PFSH: 1 item any area</td>
<td>PFSH: 1 item each area</td>
<td>PFSH: 1 item each area</td>
<td></td>
</tr>
<tr>
<td><strong>Physical Exam</strong></td>
<td>Affected body area</td>
<td>Affected body area</td>
<td>Affected body areas and 2-4 related organ systems</td>
<td>Affected body areas/systematic/ and 5-7 related organ 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
• 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

**DEFINITIONS APPLICABLE TO ALL NETWORK PRACTITIONERS:**

Medical Record content requirements for all patients:

**Chief Complaint:**
The Chief Complaint is the diagnosis, condition, problem, symptom and/or reason for the encounter.

**New Patient:**
The patient has not been seen at any time, for any purpose within the last 3 years.

A. Patient identification must include name, date of birth, and medical record number.

B. Patient demographics must also include address, home and work telephone numbers, gender, and marital status.

C. All records must be legible which is defined as the ability of at least two people to read and understand the documents.

D. Treating practitioner and credentials must be identified on each date of service.

E. All chart entries must be dated with the month, day, and year.

F. Patient history includes both the present illness and past history that includes the past and current treatments of the presenting condition.

G. Working diagnosis is supported by clinical findings.

H. Treatment plan that includes all of the following:
   • Diagnosis and contraindications to treatment
   • Description of functional status/limitations
   • Therapeutic plan – frequency and duration and type of treatment interventions to be provided
   • Educational plan – Home exercises, ADL modifications
   • Treatment goals – Measurable, functional, time-specific, patient-oriented goals
   • Specific discharge plan
   • Subsequent plans of care/progress notes should include the following
     • Home program and self-management teaching
     • Collaboration with other professionals/services
     • Measurable progress toward functional goals with updating as indicated
• Modifications to the initial plan of care
• Plans for continuing care

*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.

I. All services and dates of each service must be documented.

J. Response to care is demonstrated by a series of daily notes on a visit-to-visit basis.

K. Daily notes include SOAP documentation – must have all of the following:
   • Subjective – Impression of the patients condition
   • Objective – Observations and measurable information from the treatment session, description of the interventions provided for each procedure, and rationale including why the skills of network practitioner are needed to deliver the intervention
   • Assessment – A descriptive judgment of the patients’ condition and/or diagnosis
   • Plan – What treatment was performed and a plan or course of future treatment

L. Ancillary diagnostic studies including imaging, laboratory, and consultation reports that have all of the following:
   • Facility and practitioner where study was performed
   • Patient information that includes the name, address, DOB
   • What area of the body was imaged and what views were taken (if applicable)
   • Clinical rationale for the study
   • Study findings and conclusions
   • Recommendations based on clinical and study findings

M. Copies of reports and correspondence with other caregivers.

N. Appropriate consent forms when applicable.

O. 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.

P. 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 by Magellan Healthcare to perform a review of services.

Q. Performance Goals to Assess Quality

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 Magellan Healthcare.

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 Magellan Healthcare, 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. **Treatment Guidelines/Clinical Policy Bulletins** – health care services are considered medically necessary if they meet all of Magellan Healthcare Treatment Guidelines.

**REFERENCES**

American Chiropractic Associations Clinical Documentation Policy  
http://www.acatoday.org/level2_css.cfm?T1ID=10&T2ID=117 (accessed November 2, 2011)

Chirocode Deskbook: Chirocode Institute, Inc. (2011). Phoeniz, AZ


NCQA Guidelines for Medical Record Documentation. http://www.ncqa.org


(Guidelines for Documentation of Occupational Therapy http://aota.org

Clinical Record keeping in Speech-Language Pathology for Health Care and Third-Party Payers (http://asha.org)
Policy Statement
This policy will be used to define Durable Medical Equipment 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 (DME).

Scope
This policy will apply to all participating network practitioners.

Definition
- Durable Medical Equipment (DME) is any equipment that provides therapeutic benefits to a patient for certain conditions and/or illnesses defined below
- DME consist of items which:
  o Are used to treat a defined illness or injury
  o Are not useful to a person in the absence of illness or injury
  o Are reusable and durable enough for repeated use
  o Are appropriate for use outside of a medical setting such as home, at school, or at 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 this peer reviewed medical literature.

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 visits associated with instruction on the DME would not be covered

**DME**

DME may be subject to medical necessity review. This would include: TENS 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.

Magellan considers TENS 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.

Magellan does not consider the use of form-fitting conductive garments medically necessary.

Magellan considers the following forms of electrical stimulation not 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 and Miyasaki, 2010). There are conflicting reports of TENS compared to sham TENS in the treatment of chronic low back pain (LBP), with 2 Class II studies showing benefit, while 2 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 et al, 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. Magellan considers lumbar auto-traction devices experimental and investigational. This would include, but is not limited to: the Spinalator, the Arthrotonic stabilizer, the Anatomotor, Saunders Lumbar Hometrac, etc. Magellan also considers axial spinal uploading (gravity-dependent traction) devices 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 2016 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


Carpal tunnel syndrome: Wrist splints and hand exercises. Institute for Quality and Efficiency in Health Care; Nov 5, 2014


**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 age’s birth to 24 months.

**Scope**
Magellan Department of Network Management.

**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.

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.

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. Magellan only considers 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:
  - CPT code 97012 – Mechanical traction
  - CPT code 97014 – Unattended electrical stimulation
  - CPT code 97032 – Attended electrical stimulation
  - HCPCS code G0283 – Electrical stimulation
  - CPT code 97035 – Ultrasound
  - 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. Magellan has the ultimate authority to determine if treatment is medically necessary and appropriate.

LITERATURE SEARCH:

As of June 16, 2016, 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.

REFERENCES


Cheryl Hawk, DC, PhD, Michael J. Schneider, DC, PhD, Sharon Vallone, DC, Elise G. Hewitt, DC


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. Magellan 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 includes:
   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.

CLINICAL EXAMPLES of Medically Necessary X-Rays (from references 14-16):

- 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 spondyloarthropathology
- 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

CLINICAL EXAMPLES OF X-RAY VIEWS RECOMMENDED IN THE LITERATURE (from reference 16):

- Adult with recent unimaged thoracolumbar, lumbar or thoracic blunt trauma – AP (or PA) and lateral thoracic and/or lumbar views
- 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 sectional standing full spine (14x36) PA and lateral views in the absence of recent films

REFERENCES


