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
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>70544</td>
<td>MR Angiography Head/Brain</td>
<td>4</td>
</tr>
<tr>
<td>70547</td>
<td>MR Angiography Neck</td>
<td>4</td>
</tr>
<tr>
<td>71555</td>
<td>MR Angiography Chest (excluding myocardium)</td>
<td>4</td>
</tr>
<tr>
<td>72198</td>
<td>MR Angiography, Pelvis</td>
<td>4</td>
</tr>
<tr>
<td>73225</td>
<td>MR Angiography Upper Extremity</td>
<td>4</td>
</tr>
<tr>
<td>73725</td>
<td>MR Angiography, Lower Extremity</td>
<td>4</td>
</tr>
<tr>
<td>74185</td>
<td>MR Angiography, Abdomen</td>
<td>4</td>
</tr>
<tr>
<td>72159</td>
<td>MR Angiography Spinal Canal</td>
<td>4</td>
</tr>
<tr>
<td>74263</td>
<td>CT Colonoscopy Screening (Virtual)</td>
<td>7</td>
</tr>
<tr>
<td>76390</td>
<td>MR Spectroscopy</td>
<td>8</td>
</tr>
<tr>
<td>78451</td>
<td>Myocardial Perfusion Imaging (Nuc Card)</td>
<td>9</td>
</tr>
<tr>
<td>78472</td>
<td>MUGA Scan</td>
<td>9</td>
</tr>
<tr>
<td>78459</td>
<td>PET Scan, Heart (Cardiac)</td>
<td>14</td>
</tr>
<tr>
<td>78608</td>
<td>PET Scan, Brain</td>
<td>15</td>
</tr>
<tr>
<td>78813</td>
<td>PET Scan</td>
<td>18</td>
</tr>
<tr>
<td>G0219</td>
<td>PET Imaging whole body, melanoma - noncovered</td>
<td>21</td>
</tr>
<tr>
<td>G0235</td>
<td>PET imaging, any site, not otherwise specified</td>
<td>22</td>
</tr>
<tr>
<td>G0252</td>
<td>PET imaging, initial diagnosis of breast cancer</td>
<td>23</td>
</tr>
<tr>
<td>S8032</td>
<td>Low Dose CT for Lung Cancer Screening</td>
<td>24</td>
</tr>
<tr>
<td>MAGNETIC RESONANCE IMAGING (MRI)</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>COMPUTED TOMOGRAPHY (CT)</td>
<td>29</td>
<td></td>
</tr>
</tbody>
</table>

Prepared: August 22, 2017
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.*
NCD Manual Section Number: 210.3

CPT Codes: 74263

“FOR MEDICARE MEMBERS ONLY”

Nationally Non-Covered Indications

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

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.
LCD from Novitas Solutions, Inc., J-L: L35083

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

“FOR CMS (MEDICARE) MEMBERS ONLY”

Coverage Indications, Limitations, and/or Medical Necessity

Cardiovascular nuclear imaging employs non-invasive techniques to assess alterations in coronary artery flow, as well as ventricular function. A variety of radionuclides may be used.

The specific imaging technique (perfusion versus ventricular function) and the reason for the imaging determine what radionuclide agent is employed. In its simplest terms, a perfusion study utilizes an imaging isotope agent that reflects myocardial blood flow and, dependent on the agent and timing of image acquisition, the presence of scar and/or ischemia. Ventricular function studies utilize specific imaging isotopes to outline the borders of the left ventricular endocardium or to identify the ventricular blood pool independent of the surrounding myocardium. The motion of the left ventricle is synchronized with the electrocardiogram to generate wall motion and ejection fraction information. Both modalities may use rest and exercise images.

In instances where an exercise test cannot be performed, provocative agents may be used to alter coronary flow, thereby unmasking a suspected lesion in the coronary bed. The acquisition of the images may be planar (single plane) or by multiple planes with computer integration, Single-Photon Emission Computer Tomography (SPECT).

INDICATIONS

Radionuclide imaging may be employed in the assessment of a variety of conditions associated with primary coronary artery disease. Some of these conditions include:

1. Assessment of the functional and prognostic importance of angina, chest pain, or angina equivalent symptoms.
2. Diagnostic evaluation of patients with chest pain and uninterpretable or equivocal ECG changes occurring naturally or caused by drugs, bundle branch block, or left ventricular hypertrophy.
3. Risk assessment of re-evaluation of disease in patients who are asymptomatic or have stable symptoms, with known atherosclerotic heart disease on catheterization or SPECT perfusion imaging, who have not had a revascularization procedure within the past two years or greater than 2 years since last imaging study.
4. Detection of coronary artery disease in patients, without chest pain syndrome, with new-onset of diagnosed heart failure or left ventricular systolic dysfunction.
5. Evaluation of ischemic versus non-ischemic cardiomyopathy when cardiac catheterization / coronary angiography is not planned.
6. Evaluation of myocardial perfusion viability and/or function before and more than or equal to 5 years after coronary artery bypass surgery or greater than or equal to 2 years after
percutaneous perfusion procedures, unless new clinical signs or symptoms necessitate reevaluation.

7. Quantification and surveillance of myocardial infarction and prognostication in patient with infarction.

8. Preoperative assessment for non-cardiac surgery, when used to determine risk for surgery and/or perioperative management in:
   a. Patients with minor or intermediate clinical risk predictors and poor functional capacity.
   b. Patients with intermediate or high likelihood of coronary heart disease, or patients with poor functional capacity undergoing high risk non-cardiac surgery.

The ACA/AHA 2014 Guidelines on Perioperative Cardiovascular Evaluation and Care for Non-Cardiac Surgery (JACC 2014); provides the following information regarding categorization of surgical risk. They include:

- high risk/intermediate risk surgery: aortic and peripheral vascular surgery; intraperitoneal and intrathoracic surgery, carotid endarterectomy, head and neck surgery, orthopedic surgery and prostate surgery;
- low risk surgery: endoscopic procedure, superficial surgery, cataract surgery, breast surgery, ambulatory surgery;
- The Guidelines establish poor functional capacity as = less than 4 METS;
- Utilization of these tests is based on the presence of multiple risk factors, the level of functional capacity, the risk of surgery proposed, and the likelihood that the results of the cardiac testing would change the management.


10. Evaluation of patients in whom an accurate measure of the ejection fraction is needed to make a determination of whether to implant a defibrillator or biventricular pacemaker.

11. Evaluation of patient receiving chemotherapeutic drugs which are potentially cardiotoxic (e.g., Adriamycin, Herceptin).

First pass studies will be considered medically necessary only when information sought is immediately relevant to the management of the patient’s clinical condition and has not been previously obtained or likely to be obtained from other planned tests such as echocardiography or equilibrium gated blood pool studies. First pass studies may be indicated for the assessment and identification of shunts and are more likely to be done in suspected congenital events. It is noted that occasionally first pass studies and gated blood pool studies may be additive when RVEF is needed on the same day.

Infarct Avid Scintigraphy is indicated in patients in whom it is not possible to make a definitive diagnosis of myocardial infarction by EKG or enzyme testing.

Patient selection should be based on clinical grounds:

- Patients with a high pretest probability of disease are not usually candidates for a study for diagnostic purposes, though the size and reversibility of a defect and its functional consequences may be required for clinical decision-making.
- Patients with a moderate probability of disease benefit the most from the study when the diagnosis is in question.
- Selection of tests should be made within the context of other tests, scheduled and previously performed so that the anticipated information obtained is unique and not redundant.
- Redundant testing where multiple tests are done revealing the same information is not medically necessary and should be appropriately denied if reviewed.

**LIMITATIONS**

Given the limitations of uptake, low photon energy and redistribution, it would not be considered reasonable and necessary for the cardiac blood pool codes and perfusion imaging codes to be performed on the same date of service.

Cardiac blood pool imaging studies are described by the codes 78472, 78473, 78481, 78483, 78494 (with add on code 78496). It is not considered reasonable and necessary for more than one code from this series (with appropriate add-on) to be reported on a single date of service.

All cardiovascular nuclear tests and stress tests must be referred by a physician or a qualified non-physician. (i.e., a Nurse Practitioner (NP) or Physician Assistant (PA)).

All stress tests must be performed under the direct supervision of a physician (even in a facility). The nuclear test components must be performed under the general supervision of a physician.

Myocardial perfusion studies performed based on the presence of risk factors in the absence of cardiac symptoms, cardiac abnormalities on physical examination, or abnormalities on cardiac testing (e.g., electrocardiographic tests, echocardiography, treadmill stress testing, etc.) will be considered screening and denied as not covered by Medicare.

Tests that are anticipated to provide information duplicative of another test already performed will be denied as not medically necessary.

Tests performed when the results would not be anticipated to influence medical management decisions will be denied as not medically necessary.

Myocardial perfusion studies performed subsequent to a diagnostic myocardial PET scan will be denied as not medically necessary.

Infarct avid scintigraphy will be denied if the diagnosis of myocardial infarction has already been confirmed by enzymes and/or EKG.

Tests performed unrelated to changes in a patient’s signs or symptoms, or for immediate preoperative screening without signs or symptoms will be denied as medically unnecessary. Please see preoperative testing indications above.

Tests performed for risk assessment prior to high risk non-cardiac surgery in asymptomatic patients within one year following normal catheterization or non-invasive test will be considered medically unnecessary and denied.
Tests performed for preoperative evaluation in patients undergoing low-risk surgery will be denied.

**CPT/HCPCS Codes**

**Group 1 Paragraph:** Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

**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
78466  Heart infarct image
78468  Heart infarct image (ef)
78469  Heart infarct image (3D)
78472  Gated heart planar single
78473  Gated heart multiple
78481  Heart first pass single
78483  Heart first pass multiple
78494  Heart image spect
78496  Heart first pass add-on
A9500  Tc99m sestamibi
A9501  Technetium TC-99m teboroxime
A9502  Tc99m tetrofosmin
A9505  TL201 thallium
A9512  Tc99m pertechnetate
A9538  Tc99m pyrophosphate
A9560  Tc99m labeled rbc
J0153  Adenosine inj 1mg
J1245  Dipyridamole injection
J1250  Inj dobutamine HCL/250 mg
J2785  Regadenoson injection
J3490  Drugs unclassified injection
Non-HEU TC-99M add-on/dose

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

Documentation Requirements
1. All documentation must be maintained in the patient’s medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. Medical records must substantiate the medical necessity of the services, including a clinical diagnosis and the specific reason for the study.
5. All segments of the service must have a formal interpretation and report.
6. Requested records must be accompanied by a copy of the formal report and the reason for the referral for the test.
7. The referral order must be kept on file in the patient’s medical record.
8. When HCPCS procedure code A9505 is submitted with CPT procedure codes 78451, 78452, 78453 or 78454, the formal report must indicate that the laboratory is equipped with at least a double-headed camera as well as the appropriate software to complete the study satisfactorily.
9. When CPT code 78472 and add-on code 78496 are submitted with perfusion codes 78451, 78452, 78453, 78454, 78466, 78468 or 78469, the formal reports must document that simultaneous cardiac function studies using the first-pass technique were performed and the laboratories are equipped to perform such studies.
10. When billing for the purchase of radiopharmaceutical(s), a copy of the bill indicating the dosage administered, unit price per dose, name and total charge of the radioactive drug must be made available to Medicare upon request.
11. When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.
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:
Any request for CPT code 78609; CPT code 78609 is a non-covered service for CMS (effective date retroactive to 01/28/2005). [link to CMS guidance]

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

<table>
<thead>
<tr>
<th>FDG PET for Cancers Tumor Type</th>
<th>Initial Treatment Strategy (formerly “diagnosis” &amp; “staging”)</th>
<th>Subsequent Treatment Strategy (formerly “restaging” &amp; “monitoring response to treatment”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition</td>
<td>Coverage</td>
<td>Notes</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>----------</td>
<td>-----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Colon/rectal</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Esophagus</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Head and Neck (not thyroid, CNS)</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Lymphoma</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Non-small cell lung</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Ovary</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Brain</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Cervix</td>
<td>Cover with exceptions *</td>
<td>All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.</td>
</tr>
<tr>
<td>Small cell lung</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Soft tissue sarcoma</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Pancreas</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Testes</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Prostate</td>
<td>Non-cover</td>
<td>All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Breast (male and female)</td>
<td>Cover with exceptions *</td>
<td>All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Cover with exceptions *</td>
<td>All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.</td>
</tr>
<tr>
<td>All other solid tumors</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>Myeloma</td>
<td>Cover</td>
<td></td>
</tr>
<tr>
<td>All other cancers not listed</td>
<td>Cover</td>
<td></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.
CPT Codes: G0219

MEDICARE NATIONALLY NON-COVERD 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-COVERED 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.
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.
MAGNETIC RESONANCE IMAGING (MRI)

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.
NCD Manual Section Number: 220.1

FOR CMS (MEDICARE) MEMBERS ONLY

NATIONAL COVERAGE DETERMINATION (NCD) FOR COMPUTED TOMOGRAPHY:

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).

Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer