Guidelines for Clinical Review Determination

Preamble
NIA 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.

All inquiries should be directed to:
National Imaging Associates, Inc.
6950 Columbia Gateway Drive
Columbia, MD 21046
Attn: NIA Associate Chief Medical Officer
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August 18, 2016
CPT Codes:
- 70336  Magnetic image jaw joint
- 73221  MRI joint upr extrem w/o dye
- 73222  MRI joint upr extrem w/dye
- 73223  MRI joint upr extr w/o&w/dye
- 73721  MRI joint of lwr extre w/o dye
- 73722  MRI joint of lwr extr w/dye
- 73723  MRI joint lwr extr w/o&w/dye

“FOR CMS (MEDICARE) MEMBERS ONLY”

Coverage Indications, Limitations, and/or Medical Necessity

Diagnostic examinations of joint(s) performed on Magnetic Resonance Imaging (MRI) units are covered if they are:
- Reasonable and medically necessary for the individual patient.
- Performed on a unit that has received Food and Drug Administration (FDA) approval. Such a unit(s) must be operated within the parameters specified by that approval.
- Compliant with American College of Radiology (ACR) quality standards. Note: Refer to the guidelines listed below for office-based MRI.

Office-Based MRI

In order to maintain appropriate quality in office-based MRI, the ACR MRI Accreditation Program Requirements (http://www.acr.org/accreditation/mri/documents/mri_reqs.pdf) serve as a pertinent performance benchmark, and, using such as a reference document, it is intended that the following guidelines be followed with respect to:

Staff Competency

A provider who performs the interpretation and written report of an MRI of a joint (professional component) must possess the knowledge, skills, training and experience minimally necessary for this component of the service. Medicare coverage of these services is conditional on the competence of the individual who performs and interprets the service. Medicare expects that any provider who seeks and receives payment for the professional components of these radiographic services will be prepared to substantiate his training and/or experience if asked by Medicare to do so. Numerous pathways for achieving and maintaining competency for providing these services by physicians and technologists exist.
The qualified physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME) OR should include CME in MRI as is appropriate to the physician's practice needs. Technologists practicing MRI scanning should be licensed in the jurisdiction in which he practices, if state licensure for MRI technologists exists. The continuing education for a technologist should be 15 hours of Category A CME in MRI every three years.

An MRI of a joint may be personally performed by a physician or a technologist. When performed by a technologist, one of the following standards must be met:

- Facility must be accredited for MRI by the American College of Radiology (ACR)
- For testing performed in non-ACR accredited office facilities, the technologist must have received credentials in MRI technology as a Certified Radiologic Technologist (CRT) from the American Registry of Radiologic Technologists (ARRT).

**Quality Control and Quality Assurance**

There should be a well-documented office protocol for performing continuous quality control testing of instrumentation, in tandem with periodic preventive maintenance, which is also properly documented in service records maintained by the MRI site. In addition, appropriately documented physician peer-review activities should be an integral portion of the staff competency guidelines discussed above.

The choice of the appropriate imaging modality should be determined at an individual level. In some cases, MRI may be an appropriate initial choice; in others, standard X-rays should be used for the initial evaluation. Generally, MRI of a joint is considered medically necessary when the following disorders are present or suspected and/or the necessary information is not available from standard X-rays. Joint MRIs are indicated for the following clinical conditions:

- Tumors/masses or swelling involving or contiguous to a joint.
- Rotator cuff tears or impingement.
- Joint instability, deformities or internal derangement.
- Intra-articular osteocartilaginous body(ies).
- Occult joint injury, e.g., osteochondral injury.
- Suspected nerve entrapment or mass close to a joint.
- Suspected ligament or tendon injury.
- Kienböck's Disease of the wrist.
- Bone abnormalities of a joint related to soft tissue abnormalities.
- Occult Avascular Necrosis (AVN) or follow-up of this condition.
- Acute joint injuries.
- Actual or suspected infection or inflammation on joints or surrounding structures.
- Effect of other single or multiple system, non-joint disorders on joints and surrounding structures.
- Pain/other sensory disturbances in joints or surrounding structures.
- Weakness/other motor disturbances in joints or surrounding structures.
• Decreased range of motion; stiffness, popping/clicking, instability or discoordination related to joints and surrounding structures.
• Characterization of an abnormal finding in joints or surrounding structures detected on another test.
• Meniscal and/or ligamentous tears.
• Tendinopathy.
• Assessment of joints and surrounding structures in preparation for an interventional procedure.

Usually, an MRI of a joint is performed when standard X-rays are inconclusive and the patient may have failed a treatment regime for a disorder clinically diagnosed from medical history and examination. MRIs of a joint are generally not indicated when a surgical exploration of the joint (arthroscopic or open) will be performed regardless of the results of the MRI, unless the MRI results are to be used to provide information for planning the optimal surgical approach.

The clinical necessity of performing a joint MRI must be noted in the medical record or easily inferred from the medical record. “Screening” imaging or unnecessary duplication of imaging is not considered medically necessary.

There are relative contraindications to MRI scanning. These include cardiac pacemakers that do NOT meet CED criteria outlined in NCD 220.2.C.1, ferromagnetic clips, intraocular metal, and cochlear implants. MRI scanning under these circumstances is only covered when the medical situation is clearly explained.

Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

CPT/HCPCS Codes

Group 1 Paragraph: Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. The American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS) require the use of short CPT descriptors in policies published on the Web.

Group 1 Codes:
70336 Magnetic image jaw joint
73221 Mri joint upr extrem w/o dye
73222 Mri joint upr extrem w/dye
73223 Mri joint upr extr w/o&w/dye
73721 Mri jnt of lwr extre w/o dye
73722 Mri joint of lwr extr w/dye
73723 Mri joint lwr extr w/o&w/dye

Documentation Requirements
Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and made available to Medicare upon request.
Cranial Computerized Tomographic (CT) Scan is a very useful and informative neurodiagnostic tool. Scanning of the head in successive layers by a narrow beam of x-rays enables the transmission of x-ray photons in each layer to be measured. A computer is used to process the accumulated x-ray photon data and constructs a graphic image of a tomographic slice. Normal intracranial structures and a wide variety of intracranial disorders may be demonstrated. Cranial CT scan may be ordered without contrast (70450), with injection of standard roentgenographic contrast material (70460) or without contrast material, followed by contrast material and further sections (70470). Contrast administration is not without risk to the patient and for some conditions adds little or no benefit to the examination.

Cranial Computerized Tomographic Scans are determined to be reasonable and necessary and are a covered service when the patient has clinical evidence of an intracranial disorder or an established intracranial disorder or disease. The general indications for use of contrast CT scanning are:

1. To assess perfusion (e.g. CVA)
2. To characterize a specific lesion
3. To detect defects in blood/brain barrier (e.g. infarcts, tumors, infection, vasculitis)
4. To detect neovascularity (tumors); or
5. For staging of known lung cancer, breast cancer, and lymphomas which are likely to metastasize early to the brain

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

- 70450  COMPUTED TOMOGRAPHY, HEAD OR BRAIN: WITHOUT CONTRAST MATERIAL
- 70460  COMPUTED TOMOGRAPHY, HEAD OR BRAIN: WITH CONTRAST MATERIAL(S)
- 70470  COMPUTED TOMOGRAPHY, HEAD OR BRAIN: WITHOUT CONTRAST MATERIAL
MATERIAL, FOLLOWED BY CONTRAST MATERIAL(S) AND FURTHER SECTIONS

Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

Documentation Requirements

1. The patient’s medical record should include symptomatology indicating the medical necessity of this test.

2. The ICD-10 codes R51 (Headache) and G44.1 (Vascular headache, not elsewhere classified) will only be covered in the following situations:
   a) The patient is suffering from headaches and a head injury. Head CT is performed to rule out the possibility of an intracranial bleed.
   b) The patient is suffering from headaches unusual in duration (greater than 2 weeks) not responding to medical therapy. Head CT is performed to rule out the possibility of a tumor.
   c) The patient is suffering from new onset headache (less than 2 weeks) suggestive of intracranial bleeding as evidenced by signs (e.g. weakness or paralysis), symptoms (e.g., blurred vision, nausea and vomiting), or clinical history.

3. Any claim billed with ICD-10 code R51 (headache) or G44.1 (Vascular headache, not elsewhere classified) may be subject to manual review.

4. Claims billed with ICD-10 codes S09.19XA (Other specified injury of muscle and tendon of head, initial encounter), S09.19XD (Other specified injury of muscle and tendon of head, subsequent encounter), S09.19XS (Other specified injury of muscle and tendon of head, sequela), S09.8XXA (Other specified injuries of head, initial encounter), S09.8XXD (Other specified injuries of head, subsequent encounter), S09.8XXS (Other specified injuries of head, sequela), S09.90XA (Unspecified injury of head, initial encounter), S09.90XD (Unspecified injury of head, subsequent encounter), or S09.90XS (Unspecified injury of head, sequela) should have documented associated signs and symptoms to support the need for CT scan of the head and may be subject to manual review.

5. Documentation supporting medical necessity should be legible, maintained in the patient’s medical record, and must be made available to the A/B MAC upon request.
NCD Manual Section Number: 220.2

CPT Codes:
70544, 70545, 70546 – Brain (Head)
70547, 70548, 70549 – Neck
71555 – Chest
72198 – Pelvis
73225 – Upper Extremity
73725 – Lower Extremity
74185 – Abdomen
72159 – Spinal Canal

FOR CMS (MEDICARE) MEMBERS ONLY”

INDICATIONS FOR MRA:
Currently covered indications include using MRA for specific conditions to evaluate flow in internal carotid vessels of the head and neck, peripheral arteries of lower extremities, abdomen and pelvis, and the chest. Coverage is limited to MRA units that have received FDA premarket approval, and such units must be operated within the parameters specified by the approval. In addition, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

Head and Neck
MRA is effective for evaluating flow in internal carotid vessels of the head and neck. However, not all potential applications of MRA have been shown to be reasonable and necessary. All of the following criteria must apply in order for Medicare to provide coverage for MRA of the head and neck:

- MRA is used to evaluate the carotid arteries, the circle of Willis, the anterior, middle or posterior cerebral arteries, the vertebral or basilar arteries or the venous sinuses.

- MRA is performed on patients with conditions of the head and neck for which surgery is anticipated and may be found to be appropriate based on the MRA. These conditions include, but are not limited to, tumor, aneurysms, vascular malformations, vascular occlusion or thrombosis. Within this broad category of disorders, medical necessity is the underlying determinant of the need for an MRA in specific diseases. The medical records should clearly justify and demonstrate the existence of medical necessity.
MRA and CA are not expected to be performed on the same patient for diagnostic purposes prior to the application of anticipated therapy. Only one of these tests will be covered routinely unless the physician can demonstrate the medical need to perform both tests.

Peripheral Arteries of Lower Extremities
MRA of peripheral arteries is useful in determining the presence and extent of peripheral vascular disease in lower extremities. This procedure is non-invasive and has been shown to find occult vessels in some patients for which those vessels were not apparent when CA was performed. Medicare will cover either MRA or CA to evaluate peripheral arteries of the lower extremities. However, both MRA and CA may be useful in some cases, such as:

- A patient has had CA and this test was unable to identify a viable run-off vessel for bypass.
- When exploratory surgery is not believed to be a reasonable medical course of action for this patient, MRA may be performed to identify the viable runoff vessel.
- A patient has had MRA, but the results are inconclusive.

Abdomen and Pelvis

- Pre-operative Evaluation of Patients Undergoing Elective Abdominal Aortic Aneurysm (AAA) Repair
  Effective July 1, 1999, MRA is covered for pre-operative evaluation of patients undergoing elective AAA repair if the scientific evidence reveals MRA is considered comparable to CA in determining the extent of AAA, as well as in evaluating aortoiliac occlusion disease and renal artery pathology that may be necessary in the surgical planning of AAA repair. These studies also reveal that MRA could provide a net benefit to the patient. If preoperative CA is avoided, then patients are not exposed to the risks associated with invasive procedures, contrast media, end-organ damage, or arterial injury.
- Imaging the Renal Arteries and the Aortoiliac Arteries in the Absence of AAA or Aortic Dissection
  Effective July 1, 2003, MRA coverage is expanded to include imaging the renal arteries and the aortoiliac arteries in the absence of AAA or aortic dissection. MRA should be obtained in those circumstances in which using MRA is expected to avoid obtaining CA, when physician history, physical examination, and standard assessment tools provide insufficient information for patient management, and obtaining an MRA has a high probability of positively affecting patient management. However, CA may be ordered after obtaining the results of an MRA in those rare instances where medical necessity is demonstrated.

Chest

- Diagnosis of Pulmonary Embolism
  Current scientific data has shown that diagnostic pulmonary MRAs are improving due to recent developments such as faster imaging capabilities and gadolinium-enhancement. However, these advances in MRA are not significant enough to warrant replacement of pulmonary angiography in the diagnosis of pulmonary embolism for patients who have no contraindication to receiving intravenous iodinated contrast material. Patients who are allergic to iodinated contrast material face a high risk of developing complications if they undergo pulmonary angiography or computed tomography angiography. Therefore, Medicare will cover MRA of the chest for diagnosing a
suspected pulmonary embolism when it is contraindicated for the patient to receive intravascular iodinated contrast material.

- Evaluation of Thoracic Aortic Dissection and Aneurysm

Studies have shown that MRA of the chest has a high level of diagnostic accuracy for pre-operative and post-operative evaluation of aortic dissection of aneurysm. Depending on the clinical presentation, MRA may be used as an alternative to other non-invasive imaging technologies, such as transesophageal echocardiography and CT. Generally, Medicare will provide coverage only for MRA or for CA when used as a diagnostic test. However, if both MRA and CA of the chest are used, the physician must demonstrate the medical need for performing these tests.

While the intent of this policy is to provide reimbursement for either MRA or CA, CMS is also allowing flexibility for physicians to make appropriate decisions concerning the use of these tests based on the needs of individual patients. CMS anticipates, however, low utilization of the combined use of MRA and CA. As a result, CMS encourages contractors to monitor the use of these tests and, where indicated, require evidence of the need to perform both MRA and CA.

**Nationally Non-Covered Indications:**

*All indications for Spinal Canal MRA and Upper Extremity MRA.*
Coverage Indications, Limitations, and/or Medical Necessity

The following clinical indications apply to the Computerized Axial Tomography (CT or CAT) of the thorax:

- Evaluation of pulmonary, mediastinal, pleural and chest wall infections and their complications.
- Detection and characterization of mediastinal neoplasms and other processes.
- Assessment of cardiopulmonary failure or insufficiency.
- Diagnosis and/or staging of neoplastic and hematologic processes arising in the thorax or with potential involvement of the thorax.
- Detection and determination of nature and extent of cardiovascular abnormalities such as, but not limited to aneurysm, dissection, embolism, thrombosis, congenital anomalies, postoperative complications and sequelae of atherosclerotic disease.
- For assessing and/or guiding drainage of pulmonary or pleural fluid collections such as abscess, empyema, effusion or pneumothorax.
- For characterizing and follow-up evaluation of interstitial and alveolar lung disease due to idiopathic, allergic, collagen-vascular, environmental or other causes.
- For evaluating thoracic sequelae of remote processes including, but not limited to, pancreatitis, gastrointestinal perforation and other processes.
- For assessing injury, potential injury or thoracic sequelae after trauma, burn, surgery, transplantation, radiation therapy, chemotherapy or invasive procedure such as pacemaker placement, chest tube placement or mechanical ventilation.
- Evaluation of the patient with symptoms that may be arising from the chest, or be referred to the chest including but not limited to cough, hemoptysis, chest pain, abdominal pain and others.
- To further characterize a suspected abnormality detected by another imaging test.

In keeping with American College of Radiology (ACR) Practice Guidelines and Technical Standards, CT thorax should be provided by qualified radiology personnel (radiology technicians, diagnostic radiologists). The patient’s condition should be monitored throughout the procedure. As this involves the patient being in a closed environment, claustrophobia or medical problems exacerbated by the enclosure may be exhibited.

Qualified physicians (such as board-certified radiologists) should perform the interpretation of the films.

The computerized tomographic service should be furnished only when clinically appropriate for the patient’s symptoms or complaint. When performed as a screening function, it will not be covered.
Coding Information

CPT/HCPCS Codes

Group 1 Paragraph: Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. The American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS) require the use of short CPT descriptors in policies published on the Web.

Group 1 Codes:

71250 Ct thorax w/o dye
71260 Ct thorax w/dye
71270 Ct thorax w/o & w/dye

Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

Documentation Requirements

Documentation must be legible, relevant and sufficient to justify the services billed. This documentation must be made available to the A/B MAC upon request.

Utilization Guidelines

Reordering Identical Type of Imaging Examination: No imaging examination (pertaining to an identical CPT code only) should be ordered more frequently than six times per calendar year. Furthermore, this frequency limit shall only apply to the following outpatient Places of Service (POS): office (11), outpatient hospital (22), independent clinic (49), rural health clinic (72) and (99) independent diagnostic testing facility.

Reasonable and necessary imaging which is felt to be required more frequently than six times a calendar year must have substantial documentation to describe medical necessity.
A computed tomographic (CT) image is a display of the anatomy of a thin slice of the body developed from multiple x-ray absorption measurements made around the periphery of the body. Unlike conventional tomography, where the image of a thin section is created by blurring out the information from unwanted regions, the CT image is constructed mathematically using data arising only from the section of interest. Generating such an image is confined to cross sections of the anatomy that are oriented essentially perpendicular to the axial dimensions of the body. Reconstruction of the final image can be accomplished in any plane.

**Abdomen**

The CT of the abdomen extends from the dome of the diaphragm to the pelvic brim or pubic symphysis depending upon whether one groups the pelvis with the abdomen or treats it separately.

A CT scan of the abdomen will be considered medically reasonable and necessary under the following circumstances:

- Evaluation of abdominal pain
- Evaluation of known or suspected abdominal masses or fluid collections, primary or metastatic malignancies
- Evaluation of abdominal inflammatory processes
- Evaluation of abnormalities of abdominal vascular structures
- Evaluation of abdominal trauma
- Clarification of findings from other imaging studies or laboratory abnormalities
- Guidance for interventional diagnostic or therapeutic procedures within the abdomen
- Treatment planning for radiation therapy
- For patients being evaluated for potential transcatheter aortic valve implantation/replacement (TAVI or TAVR) provided that the patient has not undergone a CT of the abdomen within the preceding 60 days

In addition to the medical necessity requirements, the CT scan must be performed on a model of CT equipment that meets the following criteria:

- The model must be known to the Food and Drug Administration; and
- Must be in the full market release phase of development.
NOTE: Plain and upright or lateral decubitus roentgenograms of the abdomen represent the basic screening tool in identifying abnormalities involving the abdomen. It is expected that the abdominal x-ray is used to evaluate patients who present with signs and symptoms suggestive of abdominal pathology prior to proceeding to a CT scan.

**Pelvis**

The CT scan of the pelvic area includes the bladder, prostate, ovaries, uterus, lower retroperitoneum, and iliac lymph node chains. In males this includes the bladder and prostate and in females the bladder, uterus, and adnexa. The CT scan of the pelvis is useful in evaluating cysts, tumors, masses, metastases to one or more of these organs, and iliac lymph nodes. Intravenous contrast material may be administered.

A CT scan of the pelvis will be considered medically necessary and reasonable under the following circumstances:

- Evaluation of cysts, tumors, or masses of the pelvic structure (i.e., that which lies at or below the pelvic brim or true pelvis)
- Evaluation of metastasis of primary cancers to this region
- Evaluation of inflammatory processes in this region
- Evaluation of abnormalities of pelvic vascular structures
- Evaluation of lymphadenopathies of this region
- Evaluation of lower abdominal, generalized abdominal or pelvic pain
- Evaluation of other genitourinary disorders in which the physician cannot make a diagnosis on physical examination and/or by ultrasound
- Evaluation of trauma to the pelvic structure/organs
- Evaluation of the effectiveness of a radiation treatment plan
- For patients being evaluated for potential transcatheter aortic valve implantation/replacement (TAVI or TAVR) provided that the patient has not undergone a CT of the pelvis within the preceding 60 days.

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

- 72192  COMPUTED TOMOGRAPHY, PELVIS; WITHOUT CONTRAST MATERIAL
- 72193  COMPUTED TOMOGRAPHY, PELVIS; WITH CONTRAST MATERIAL(S)
- 72194  COMPUTED TOMOGRAPHY, PELVIS; WITHOUT CONTRAST MATERIAL, FOLLOWED BY CONTRAST MATERIAL(S) AND FURTHER SECTIONS
- 74150  COMPUTED TOMOGRAPHY, ABDOMEN; WITHOUT CONTRAST MATERIAL
Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

Documentation Requirements
Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient's medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure report.

Documentation should support the criteria for coverage as set forth in the Coverage Indications, Limitations and/or Medical Necessity section of this policy.

Documentation supporting medical necessity should be legible, maintained in the patient's medical record, and must be made available to the A/B MAC upon request.
Indications

Computed Tomography (CT) colonography, also known as virtual colonoscopy, utilizes helical computed tomography of the abdomen and pelvis along with 2D or 3D reconstruction to visualize the colon lumen. The test requires colonic preparation similar to that required for instrument (fiberoptic, video) colonoscopy, as well as air insufflation to achieve colonic distention.

Virtual colonoscopy is only indicated in those patients in whom a diagnostic or surveillance instrument colonoscopy of the entire colon is incomplete due to an inability to fully pass the colonoscope proximally, and a repeat attempt is not indicated. Incomplete colonoscopy must be due to one of the following:

1. An obstructing neoplasm.
2. Intrinsic scarring, stricture, aberrant anatomy, or obstruction from prior surgery, radiation, or diverticular disease.
3. Extrinsic compression.

Limitations

CPT 74263 Computed tomographic (CT) colonography (i.e., virtual colonoscopy) screening is never covered.
CT colonography is not covered when used for screening, or in the absence of signs or symptoms of disease, regardless of family history or other risk factors for the development of colonic disease.

CT colonography is not covered when used as an alternative to instrument colonoscopy for screening or in the absence of signs or symptoms of disease.

CT colonography is not covered following incomplete colonoscopy if the reason for the colonoscopy is other than one of those described above.

CT colonography is intended for use in pre-operative planning when imaging of the non-visualized colon proximal to the obstruction is necessary in making decisions involving the approach to the patient.

**CPT/HCPCS Codes**

**Group 1 Paragraph: CPT code**

74261 Ct colonography dx
74262 Ct colonography dx w/dye

*Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.*

**Documentation Requirements**

Documentation must be legible, relevant and sufficient to justify the services performed for each date of service billed. This documentation must be made available to the A/B MAC upon request.

1. The results of an incomplete instrument colonoscopy that resulted in the order for the CT colonography (virtual colonoscopy) must be retained in the patient’s medical record. Similarly, documentation of the presence and severity of a relative contraindication as justification for a CT colonographic examination must be retained in the medical record.
2. The order/prescription from the referring physician must be retained in the patient’s medical record.

**Utilization Guidelines**

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.
NCD Manual Section Number: 210.3

CPT Codes: 74263

“FOR MEDICARE MEMBERS ONLY”

Nationally Non-Covered Indications

- CT (Virtual) Colonoscopy for Screening (CTC)¹

TOC

75571 – Electron Beam Tomography (EBCT)
75572 – CT Heart
75574 – CTA Coronary Arteries (CCTA)

LCD from Palmetto GBA, J-M L33426

CPT Codes:

75571  Ct hrt w/o dye w/ca test
75572  Ct hrt w/3d image
75573  Ct hrt w/3d image congen
75574  Ct angio hrt w/3d image

“FOR CMS (MEDICARE) MEMBERS ONLY”

Coverage Indications, Limitations, and/or Medical Necessity

Cardiac computed tomographic angiography (CCTA), also known as computed tomography of the heart and coronary arteries, or multidetector computed cardiac tomography (MDCT) is considered reasonable and necessary for the evaluation of suspected symptomatic coronary artery disease (CAD) and for the detection of structural and morphologic intra- and extra-cardiac conditions.

Use of a CCTA is expected to avoid diagnostic cardiac catheterization. If high pre-test probability of CAD exists, Palmetto expects the patient to undergo invasive coronary angiography with appropriate percutaneous coronary intervention.

To establish CCTA medical necessity, your case must meet at least one indication in the following two categories:

Symptomatic Coronary Artery Disease (CAD)

1. Evaluation of Acute Chest Pain, unexplained dyspnea or symptoms suggesting angina pectoris (such as jaw pain) when there is:
   - Intermediate pre-test probability of CAD*, **and**
   - No EKG changes to suggest acute myocardial injury or ischemia, **and**
   - Normal initial cardiac markers.

2. Evaluation of Chest Pain Syndrome, when there is:
   - Intermediate pre-test probability of CAD*, **and**
   - Uninterpretable EKG** or patient is unable to exercise, **or**
   - Uninterpretable or equivocal stress test (exercise, perfusion or stress echo)

*Intermediate pretest probability of CAD by age, gender and symptoms is between 10 and 90% as referenced in the ACCF/ACR 2006 Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging.
** Uninterpretable EKG refers to EKGs with resting ST segment depression greater than or equal to 0.10mV, complete left bundle branch block, pre-excitation, or paced rhythm.


** Suspected Cardiac Structural/Morphologic Anomalies

1. Detection of intracardiac and extracardiac structures in:
   - Evaluation of cardiac mass (suspected tumor or thrombus) or
   - Evaluation of pericardial conditions (mass, constrictive pericarditis, or complications of cardiac surgery), or
   - Patients with technically limited images from echocardiogram, MRI or TEE.

2. Detection of morphologic intracardiac and extracardiac structures for:
   - Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation. While data is limited for 3D reconstruction of the left atrium for ablations, there is broad consensus among cardiologists that these images, which are integrated and used in real-time in the procedure room to shorten procedure time, improve therapeutic success and enhance patient safety, or
   - Non-invasive coronary vein mapping prior to placement of biventricular pacemaker, or
   - Non-invasive coronary arterial mapping, including internal mammary artery, prior to repeat cardiac surgical revascularization, or
   - Detection of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chamber and valves, or
   - Evaluation of coronary arteries in patients with new onset heart failure to assess etiology.

** Limitations:

1. Coverage of CCTA is limited to CT devices that process thin, high resolution slices. Decreased resolution and slower rotation speeds result in a higher number of non-evaluable segments. At the current time, Medicare requires the multidetector scanner to have collimation of 0.625 mm or less, and a rotational speed of 375 msec or less, OR to have at least 64 slice detector design. Do not submit studies from scanners that do not meet these requirements.

2. Medicare does not cover a screening CCTA for asymptomatic patients, for risk stratification or for quantitative evaluation of coronary calcium.

Ultrafast CT scan of the heart (electron-beam tomography [EBT] or electron-beam computed tomography [EBCT]) is not a covered service.

3. Simultaneous exclusion of obstructive CAD, pulmonary embolism, and aortic dissection (“triple rule-out”) in the emergency department is not covered. In order to optimize imaging of the right coronary artery (RCA), contrast must be cleared from the right sided chambers during acquisition, a process that leads to suboptimal contrast timing in the pulmonary arteries. Simultaneous rule-out of aortic pathology (at the low pitch needed to properly image the coronaries) mandates thicker slices in order to capture the total volume required in a reasonable breath hold. The increased slice
thickness degrades coronary image quality.

4. CCTA patients must be able to lie still, follow breathing instructions, take nitroglycerine for coronary dilatation and take a beta-blocker or calcium blocker to achieve heart rates less than 70 BPM.

5. Prior to the initiation of a CCTA, there must be an imaging assessment of coronary calcification (calcium scoring). The physician must make an assessment of the anatomic location, degree and intensity of calcification and impact of calcification on the utility of the test results. CCTAs performed on patients with elevated quantitative calcium scores that preclude accurate assessment of coronary anatomy are not covered by Medicare.

CPT/HCPCS Codes

Group 1 Paragraph: CPT Codes

Group 1 Codes:
75571 Ct hrt w/o dye w/ca test
75572 Ct hrt w/3d image
75573 Ct hrt w/3d image congen
75574 Ct angio hrt w/3d image

Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

Documentation Requirements

Medical record documentation should be legible, relevant and sufficient to justify services billed. This documentation should be maintained in the patient’s medical record, and must be made available to the A/B MAC upon request.

When patient records are requested, Palmetto GBA expects the cardiac CT angiogram to be performed for indications listed in this policy.

Utilization Guidelines

Palmetto GBA expects that CCTA is performed under the direct supervision of a physician with appropriate training in CT coronary angiography and cardiac CT imaging equivalent to guidelines set forth by the ACC or ACR (Circulation. 2005;112(4):598-617/ J Am Coll Cardiol. 2005;46(2):383-402.)
NCD Manual Section Number: 220.2.1

CPT Codes: 76390

FOR CMS (MEDICARE) MEMBERS ONLY

INDICATIONS AND LIMITATIONS OF COVERAGE FOR BRAIN MRS:

Nationally Covered Indications
- Not applicable.

Nationally Noncovered Indications
- After thorough review and reconsideration of the existing national noncoverage determination for MRS, as well as the available evidence for the use of MRS as a diagnostic tool for distinguishing indeterminate brain lesions, and/or as an aid in conducting brain biopsies, CMS has determined that the evidence is not adequate to conclude that MRS is reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act, for use in the diagnosis of brain tumors. Therefore, CMS reaffirms its current national noncoverage determination for all indications of MRS.
Coverage Indications, Limitations, and/or Medical Necessity

The two types of radionuclide studies commonly used for cardiac evaluation are myocardial perfusion imaging and cardiac blood pool imaging (multiple gated acquisition scanning (MUGA), ventriculography). Myocardial perfusion imaging is used primarily for the evaluation of coronary artery disease. Ventriculography is sometimes referred to as multiple gated acquisition scanning (MUGA) or cardiac blood pool imaging and is primarily used to evaluate valvular disease and cardiomyopathies. Either type of study may be obtained at rest or with stress. Stress may be provided by exercise or with pharmacologic agents.

Myocardial perfusion imaging is a diagnostic procedure that evaluates blood flow to cardiac muscle using radionuclides. A gamma camera is used to record images in planar or tomographic (single photon emission computed tomography (SPECT)) projections. Use of dual radiopharmaceuticals permits concurrent studies at rest and after stress, which are then compared and interpreted by a nuclear physician. Since the radiopharmaceutical accumulates in the myocardium in relation to blood flow, ischemic and infarcted myocardium can be detected.

With the use of technetium based radiopharmaceuticals, the perfusion imaging may be linked to acquisition of “first pass” data to visualize blood flow through the right heart, lungs and left heart giving diagnostically useful information about cardiac chamber shunts, wall motion, cardiac output, ejection fraction, left ventricular volume, shunt fraction and valvular regurgitation.

Effective for services performed on or after March 14, 1995, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA approved radiopharmaceutical Rubidium 82 (Rb 82) are covered, provided the requirements below are met:

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or

- The PET scan whether at rest alone or rest with stress is used following a SPECT that was found to be inconclusive.

In these cases the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient.
(For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient’s other clinical data and must be documented in the beneficiary’s file.)

The following studies are considered **investigational** and will not be covered:
- Ambulatory radionuclide cardiac monitoring
- Monoclonal anti-myosin imaging
- Radionuclide imaging of thrombi
- Radionuclide imaging of cardiac adrenergic nerves

**Myocardial Perfusion Imaging (CPT codes 78451-78454, 78491, 78492)**

Patients with a high pretest probability of disease are usually not candidates for this study unless determination of the size and reversibility of a defect are required for clinical decision making. Patients whose diagnosis is in question benefit most from this study. Patients with a low pretest probability of disease are usually not studied except when a prior exercise stress test by treadmill ECG or echo is a presumed false positive. Stress myocardial perfusion imaging, preceded by satisfactory stress echocardiography (CPT code 93350), is not medically necessary.

**Indications for Myocardial Perfusion Imaging**

1. **Acute myocardial infarction** - Myocardial perfusion imaging is not typically performed during the acute period of myocardial infarction, if the diagnosis is established by other means. In selected patients, imaging is appropriate in the assessment of:
   - Disease severity
   - Risk assessment and/or prognosis
   - Efficacy of acute reperfusion therapy
   - Evidence of myocardial salvage
   - Suspected infarction when the combination of history and other tests is not diagnostic.

2. **Unstable angina** - Myocardial perfusion imaging may be useful as an adjunct to other tests in the diagnosis or treatment of unstable angina only when the combination of history and other tests is not diagnostic. In selected patients, imaging is appropriate for:
   - Identification of ischemia in the distribution of a known lesion or in remote areas
   - Identification of the severity/extent of disease in patients with medically unstable angina or ongoing ischemia
   - Measurement of left ventricular function.

3. **Chronic ischemic heart disease** - The use of myocardial perfusion imaging is well established in the diagnosis and management of coronary artery disease (CAD) and is covered in these situations:
   - Diagnosis of CAD, especially in patients with atypical chest pain
   - Evaluation of abnormal or suspected false positive stress ECG
   - Evaluation of other symptoms suspicious for the diagnosis of CAD such as syncope and ventricular arrhythmia
   - Assessment of myocardial viability after revascularization or medical management
   - Planning PTCA to identify lesions causing ischemia, if unknown
• Evaluation of suspected or known CAD prior to high risk surgical procedures
• Identification of the presence, location, extent, and severity of myocardial ischemia
• Assessment of drug therapy
• Assessment of symptoms suggesting restenosis following PTCA
• Assessment of symptoms suggesting ischemia following CABG
• Follow up of symptomatic ischemic heart disease.

4. Congenital heart disease - Echocardiography is the method of choice for evaluating patients with known or suspected congenital heart disease. Selected patients may benefit from myocardial perfusion imaging when assessing for:
   • Diagnosis of anomalies of the coronary circulation
   • Kawasaki's disease

5. Post-transplant cardiac disease
   • Assessment of coronary arteriopathy
   • Evaluation for ventricular dysfunction with post-transplant rejection

Cardiac Blood Pool Imaging (MUGA, Ventriculography) (CPT codes 78472, 78473, 78481, 78483, 78494, 78496)

These services are allowed for the evaluation of ventricular size, wall motion, stroke volume, and ejection fraction when this information is medically necessary to direct further evaluation and management of the cardiac condition.

Indications for Cardiac Blood Pool Imaging (MUGA, Ventriculography):

1. Cardiomyopathy - Cardiac blood pool imaging (MUGA, ventriculography) is covered for:
   • Diagnosis of hypertrophic cardiomyopathy and/or myocardial ischemia
   • Differentiation of ischemic from non-ischemic cardiomyopathy

2. Post-transplant cardiac disease
   • Assessment of coronary arteriopathy
   • Evaluation for ventricular dysfunction with post-transplant rejection

3. Assessment of cardiac function for cardiotoxic chemotherapy
   A. One baseline study is considered medically necessary prior to the initiation of cardiotoxic chemotherapy when one of the following conditions is met:
      1. No echocardiogram is planned or performed
      2. Prior echocardiogram is uninterpretable due to poor visualization window
   
   B. Cardiac function monitoring during or at the completion of cardiotoxic chemotherapy. Cardiotoxic chemotherapy includes any of the following medications:
      • 5-FU (5 fluorouracil)
      • Adriamycin® (doxorubicin)
      • Avastin® (bevacizumab)
      • Cerubidine® (daunorubicin)
· Clolar® (clofarabine)
· Cytoxan® (cyclophosphamide)
· Epirubicin (Pharmorubicin®)
· Gleevec® (imatinib)
· Herceptin® (trastuzumab)
· Ifex® (ifosfamide)
· Mutamycin® (mitomycin)
· Nexavar® (sorafenib)
· Novantrone® (mitoxantrone)
· Sutent® (sunitinib)
· Taxol® (paclitaxel)
· Taxotere® (docetaxel)
· Tykerb® (lapatinib)
· Valstar® (valrubicin)
· Xeloda® (capecitabine)
· Zavedos® (idarubicin)

Pharmacologic Stress Agents (HCPCS codes J0153, J0280, J0461, J1245, J1250)

For those patients who are unable to reach 75-100% of their age predicted maximum heart rate by physiologic exercise, vasodilation can be achieved with the use of either dipyridamole or adenosine. Use of pharmacologic agents in myocardial perfusion imaging (CPT codes 78451-78454, 78491, 78492) is not a standard of care and is not medically necessary unless exercise is not possible. In some cases dobutamine may be used to effect stress through its inotropic effect.

1. Dipyridamole is typically administered intravenously at 0.57 mg/kg over a 4-minute period. The maximum dose should not exceed 60 mg. Since the dilation effect persists, after injection of the radiopharmaceutical, its effect is typically reversed with intravenous aminophylline, which must be available to reverse ischemia when it occurs. Dipyridamole is relatively contraindicated in patients with:

   - Known bronchospastic lung disease (asthma)
   - Systemic hypotension (systolic BP below 100 mm Hg.)
   - Acute myocardial infarction less than 48 hours old
   - Unstable angina

2. Adenosine is administered intravenously at 0.14 mg/kg/min over 6 minutes (0.84mg/kg). The vasodilation effect is short lived. Adenosine is contraindicated in patients with:

   - Second or third degree AV block
   - Sinus node disease, except those with a functioning pacemaker
   - Known or suspected bronchoconstrictive or bronchospastic lung disease
   - Known hypersenstivity to adenosine

3. Dobutamine is administered intravenously, starting at 0.5-1.0 mcg/kg/min and titrated to reach
the maximum heart rate for 2-5 minutes. The maximum dose is 40 mcg/kg. Atropine may be added in appropriate doses IV. Dobutamine is contraindicated in patients with:

- Idiopathic subaortic stenosis
- Acute myocardial infarction

Physician Supervision Requirements

Myocardial perfusion and blood pool imaging require general supervision by a qualified physician licensed to administer radioactive materials. Cardiology stress procedures (CPT codes 93015-93018) performed in conjunction with nuclear myocardial perfusion imaging studies are covered by Medicare only when performed under the direct supervision of a qualified physician, who provides:

- Medical expertise required for performance of the test
- Medical treatment for complications and side effects of the test
- Medical services required as part of the test such as injections of medications
- Medical expertise in the interpretation of the cardiovascular stress test component, some of which has to be provided during the test and before the patient is discharged from the testing suite.

CPT/HCPCS Codes

**Group 1 Paragraph: NOTE:** For Part A services only, the provider should bill the appropriate procedure code on the UB-04 for 11X bill type.

**Use CPT code 78496 in conjunction with CPT code 78472.**

**Group 1 Codes:**

78451  Ht muscle image spect sing  
78452  Ht muscle image spect mult  
78453  Ht muscle image planar sing  
78454  Ht musc image planar mult  
78472  Gated heart planar single  
78473  Gated heart multiple  
78481  Heart first pass single  
78483  Heart first pass multiple  
78491  Heart image (pet) single  
78492  Heart image (pet) multiple  
78494  Heart image spect  
78496  Heart first pass add-on

**Group 2 Paragraph: HCPCS Codes**
**Group 2 Codes:**

- A4641 Radiopharm dx agent noc
- A9500 Tc99m sestamibi
- A9501 Technetium TC-99m teboroxime
- A9502 Tc99m tetrofosmin
- A9505 TL201 thallium
- A9526 Nitrogen N-13 ammonia
- A9555 Rb82 rubidium

*Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.*

**Documentation Requirements**

The patient's medical record must document the medical necessity of services performed for each date of service submitted on a claim, and documentation must be available to A/B MAC on request.

The medical record must document when significant resting ECG abnormalities are present, or a medication is being used and cannot be withdrawn, that would interfere with interpretation of a stress ECG, resulting in the selection of myocardial perfusion study.

The rationale for selecting pharmacologic stress rather than exercise stress must be indicated in the medical record.

Claims submitted for stress tests performed as preoperative evaluation of patients without symptoms of CAD who are deemed to be at moderate risk must document one of the following at-risk conditions in the medical record: Diabetes mellitus with complications, peripheral vascular disease, aortic aneurysm or cerebrovascular disease.

**Utilization Guidelines**

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.
NCD Manual Section Number:
  220.6.1 – Perfusion of the Heart
  220.6.8 – Myocardial Viability

CPT Codes: 78459, 78491, 78492

FOR CMS (MEDICARE) MEMBERS ONLY

Perfusion of the Heart: (NCD 220.6.1)
PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82) or Ammonia N-13 are covered, provided the requirements below are met.

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a SPECT.
- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the patient’s file.)

Myocardial Viability: (NCD 220.6.8)
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. Diagnostic tests such as FDG PET 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.

- For the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT.

Limitations:
In the event a patient receives a SPECT test with inconclusive results, a PET scan may be covered. However, if a patient receives a FDG PET study with inconclusive results, a follow up SPECT test is not covered.
NCD Manual Section Number: 
220.6.9 & 220.6.13

CPT Codes: 78608

FOR CMS (MEDICARE) MEMBERS ONLY”

IMPORTANT NOTE:

INDICATIONS AND LIMITATIONS OF COVERAGE FOR BRAIN PET:

For patients with epilepsy (Refractory Seizures): (NCD 220.6.9)

- Pre surgical evaluation for refractory seizures (seizures continue to occur despite treatment).

FDG PET for Dementia and Neurodegenerative Diseases: (NCD 220.6.13)

A. General
Medicare covers FDG Positron Emission Tomography (PET) scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer’s disease (AD) under specific requirements; OR, its use in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of FDG PET in the diagnosis or treatment of dementing neurodegenerative diseases. Specific requirements for each indication are clarified below:

Indications and Limitations of Coverage

B. Nationally Covered Indications
1. FDG PET Requirements for Coverage in the Differential Diagnosis of AD and FTD
An FDG PET scan is considered reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain. The following additional conditions must be met before an FDG PET scan will be covered:
   a. The patient’s onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline. Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD;
   b. The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and
mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);

c. The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;

d. The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through FDG PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment;

e. The FDG PET scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia;

f. A brain single photon emission computed tomography (SPECT) or FDG PET scan has not been obtained for the same indication. (The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains uncertain.) The results of a prior SPECT or FDG PET scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, an FDG PET scan may be covered after one year has passed from the time the first SPECT or FDG PET scan was performed.)

g. The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Providers should establish the medical necessity of an FDG PET scan by ensuring that the following information has been collected and is maintained in the beneficiary medical record:

- Date of onset of symptoms;
- Diagnosis of clinical syndrome (normal aging; mild cognitive impairment (MCI); mild, moderate or severe dementia);
- Mini mental status exam (MMSE) or similar test score;
- Presumptive cause (possible, probable, uncertain AD);
- Any neuropsychological testing performed;
- Results of any structural imaging (MRI or CT) performed;
- Relevant laboratory tests (B12, thyroid hormone); and,
- Number and name of prescribed medications.

The billing provider must furnish a copy of the FDG PET scan result for use by CMS and its Medicare Administrative Contractors upon request. These verification requirements are consistent with Federal requirements set forth in 42 Code of Federal Regulations, section 410.32 generally for diagnostic x-ray tests, diagnostic laboratory tests, and other tests. In summary, section 410.32 requires the billing physician and the referring physician to maintain information in the medical record of each patient to demonstrate medical necessity [410.32(d)(2)] and submit the information demonstrating medical necessity to CMS and/or its agents upon request [410.32(d)(3)(I)] (OMB number 0938-0685).
2. FDG PET Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of FDG PET in the Diagnosis, and Treatment of Neurodegenerative Dementing Diseases

An FDG PET scan is considered reasonable and necessary in patients with MCI or early dementia (in clinical circumstances other than those specified in subparagraph 1) only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the FDG PET scan. The clinical trial must compare patients who do and do not receive an FDG PET scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:

a. Written protocol on file;
b. Institutional Review Board review and approval;
c. Scientific review and approval by two or more qualified individuals who are not part of the research team; and,
d. Certification that investigators have not been disqualified.

C. Nationally Non-Covered Indications
All other uses of FDG PET for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeld-Jacob disease) for which CMS has not specifically indicated coverage continue to be noncovered.
NCD Manual Section Number:
220.6.17 – Oncologic Conditions
220.6.16 – Infection and Inflammation

78811 - Limited area e.g. Chest, head/neck
78812 - Skull base to mid thigh
78813 - Whole Body
78814 - With CT attenuation (Limited area e.g. Chest, head/neck)
78815 - With CT attenuation (Skull base to mid thigh)
78816 - With CT attenuation (Whole Body)
G0219 - PET imaging whole body, melanoma for non-covered indications
G0235 - PET imaging, any site, not otherwise specified
G0252 - PET imaging, initial diagnosis of breast cancer and/or surgical planning for breast cancer

FOR CMS (MEDICARE) MEMBERS ONLY

CMS continues to believe that the evidence is adequate to determine that the results of FDG PET imaging are useful in determining the appropriate initial anti-tumor treatment strategy for beneficiaries with suspected cancer and improve health outcomes and thus are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act).

Therefore, CMS continues to nationally cover one FDG PET study for beneficiaries who have cancers that are biopsy proven or strongly suspected based on other diagnostic testing when the beneficiary’s treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial anti-tumor treatment strategy:

- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

NATIONALLY NON-COVERED INDICATIONS:

- CMS continues to nationally non-cover initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate.
- CMS continues to nationally non-cover FDG PET imaging for initial anti-tumor treatment strategy for the evaluation of regional lymph nodes in melanoma.
- CMS continues to nationally non-cover FDG PET imaging for the diagnosis of cervical cancer related to initial anti-tumor treatment strategy.
Infection and/or Inflammation - PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin. (NCD 220.6.16)

- CPT code G0219: PET imaging whole body melanoma for non-covered indications. CMS does not cover this code.
- CPT code G0235: PET imaging, any site, not otherwise specified. CMS does not cover this code.
- CPT code G0252: FDG PET imaging for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes). CMS does not cover this code.

NATIONALLY COVERED INDICATIONS:

Indications and Limitations of Coverage (NCD 220.6.17)

Initial Anti-Tumor Treatment Strategy Nationally Covered Indications
  a. CMS continues to nationally cover FDG PET imaging for the initial anti-tumor treatment strategy for male and female breast cancer only when used in staging distant metastasis.
  b. CMS continues to nationally cover FDG PET to determine initial anti-tumor treatment strategy for melanoma other than for the evaluation of regional lymph nodes.
  c. CMS continues to nationally cover FDG PET imaging for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging.

Initial Anti-Tumor Treatment Strategy Nationally Non-Covered Indications
  a. CMS continues to nationally non-cover initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate.
  b. CMS continues to nationally non-cover FDG PET imaging for diagnosis of breast cancer and initial staging of axillary nodes.
  c. CMS continues to nationally non-cover FDG PET imaging for initial anti-tumor treatment strategy for the evaluation of regional lymph nodes in melanoma.
  d. CMS continues to nationally non-cover FDG PET imaging for the diagnosis of cervical cancer related to initial anti-tumor treatment strategy.

Subsequent Anti-Tumor Treatment Strategy Nationally Covered Indications
Three FDG PET scans are nationally covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy. Coverage of more than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy shall be determined by the local Medicare Administrative Contractors.

Synopsis of Coverage of FDG PET for Oncologic Conditions

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<th>FDG PET for Cancers Tumor Type</th>
<th>Initial Treatment Strategy (formerly “diagnosis” &amp;</th>
<th>Subsequent Treatment Strategy (formerly</th>
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<td>Non-cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Breast (male and female)</td>
<td>Cover with exceptions *</td>
<td>Cover</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Cover with exceptions *</td>
<td>Cover</td>
</tr>
<tr>
<td>All other solid tumors</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Myeloma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>All other cancers not listed</td>
<td>Cover</td>
<td>Cover</td>
</tr>
</tbody>
</table>

*Cervix*: Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.

*Breast*: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.

*Melanoma*: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy for melanoma are nationally covered.
Coverage Indications, Limitations, and/or Medical Necessity

The following may be medically necessary indications for stress echocardiography:

- To provide additional diagnostic information in patients with a previous non-diagnostic treadmill stress test who have signs or symptoms of suspected coronary artery disease;
- To provide additional diagnostic information in patients with known or suspected coronary artery disease who are in groups known to have a high false-positive rate for electrocardiographic (EKG) changes with stress tests; (Examples are women and patients who are undergoing drug therapy which may alter the EKG response.)
- To provide additional diagnostic information in patients with conduction or repolarization abnormalities in whom the electrocardiographic diagnosis of stress-induced ischemia may be difficult;
- To determine the extent and location of ischemic wall motion abnormalities in patients who have a positive stress test;
- To observe the physiological significance of a lesion or to follow the changes after vascular intervention, before or after an acute invasive intervention;
- To provide prognostic information following myocardial infarction; (Pharmacological stress is often used in this setting.)
  For an assessment of ischemic cause, and/or for evaluation of viability in patients who have reduced left ventricular ejection fraction (e.g., <45%) or congestive heart failure without obvious other reason and when coronary artery disease cannot be ruled out;
- To assess the gradient during exercise or to assess the response to therapy initiated to limit the gradient during exercise in patients with hypertrophic cardiomyopathy and known or suspected left ventricular outflow tract obstruction;
- To provide additional diagnostic information in patients with stenotic valvular heart disease (e.g., mitral stenosis and aortic stenosis) when results of a resting image or angiography are inadequate for diagnosing a valvular lesion causing symptomatic exercise intolerance;
- For evaluation of known or suspected post-cardiac transplant coronary artery disease;
- For risk stratification prior to surgery; and
- To obtain diagnostic information in patients with moderate coronary artery disease.

Pharmacological stress may be utilized in patients who are unable to exercise to the maximum heart rate.

The use of a computer-based digitized imaging technique is required for stress echocardiography.
interpretation.

Stress echocardiography and nuclear ventriculography procedures provide similar diagnostic information. Therefore, it may not be medically necessary for both procedures to be performed on a beneficiary during the same episode of illness unless there is documentation in the medical record indicating that the results of the initial test are technically suboptimal due to reasons other than equipment problems or technician error.

Limitations of the echocardiography technique may diminish its reliability in assessing myocardial disease. These limitations are particularly relevant in the following circumstances:

- When a poor acoustic window precludes adequate myocardial definition and the ability to evaluate ischemia with confidence (e.g., chest wall abnormalities, severe chronic obstructive pulmonary disease or obesity);
- When the sonographer does not have extensive training in the acquisition of images and in regional wall motion analysis (interpretation of stress echocardiograms has a larger inter-observer variability than the interpretation of nuclear studies);
- When the echocardiographic imaging is not done promptly after completion of exercise (regional wall abnormalities tend to resolve within the first 1 to 2 minutes after stress, especially in patients not achieving an adequate work load);
- In patients with left bundle branch block which produces dyssynergia of the septal wall;
- In patients who exhibit a hypertensive response to exercise there may be decreased exercise-induced contractility in the absence of underlying epicardial vessel stenosis; and,
- In patients with known left ventricular hypertrophy and reduced left-ventricular end-diastolic dimensions there may be reduced sensitivity and Dobutamine stress echo may produce suboptimal diagnostic information.

Note: When ultrasound contrast enhancement is used for visualizing the ventricular chambers and endocardial border, the supply is considered separate from the procedure for reimbursement from Medicare.

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>93350</td>
<td>ECHOCARDIOGRAPHY, TRANSTHORACIC, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, DURING REST AND CARDIOVASCULAR STRESS TEST USING TREADMILL, BICYCLE EXERCISE AND/OR PHARMACOLOGICALLY INDUCED STRESS, WITH INTERPRETATION AND REPORT:</td>
</tr>
<tr>
<td>93351</td>
<td>ECHOCARDIOGRAPHY, TRANSTHORACIC, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, DURING REST AND CARDIOVASCULAR STRESS TEST</td>
</tr>
</tbody>
</table>
Using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional.

93352 Echocardiography (list separately in addition to code for primary procedure)

Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

Documentation Requirements

Appropriate diagnostic ICD-10 codes supporting the medical necessity of the services must be submitted with each claim. Claims submitted without such evidence will be denied as not being medically necessary. The patient record is expected to support the diagnosis should chart review become necessary. Medicare does not pay for procedures that are not medically necessary.

Documentation supporting medical necessity should be legible, maintained in the patient’s medical record, and made available to AB MAC upon request.

Documentation in the patient’s progress notes must exist to justify the medical necessity for the use of pharmacologic stress agents, and must be available if requested.
CPT Codes: G0219

MEDICARE NATIONALLY NON-COVERED INDICATIONS:

- CPT code G0219: PET imaging whole body melanoma for non-covered indications. CMS does not cover this code.
CPT Codes: G0235

MEDICARE NATIONALLY NON-COVERD INDICATIONS:

- CPT code G0235: PET imaging, any site, not otherwise specified. CMS does not cover this code.
CPT Codes: G0252

MEDICARE NATIONALLY NON-COVERED INDICATIONS:

- CPT code G0252: FDG PET imaging for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes). CMS does not cover this code.
S8032 – Low Dose CT for Lung Cancer Screening

NCD Manual Section Number: 210.14

Codes: S8032, G0297

“FOR MEDICARE MEMBERS ONLY”

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to add a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, annual screening for lung cancer with low dose computed tomography (LDCT), as an additional preventive service benefit under the Medicare program only if all of the following criteria are met.

Counseling and Shared Decision Making Visit

*Before the beneficiary’s first lung cancer LDCT screening, the beneficiary must receive counseling and shared decision making visit that meets all of the following criteria, and is appropriately documented in the beneficiary’s medical records:*

- Must be furnished by a physician (as defined in Section 1861(r)(1) of the Social Security Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Social Security Act), and
- Must include all of the following elements:
  - Determination of beneficiary eligibility including age, absence of signs or symptoms of lung cancer, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting;
  - Shared decision making, including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure;
  - Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment;
  - Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and, if appropriate, furnishing of information about tobacco cessation interventions; and
  - If appropriate, the furnishing of a written order for lung cancer screening with LDCT.

Written Orders for Subsequent Annual Lung Cancer Screenings with LDCT

For subsequent annual lung cancer LDCT screenings, the beneficiary must receive a written order for lung cancer LDCT screening. The written order may be furnished during any appropriate visit with a physician (as defined in Section 1861(r)(1) of the Social Security Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in Section 1861(aa)(5) of the Social Security Act).
If a physician or qualified non-physician practitioner elects to provide a lung cancer screening counseling and shared decision making visit before a subsequent annual lung cancer LDCT screening, the visit must meet all of the criteria described above for a counseling and shared decision making visit.

**Beneficiary eligibility criteria:**

For purposes of Medicare coverage of lung cancer screening with LDCT, beneficiaries must *meet all* of the following eligibility criteria:

- Age 55 – 77 years;
- Asymptomatic (no signs or symptoms of lung cancer);
- Tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Current smoker or one who has quit smoking within the last 15 years; and
- Receive a written order for lung cancer screening with LDCT. Written orders for lung cancer LDCT screenings must be appropriately documented in the beneficiary’s medical records, and must contain the following information:
  - Beneficiary date of birth;
  - Actual pack – year smoking history (number);
  - Current smoking status, and for former smokers, the number of years since quitting smoking;
  - Statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer); and
  - National Provider Identifier (NPI) of the ordering practitioner.
NCD Manual Section Number: 220.2

FOR CMS (MEDICARE) MEMBERS ONLY

NATIONAL COVERAGE DETERMINATION (NCD) FOR MAGNETIC RESONANCE IMAGING:

Item/Service Description

A. General

1. Method of Operation
Magnetic Resonance Imaging (MRI), formerly called nuclear magnetic resonance (NMR), is a non-invasive method of graphically representing the distribution of water and other hydrogen-rich molecules in the human body. In contrast to conventional radiographs or computed tomography (CT) scans, in which the image is produced by x-ray beam attenuation by an object, MRI is capable of producing images by several techniques. In fact, various combinations of MRI image production methods may be employed to emphasize particular characteristics of the tissue or body part being examined. The basic elements by which MRI produces an image are the density of hydrogen nuclei in the object being examined, their motion, and the relaxation times, and the period of time required for the nuclei to return to their original states in the main, static magnetic field after being subjected to a brief additional magnetic field. These relaxation times reflect the physical-chemical properties of tissue and the molecular environment of its hydrogen nuclei. Only hydrogen atoms are present in human tissues in sufficient concentration for current use in clinical MRI.

2. General Clinical Utility
Overall, MRI is a useful diagnostic imaging modality that is capable of demonstrating a wide variety of soft-tissue lesions with contrast resolution equal or superior to CT scanning in various parts of the body.
Among the advantages of MRI are the absence of ionizing radiation and the ability to achieve high levels of tissue contrast resolution without injected iodinated radiological contrast agents. Recent advances in technology have resulted in development and Food and Drug Administration (FDA) approval of new paramagnetic contrast agents for MRI which allow even better visualization in some instances. Multi-slice imaging and the ability to image in multiple planes, especially sagittal and coronal, have provided flexibility not easily available with other modalities. Because cortical (outer layer) bone and metallic prostheses do not cause distortion of MR images, it has been possible to visualize certain lesions and body regions with greater certainty than has been possible with CT. The use of MRI on certain soft tissue structures for the purpose of detecting disruptive, neoplastic, degenerative, or inflammatory lesions has now become established in medical practice.

Indications and Limitations of Coverage

B. Nationally Covered MRI Indications

1. MRI
Although several uses of MRI are still considered investigational and some uses are clearly contraindicated (see subsection C), MRI is considered medically efficacious for a number of uses. Use the following descriptions as general guidelines or examples of what may be considered covered rather than as a restrictive list of specific covered indications. Coverage is limited to MRI units that have received FDA premarket approval, and such units must be operated within the parameters
specified by the approval. In addition, the services must be reasonable and necessary for the
diagnosis or treatment of the specific patient involved.
a) Effective November 22, 1985:
a. MRI is useful in examining the head, central nervous system, and spine.
b. Multiple sclerosis can be diagnosed with MRI and the contents of the posterior fossa are
visible.
c. The inherent tissue contrast resolution of MRI makes it an appropriate standard
diagnostic modality for general neuroradiology.
b) Effective November 22, 1985:
a. MRI can assist in the differential diagnosis of mediastinal and retroperitoneal masses,
including abnormalities of the large vessels such as aneurysms and dissection.
b. When a clinical need exists to visualize the parenchyma of solid organs to detect anatomic
disruption or neoplasia, this can be accomplished in the liver, urogenital system, adrenals,
and pelvic organs without the use of radiological contrast materials. When MRI is considered
reasonable and necessary, the use of paramagnetic contrast materials may be covered as
part of the study.
c. MRI may also be used to detect and stage pelvic and retroperitoneal neoplasms and
d. to evaluate disorders of cancellous bone and soft tissues.
e. It may also be used in the detection of pericardial thickening.
f. Primary and secondary bone neoplasm and aseptic necrosis can be detected at an early
stage and monitored with MRI.
g. Patients with metallic prostheses, especially of the hip, can be imaged in order to detect
the early stages of infection of the bone to which the prosthesis is attached.
c) Effective March 22, 1994:
a. MRI may also be covered to diagnose disc disease without regard to whether radiological
imaging has been tried first to diagnose the problem.
d) Effective March 4, 1991:
a. MRI with gating devices and surface coils, and gating devices that eliminate distorted
images caused by cardiac and respiratory movement cycles are now considered state of the
art techniques and may be covered. Surface and other specialty coils may also be covered, as
they are used routinely for high resolution imaging where small limited regions of the body
are studied. They produce high signal-to-noise ratios resulting in images of enhanced
anatomic detail.

C. Contraindications and Nationally Non-Covered Indications
1. Contraindications
The MRI is not covered when the following patient-specific contraindications are present:
MRI is not covered for patients with cardiac pacemakers or with metallic clips on vascular
aneurysms unless the Medicare beneficiary meets the provisions of the following exceptions:
Effective July 7, 2011, the contraindications will not apply to pacemakers when used according to
the FDA-approved labeling in an MRI environment

2. Nationally Non-Covered Indications
CMS has determined that MRI of cortical bone and calcifications, and procedures involving spatial
resolution of bone and calcifications, are not considered reasonable and necessary indications
within the meaning of section 1862(a)(1)(A) of the Act, and are therefore non-covered.

D. Other
Effective June 3, 2010, all other uses of MRI or MRA for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local MAC discretion.
Item/Service Description
A. General
Diagnostic examinations of the head (head scans) and of other parts of the body (body scans) performed by computerized tomography (CT) scanners are covered if medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: (1) reasonable and necessary for the individual patient; and (2) performed on a model of CT equipment that meets the criteria in C below.
CT scans have become the primary diagnostic tool for many conditions and symptoms. CT scanning used as the primary diagnostic tool can be cost effective because it can eliminate the need for a series of other tests, is non-invasive and thus virtually eliminates complications, and does not require hospitalization.

Indications and Limitations of Coverage for NCD 220.1

B. Determining Whether a CT Scan Is Reasonable and Necessary
Sufficient information must be provided with claims to differentiate CT scans from other radiology services and to make coverage determinations. Carefully review claims to insure that a scan is reasonable and necessary for the individual patient; i.e., the use must be found to be medically appropriate considering the patient's symptoms and preliminary diagnosis.
There is no general rule that requires other diagnostic tests to be tried before CT scanning is used. However, in an individual case the contractor's medical staff may determine that use of a CT scan as the initial diagnostic test was not reasonable and necessary because it was not supported by the patient's symptoms or complaints stated on the claim form; e.g., "periodic headaches."
Claims for CT scans are reviewed for evidence of abuse which might include the absence of reasonable indications for the scans, an excessive number of scans or unnecessarily expensive types of scans considering the facts in the particular cases.

Approved Models of CT Equipment
1. Criteria for Approval
In the absence of evidence to the contrary, the MAC may assume that a CT scan for which payment is requested has been performed on equipment that meets the following criteria:
a. The model must be known to the Food and Drug Administration (FDA), and
b. Must be in the full market release phase of development.
Should it be necessary to confirm that those criteria are met, ask the manufacturer to submit the information in C.2. If manufacturers inquire about obtaining Medicare approval for their equipment, inform them of the foregoing criteria.

2. Evidence of Approval
a. The letter sent by the Bureau of Radiological Health, FDA, to the manufacturer acknowledging the FDA's receipt of information on the specific CT scanner system model

b. A letter signed by the chief executive officer or other officer acting in a similar capacity for the manufacturer which:
   i. Furnishes the CT scanner system model number, all names that hospitals and physicians’ offices may use to refer to the CT scanner system on claims, and the accession number assigned by FDA to the specific model;
   ii. Specifies whether the scanner performs head scans only, body scans only (i.e., scans of parts of the body other than the head), or head and body scans;
   iii. States that the company or corporation is satisfied with the results of the developmental stages that preceded the full market release phase of the equipment, that the equipment is in the full market release phase, and the date on which it was decided to put the product into the full market release phase.

D. Mobile CT Equipment

CT scans performed on mobile units are subject to the same Medicare coverage requirements applicable to scans performed on stationary units, as well as certain health and safety requirements recommended by the Health Resources and Services Administration. As with scans performed on stationary units, the scans must be determined medically necessary for the individual patient. The scans must be performed on types of CT scanning equipment that have been approved for use as stationary units (see C above), and must be in compliance with applicable State laws and regulations for control of radiation.

1. Hospital Setting

The hospital must assume responsibility for the quality of the scan furnished to inpatients and outpatients and must ensure that a radiologist or other qualified physician is in charge of the procedure. The radiologist or other physician (i.e., one who is with the mobile unit) who is responsible for the procedure must be approved by the hospital for similar privileges.

2. Ambulatory Setting

If mobile CT scan services are furnished at an ambulatory health care facility other than a hospital-based facility, e.g., a freestanding physician-directed clinic, the diagnostic procedure must be performed by, or under the direct personal supervision of, a radiologist or other qualified physician. In addition, the facility must maintain a record of the attending physician’s order for a scan performed on a mobile unit.

3. Billing for Mobile CT Scans

Hospitals, hospital-associated radiologists, ambulatory health care facilities, and physician owner/operators of mobile units may bill for mobile scans as they would for scans performed on stationary equipment.

4. Claims Review

Evidence of compliance with applicable State laws and regulations for control of radiation should be requested from owners of mobile CT scan units upon receipt of the first claims. All mobile scan claims should be reviewed very carefully in accordance with instructions applicable to scans performed on fixed units, with particular emphasis on the medical necessity for scans performed in an ambulatory setting.

E. Multi-Planar Diagnostic Imaging (MPDI)

In usual CT scanning procedures, a series of transverse or axial images are reproduced. These transverse images are routinely translated into coronal and/or sagittal views. MPDI is a process which further translates the data produced by CT scanning by providing reconstructed oblique images which can contribute to diagnostic information. MPDI, also known as planar image
reconstruction or reformatted imaging, is covered under Medicare when provided as a service to an entity performing a covered CT scan.

**F. Computed Tomographic Angiography (CTA)**

CTA is a general phrase used to describe a non-invasive method, using intravenous contrast, to visualize the coronary arteries (or other vessels) using high-resolution, high-speed CT.

After examining the medical evidence, the Centers for Medicare and Medicaid Services has determined that *no national coverage determination is appropriate at this time* (March 12, 2008). Section 1862(a)(1)(A) of the Social Security Act decisions should be made by local MACs through a local coverage determination process or case-by-case adjudication. See Heckler v. Ringer, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003).