POSITRON EMISSION TOMOGRAPHY & COMPUTED TOMOGRAPHY (PET/CT)

[Preauthorization Required]

Medical Policy: MP-RA-01-04
Original Effective Date: October 1, 2005
Reviewed: September 29, 2011
Revised: June 10, 2010

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), MCS Health Management Options, Inc. (HMO) and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

**Positron Emission Tomography** (PET) is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body. A positron camera (Tomography) is used to produce cross sectional tomographic images which are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2(F-18) Fluoro-D-Glucose (FDG), that is administered intravenously to the patient.

**Computed tomography** (CT) and PET are often combined to provide both metabolic (PET) and anatomic (CT) information during a single imaging procedure. Practice guidelines from professional societies such as the Society of Nuclear Medicine and the American College of Radiology have established FDG-PET/CT use for oncologic imaging in adult and pediatric patients.

**Definitions**

For all uses of PET, excluding Rubidium 82 for perfusion of the heart, myocardial viability and refractory seizures, the following definitions apply:

- **Diagnosis**: PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are generally performed for the purpose of staging, rather than diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare.

- **Staging**: PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging
(computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified.

**NOTE:** The terms “diagnosis” and “staging” were replaced with “Initial Treatment Strategy.” For further information on this new term, refer to Pub. 100-03, NCD Manual, section 220.6.17.


- **Restaging:** PET will be covered for restaging: (1) after the completion of treatment for the purpose of detecting residual disease, (2) for detecting suspected recurrence, or metastasis, (3) to determine the extent of a known recurrence, or (4) if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is to determine the extent of a known recurrence, or if study information is insufficient for the clinical management of the patient. Restaging applies to testing after a course of treatment is completed and is covered subject to the conditions above.

- **Monitoring:** Use of PET to monitor tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated).

**NOTE:** The terms “restaging” and “monitoring” were replaced with “Subsequent Treatment Strategy.” For further information on this new term, refer to Pub. 100-03, NCD Manual, section 220.6.17.


Medical Card System (MCS) is adopting Center of Medicare & Medicaid Services (CMS) two-part coverage framework that replaces its four-part framework of diagnosis, staging, restaging, and monitoring response to treatment categories. This two-part framework differentiates FDG-PET imaging for determining initial antitumor treatment strategy from PET imaging to monitor cancer progression or remission after cancer treatment has begun. This applies to all oncologic conditions.

**INDICATIONS**

I. **MCS coverage of Positron Emission Tomography (PET) for cardiac indications:**


   **Evaluation of Coronary Artery Disease**

   PET scans using rubidium-82 (Rb-82) or N-13 ammonia done at rest or with pharmacological stress are considered medically necessary for noninvasive imaging of the perfusion of the heart for the
diagnosis and management of members with known or suspected coronary artery disease, provided such scans meet either one of the two following criteria:

1. 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

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

II. MCS coverage of Positron Emission Tomography (PET) for Myocardial Viability:

For the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization; and

1. For the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization; and

2. For FDG PET when used as a follow-up to an inconclusive SPECT.

3. If a patient received a FDG PET study with inconclusive results, a follow-up SPECT is not considered necessary.

Note: In the event that a member has received a single photon computed tomography test (SPECT) with inconclusive results, MCS will consider a PET scan to be medically necessary.

III. MCS coverage of Positron Emission Tomography FDG PET for Oncologic Conditions:

1. New Framework differentiates PET into use for:
   A. Initial Anti-Tumor Treatment Strategies (formerly diagnosis and initial staging)
   B. Subsequent Anti-Tumor Treatment Strategies (formerly treatment monitoring and restaging/detection of suspected recurrence)

A. Initial Anti-Tumor Treatment Strategies

MCS will consider one FDG PET Study for members who have solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing when the member 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:

1. To determine whether or not the member is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or,
2. To determine the optimal anatomical location for an invasive procedure; or,

3. To determine the anatomical extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

- **Non-Covered indications to Initial Anti-Tumor Treatment Strategy:**

1. *Diagnosis* of prostate cancer and *initial staging* of newly diagnosed prostate cancer (Adenocarcinoma of the prostate)

2. *Diagnosis* and *initial staging* of axillary nodes of breast cancer (staging of distance metastasis in breast cancer will continue to be covered)

3. *Evaluation* of regional lymph nodes in melanoma (Other uses to determine initial treatment strategy will be covered)

**Note:** Medical Card System, Inc., (MCS) just like The Centers for Medicare & Medicaid Services (CMS) will continue to cover FDG PET imaging a an adjunct test for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging that is negative for extra-pelvic metastasis. All other uses of FDG PET for initial treatment strategy for members diagnosed with cervical cancer will only continue to be covered through coverage with evidence development (CED).

**B. Subsequent Anti-Tumor Treatment Strategies**

MCS will **not** consider FDG PET imaging for *subsequent anti-tumor treatment strategy* for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, thyroid, ovarian cancer, cervical cancer and myeloma.

1. MCS will **cover** a subsequent anti-tumor treatment strategy FDG PET study for all other tumor types **other than the indications noted above, when the members treating physician determines** that the FDG PET study is needed to inform the subsequent anti-tumor treatment strategy and the member is enrolled in, and the FDG PET provider is participating in a type of prospective clinical study (CED). [http://www.cms.hhs.gov/MedicareApprovedFacilities/NOPR/list.asp](http://www.cms.hhs.gov/MedicareApprovedFacilities/NOPR/list.asp)

2. PET (FDG) for *subsequent anti-tumor treatment strategy* is **medically necessary** when it is used if performed:

   1. During a planned course of treatment when a change in treatment is being considered

   2. If performed after completion of treatment:

      - To detect residual disease
      - To detect suspected recurrence
      - To assess extent of known recurrence

3. **NOT** for surveillance of asymptomatic, previously treated patients
NOTE: PET coverage for subsequent treatment strategy evaluation requires participation in this registry. www.pet_registry@phila.acr.org

IV. MCS coverage of FDG PET for Refractory Seizures:  

- For pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.

V. MCS considers FDG PET medically necessary for Characterization of Single Pulmonary Nodules (SPNs) NCD for PET (FDG) for Lung Cancer (220.6.2).mht

- Characterization of Single Pulmonary Nodules (SPNs) the primary purpose of such characterization should be to determine the likelihood of malignancy in order to plan future management and treatment for the patient.

- MCS considers regional FDG PET chest scans, on any FDA-approved scanner, for the characterization of SPNs.

- PET Chest scans for characterizing SPNs should include evidence of the initial detection of a primary lung tumor, usually by a computed tomography (CT). This should include, but is not restricted to, a report on the results of such CT or other detection method, indicating an indeterminate or possibly malignant lesion, not exceeding 4 centimeters (cm) in diameter.

VI. MCS coverage of FDG PET for Dementia and Neurodegenerative Diseases:  

FDG-PET scan is considered reasonable and medically necessary for patients with a recent diagnosis of dementia and documented cognitive decline of at least six months, who meet the diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternative neurodegenerative diseases or causative factors, but the cause of the clinical

- symptoms remains uncertain. If a patient had a diagnosis of Alzheimer’s disease it is not covered.

The following additional conditions must be met before an FDG-PET scan can be ordered:

- The patient's onset, clinical presentation, or course of cognitive impairment is aberrant for AD, and 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;

- The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) 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);

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

- 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 and/or help guide future treatment;

- 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;

- 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 (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 SPECT or FDG-PET scan was performed.


- Evidence is **NOT** sufficient to determine that the results of NaF-18 PET imaging to identify bone metastases improve health outcomes of members with cancer and is not reasonable and necessary **unless** it is to **inform initial antitumor treatment strategy** or to **guide subsequent antitumor treatment strategy** after completion of initial treatment, and then **only** under Coverage with Evidence Development (CED). *(See Appendix A – Clinical studies for which Centers of Medicare & Medicaid Services (CMS) will provide coverage)*
• All other uses and clinical indications of NaF-18 PET are non-covered.

VIII. MCS coverage of FDG PET for Infection and Inflammation is NOT covered because evidence is inadequate to conclude that FDG PET for the conditions below improves health outcomes.


• Chronic Osteomyelitis
• infection of hip arthroplasty, and
• fever of unknown origin improves

LIMITATIONS:

1. PET is not considered a screening test (i.e., testing patients without specific signs and symptoms of disease).
2. Coverage with Evidence (CED) participation will only apply to MCS Classicare line of business.
3. PET coverage for subsequent treatment strategy evaluation requires participation in the NOPR registry.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.

CODING INFORMATION

CPT® Codes

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>78608</td>
<td>Brain imaging, Positron Emission Tomography (PET); metabolic evaluation</td>
</tr>
<tr>
<td>78811</td>
<td>Positron Emission Tomography (PET) imaging; limited area (e.g., chest, head/neck)</td>
</tr>
<tr>
<td>78812</td>
<td>Positron Emission Tomography (PET); skull base to mid-thigh</td>
</tr>
<tr>
<td>78813</td>
<td>Positron Emission Tomography (PET) imaging; whole body</td>
</tr>
<tr>
<td>78814</td>
<td>Positron Emission Tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)</td>
</tr>
<tr>
<td>78815</td>
<td>Positron Emission Tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh</td>
</tr>
<tr>
<td>78816</td>
<td>Positron Emission Tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body</td>
</tr>
<tr>
<td>78459</td>
<td>Myocardial Imaging, Positron Emission Tomography (PET), Metabolic Evaluation</td>
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</table>
**Medical Policy Department**  
**Clinical Affairs Division**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>78491</td>
<td>Myocardial Imaging, Positron Emission Tomography (PET), Perfusion; Single Study at REST or STRESS</td>
</tr>
<tr>
<td>78492</td>
<td>Myocardial Imaging, Positron Emission Tomography (PET), Perfusion; Multiple Studies at REST and/or STRESS</td>
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**Tracers Codes Required for PET Scans**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9555</td>
<td>Rubidium RB-82, Diagnostic, Per Study Dose, up to 60 millicuries</td>
</tr>
<tr>
<td>A9526</td>
<td>Nitrogen N-13 Ammonia, Diagnostic, Per Study Dose, up to 40 millicuries</td>
</tr>
</tbody>
</table>

The above tracer codes are applicable only to CPT 78491 and 78492. They cannot be reported with any other code.

The following tracer codes are applicable only to CPT 78459, 78608, 78811-78816. They cannot be reported with any other code:

<table>
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<tr>
<th>HCPCS Codes</th>
<th>DESCRIPTION</th>
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</thead>
<tbody>
<tr>
<td>A9552</td>
<td>Fluorodeoxyglucose F18, FDG, Diagnostic, Per study dose, Up to 45 Millicuries</td>
</tr>
<tr>
<td>A9580</td>
<td>Sodium Fluoride F-18, Diagnostic, per study dose, up to 30 Millicuries</td>
</tr>
</tbody>
</table>

**Note:** Effective for claims with dates of service on and after February 26, 2010, MCS Classicare shall pay for NaF-18 PET oncologic claims to inform of initial treatment strategy (PI) or subsequent treatment strategy (PS) for suspected or biopsy proven bone metastasis ONLY in the context of a clinical study and as specified in Pub. 100-03, section 220.6 of the CMS Manual. All other claims for NaF-18 PET oncology claims remain non-covered.

**MODIFIERS**

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<thead>
<tr>
<th>MODIFIERS</th>
<th>DESCRIPTION</th>
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<tr>
<td>PI</td>
<td>Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing. Short descriptor: PET tumor init. Tx strat.</td>
</tr>
<tr>
<td>PS</td>
<td>Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary’s treating physician determines that the PET study is needed to inform subsequent antitumor strategy. Short descriptor: PET tumor subsq. Tx strategy.</td>
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<tr>
<td>Q0</td>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study. (For claims approved for Coverage under Evidence Development (CED)</td>
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### ICD-9 CM® Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9 CM® CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td><strong>Myocardial Viability</strong></td>
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<tr>
<td>411.0</td>
<td>Post myocardial Infarction Syndrome</td>
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<tr>
<td>411.81</td>
<td>Acute Coronary Occlusion without myocardial infarction</td>
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<tr>
<td>412</td>
<td>Old myocardial infarction</td>
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<td>413.1</td>
<td>Prinzmetal angina</td>
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<tr>
<td>414.00</td>
<td>Coronary Atherosclerosis of unspecified type vessel Native or Graft</td>
</tr>
<tr>
<td>414.01</td>
<td>Coronary Atherosclerosis of Native Coronary Artery</td>
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<tr>
<td>414.02</td>
<td>Coronary Atherosclerosis of Autologous Vein Bypass Graft</td>
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<tr>
<td>414.03</td>
<td>Coronary Atherosclerosis of Non-Autologous Biological Bypass Graft</td>
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<tr>
<td>414.06</td>
<td>Coronary Atherosclerosis of Native Coronary Artery of Transplanted Heart</td>
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<tr>
<td>414.07</td>
<td>Coronary Atherosclerosis of Bypass Graft (Artery) (Vein)of Transplanted Heart</td>
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<tr>
<td>414.10</td>
<td>Aneurysm of Heart (Wall)</td>
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<tr>
<td>414.11</td>
<td>Aneurysm of Coronary Vessels</td>
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<td>414.12</td>
<td>Dissection of Coronary Artery</td>
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<td>414.19</td>
<td>Other Aneurysm of Heart</td>
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<td>414.3</td>
<td>Coronary Atherosclerosis due to Lipid Rich Plaque</td>
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<td>414.8</td>
<td>Other specified forms of Chronic Ischemic Heart Disease</td>
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<td>426.2</td>
<td>Left Bundle Branch Hemiblock</td>
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<td>426.3</td>
<td>Other Left Bundle Branch Hemiblock</td>
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<tr>
<td>426.4</td>
<td>Right Bundle Branch Block</td>
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<td>426.50-426.54</td>
<td>Bundle Branch Block Unspecified-Trifascicular Block</td>
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<tr>
<td>426.6</td>
<td>Other Heart Block</td>
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<td>427.31</td>
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<td>Left Heart Failure</td>
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<td>428.20-428.23</td>
<td>Unspecified Systolic Heart Failure-Acute or Chronic Systolic Heart Failure</td>
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<td>428.30-428.33</td>
<td>Unspecified Diastolic Heart Failure-Acute or Chronic Systolic Heart Failure</td>
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<td>428.40-428.43</td>
<td>Unspecified Combined Systolic and Diastolic Heart Failure-Acute or Chronic Combined Systolic and Diastolic Heart Failure</td>
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<td>428.9</td>
<td>Heart Failure Unspecified</td>
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<td><strong>Refractory Seizure</strong></td>
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<tr>
<td>345.11</td>
<td>Generalized nonconvulsive epilepsy with intractable epilepsy</td>
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<tr>
<td>345.41</td>
<td>Localization related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures with intractable epilepsy</td>
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<tr>
<td>345.51</td>
<td>Localization related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures with intractable epilepsy</td>
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<td>345.61</td>
<td>Infantile spasms with intractable epilepsy</td>
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<td>345.71</td>
<td>Epilepsia partialis continua with intractable epilepsy</td>
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<td>Other forms of epilepsy and recurrent seizures with intractable epilepsy</td>
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<td>Code</td>
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<tr>
<td>345.91</td>
<td>Epilepsy, unspecified with intractable epilepsy</td>
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<tr>
<td>780.39</td>
<td>Other convulsions</td>
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<tr>
<td>780.93</td>
<td>Memory loss</td>
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**Dementia, Alzheimer’s disease, Fronto-temporal dementia**

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<tbody>
<tr>
<td>290.0</td>
<td>Senile dementia, uncomplicated</td>
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<tr>
<td>290.10</td>
<td>Presenile dementia, uncomplicated</td>
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<td>290.13</td>
<td>Presenile dementia with depressive features</td>
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<td>290.20</td>
<td>Senile dementia with delusional features</td>
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<td>290.21</td>
<td>Senile dementia with depressive features</td>
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<tr>
<td>290.3</td>
<td>Senile dementia with delirium</td>
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<td>331.0</td>
<td>Alzheimer’s disease</td>
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<td>331.11</td>
<td>Pick’s disease</td>
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<td>331.19</td>
<td>Other frontotemporal dementia</td>
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<td>331.2</td>
<td>Senile degeneration of brain</td>
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<td>331.9</td>
<td>Cerebral degeneration unspecified</td>
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**Colorectal**

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>153.0-153.9</td>
<td>Malignant neoplasm of colon</td>
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<tr>
<td>154.0-154.3</td>
<td>Malignant neoplasm of rectum, rectosigmoid junction, and anus</td>
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<tr>
<td>154.8</td>
<td>Other</td>
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**Esophagus**

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<tr>
<td>150.0-150.5</td>
<td>Malignant neoplasm of esophagus</td>
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<td>150.8</td>
<td>Other specified parts</td>
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<td>150.9</td>
<td>Esophagus, unspecified</td>
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**Head & Neck (not Thyroid, CNS)**

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<tr>
<td>140.0-140.6</td>
<td>Other sites of lip</td>
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<td>140.8</td>
<td>Lip, unspecified, vermilion border</td>
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<td>141.0-141.6</td>
<td>Malignant neoplasm of the tongue</td>
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<tr>
<td>141.8</td>
<td>Other sites of the tongue</td>
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<tr>
<td>141.9</td>
<td>Tongue, unspecified</td>
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<td>142.0-142.2</td>
<td>Malignant neoplasm of major salivary glands</td>
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<td>142.8</td>
<td>Other major salivary glands</td>
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<td>142.9</td>
<td>Salivary glands, unspecified</td>
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<td>143.0-143.1</td>
<td>Malignant neoplasm of gum</td>
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<tr>
<td>143.8</td>
<td>Other sites of gum</td>
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<tr>
<td>144.9</td>
<td>Floor of mouth, part unspecified</td>
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<tr>
<td>145.0-145.6</td>
<td>Malignant neoplasm of others and unspecified part of the mouth</td>
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<tr>
<td>145.8</td>
<td>Other specified parts of the mouth</td>
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<td>145.9</td>
<td>Mouth, unspecified</td>
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<tr>
<td>146.0-146.9</td>
<td>Malignant neoplasm of oropharynx</td>
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<tr>
<td>147.0-147.3</td>
<td>Malignant neoplasm of nasopharynx</td>
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<td>Code</td>
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<td>147.8</td>
<td>Other specified sites of nasopharynx</td>
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<td>147.9</td>
<td>Nasopharynx, unspecified</td>
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<tr>
<td>148.0-148.3</td>
<td>Malignant neoplasm of hypopharynx</td>
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<td>148.8</td>
<td>Other specified sites of hypopharynx</td>
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<td>148.9</td>
<td>Hypopharynx, unspecified</td>
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<tr>
<td>149.0-149.1</td>
<td>Malignant neoplasm of other and ill defined sites within the lip, oral cavity, and pharynx</td>
</tr>
<tr>
<td>149.8</td>
<td>Other</td>
</tr>
<tr>
<td>149.9</td>
<td>Ill-defined</td>
</tr>
<tr>
<td>160.0-160.5</td>
<td>Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses</td>
</tr>
<tr>
<td>160.8</td>
<td>Other</td>
</tr>
<tr>
<td>160.9</td>
<td>Accessory sinus, unspecified</td>
</tr>
<tr>
<td>161.0-161.3</td>
<td>Malignant neoplasm of larynx</td>
</tr>
<tr>
<td>161.8</td>
<td>Other specified sites of larynx</td>
</tr>
<tr>
<td>161.9</td>
<td>Larynx, unspecified</td>
</tr>
<tr>
<td>195.0</td>
<td>Malignant neoplasm of other and ill defined sites; head, face, and neck</td>
</tr>
</tbody>
</table>

**Lymphoma**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>200.0-200.88</td>
<td>Lymphosarcoma and reticulosarcoma and other specified malignant tumors of lymphatic tissue</td>
</tr>
<tr>
<td>201.00-201.98</td>
<td>Hodgkin’s disease</td>
</tr>
<tr>
<td>202.00-202.38</td>
<td>Other malignant neoplasms of lymphoid and histiocytic tissue</td>
</tr>
<tr>
<td>202.50-202.98</td>
<td>Letterer-Siwe Disease</td>
</tr>
</tbody>
</table>

**Non-Small Cell Lung**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>162.0-162.5</td>
<td>Malignant neoplasm of trachea, bronchus, and lung</td>
</tr>
<tr>
<td>162.8</td>
<td>Other parts of bronchus or lung</td>
</tr>
<tr>
<td>162.9</td>
<td>Bronchus and lung, unspecified</td>
</tr>
<tr>
<td>518.89</td>
<td>Other diseases of lung, not elsewhere classified</td>
</tr>
</tbody>
</table>

**Ovary**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>183.0-183.9</td>
<td>Malignant neoplasm of ovary and other uterine adnexa</td>
</tr>
</tbody>
</table>

**Brain**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>191.0-191.9</td>
<td>Malignant neoplasm of brain</td>
</tr>
</tbody>
</table>

**Cervix**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>180.0-180.1</td>
<td>Malignant neoplasm of cervix uteri</td>
</tr>
<tr>
<td>180.8</td>
<td>Other specified sites of cervix</td>
</tr>
<tr>
<td>180.9</td>
<td>Cervix, uteri, unspecified</td>
</tr>
</tbody>
</table>

**Small Cell Lung**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>162.0-162.5</td>
<td>Malignant neoplasm of trachea, bronchus and lung</td>
</tr>
<tr>
<td>162.8</td>
<td>Other parts of bronchus or lung</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>162.9</td>
<td>Bronchus and lung, unspecified</td>
</tr>
<tr>
<td>518.89</td>
<td>Other diseases of lung, not elsewhere classified</td>
</tr>
</tbody>
</table>

**Soft Tissue Sarcoma**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>171.0-171.9</td>
<td>Malignant neoplasm of connective and other soft tissue</td>
</tr>
<tr>
<td>176.0-176.5</td>
<td>Kaposi’s sarcoma</td>
</tr>
<tr>
<td>176.8</td>
<td>Other specified sites</td>
</tr>
<tr>
<td>176.9</td>
<td>Unspecified</td>
</tr>
</tbody>
</table>

**Pancreas**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>157.0-157.4</td>
<td>Malignant neoplasm of pancreas</td>
</tr>
<tr>
<td>157.8</td>
<td>Other specified sites of pancreas</td>
</tr>
<tr>
<td>157.9</td>
<td>Pancreas, part unspecified</td>
</tr>
</tbody>
</table>

**Testes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>186.0</td>
<td>Malignant neoplasm of testis</td>
</tr>
<tr>
<td>186.9</td>
<td>Other and unspecified testis</td>
</tr>
</tbody>
</table>

**Breast (female and male)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>174.0-174.6</td>
<td>Malignant neoplasm of female breast</td>
</tr>
<tr>
<td>174.8</td>
<td>Other specified sites of female breast</td>
</tr>
<tr>
<td>174.9</td>
<td>Breast (female), unspecified</td>
</tr>
<tr>
<td>175.0</td>
<td>Malignant neoplasm of male breast</td>
</tr>
<tr>
<td>175.9</td>
<td>Other and unspecified sites of male breast</td>
</tr>
</tbody>
</table>

**Melanoma**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>172.0-172.9</td>
<td>Malignant melanoma of skin</td>
</tr>
</tbody>
</table>

**Prostate (non cover)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>185 (CED)</td>
<td>Malignant neoplasm of prostate</td>
</tr>
</tbody>
</table>

**Thyroid**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>193</td>
<td>Malignant neoplasm of thyroid gland</td>
</tr>
</tbody>
</table>

**Myeloma**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>203.00-203.12</td>
<td>Multiple myeloma and immunoproliferative neoplasms</td>
</tr>
</tbody>
</table>

**All other Solid Tumors**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>151.0-151.9</td>
<td>Malignant neoplasm of stomach</td>
</tr>
<tr>
<td>152.0-152.9</td>
<td>Malignant neoplasm of small intestine, including duodenum</td>
</tr>
<tr>
<td>155.0-155.2</td>
<td>Malignant neoplasm of liver and intrahepatic bile ducts</td>
</tr>
</tbody>
</table>

Medical technology is constantly changing and we reserves the right to review and update our policies periodically.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>156.0-156.9</td>
<td>Malignant neoplasm of gallbladder and extrahepatic bile duct</td>
</tr>
<tr>
<td>158.0-158.9</td>
<td>Malignant neoplasm of retroperitoneum and peritoneum</td>
</tr>
<tr>
<td>159.0-159.9</td>
<td>Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum</td>
</tr>
<tr>
<td>163.0-163.9</td>
<td>Malignant neoplasm of pleura</td>
</tr>
<tr>
<td>164.0-164.9</td>
<td>Malignant neoplasm of thymus, heart, and mediastinum</td>
</tr>
<tr>
<td>165.0-165.9</td>
<td>Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs</td>
</tr>
<tr>
<td>170.0-170.9</td>
<td>Malignant neoplasm of bone and articular cartilage</td>
</tr>
<tr>
<td>171.0-171.9</td>
<td>Malignant neoplasm of connective and other soft tissues</td>
</tr>
<tr>
<td>173.0-173.9</td>
<td>Other malignant neoplasm of skin</td>
</tr>
<tr>
<td>179</td>
<td>Malignant neoplasm of uterus, part unspecified</td>
</tr>
<tr>
<td>181</td>
<td>Malignant neoplasm of placenta</td>
</tr>
<tr>
<td>182.0-182.8</td>
<td>Malignant neoplasm of body of uterus</td>
</tr>
<tr>
<td>184.0-184.9</td>
<td>Malignant neoplasm of other and unspecified female genital organs</td>
</tr>
<tr>
<td>187.1-187.9</td>
<td>Malignant neoplasm of penis and other male genital organs</td>
</tr>
<tr>
<td>188.0-188.9</td>
<td>Malignant neoplasm of bladder</td>
</tr>
<tr>
<td>189.0-189.9</td>
<td>Malignant neoplasm of kidney and other and unspecified urinary organs</td>
</tr>
<tr>
<td>190.0-190.9</td>
<td>Malignant neoplasm of eye</td>
</tr>
<tr>
<td>192.0-192.9</td>
<td>Malignant neoplasm of other and unspecified parts of nervous system</td>
</tr>
<tr>
<td>194.0-194.9</td>
<td>Malignant neoplasm of endocrine glands and related structures</td>
</tr>
<tr>
<td>195.1-195.8</td>
<td>Malignant neoplasm of other and ill-defined sites</td>
</tr>
<tr>
<td>199.0-199.2</td>
<td>Malignant neoplasm without specification of site</td>
</tr>
<tr>
<td>209.00-209.36</td>
<td>Neuroendocrine tumors</td>
</tr>
<tr>
<td>209.70-209.79</td>
<td>Secondary neuroendocrine tumors</td>
</tr>
<tr>
<td>202.40-202.48</td>
<td>Other malignant neoplasms of lymphoid and histocytic tissue</td>
</tr>
<tr>
<td>203.80-203.82</td>
<td>Multiple myeloma and immunoproliferative neoplasms</td>
</tr>
<tr>
<td>204.00-204.92</td>
<td>Lymphoid leukemia</td>
</tr>
<tr>
<td>205.00-205.92</td>
<td>Myeloid leukemia</td>
</tr>
<tr>
<td>206.00-206.92</td>
<td>Monocytic leukemia</td>
</tr>
<tr>
<td>207.00-207.82</td>
<td>Other specified leukemia</td>
</tr>
<tr>
<td>208.00-208.92</td>
<td>Leukemia of unspecified cell type</td>
</tr>
</tbody>
</table>

All other cancers not listed herein (CED)

### ICD-9 CM® for FDG PET Scans for Oncological Conditions

<table>
<thead>
<tr>
<th>Tumor Type</th>
<th>Initial Treatment Strategy (formerly &quot;diagnosis&quot; &amp; &quot;staging&quot;)</th>
<th>Subsequent Treatment Strategy (formerly &quot;restaging&quot; &amp; &quot;monitoring response to treatment&quot;)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PI modifier</td>
<td>PS modifier</td>
</tr>
<tr>
<td>Colorectal</td>
<td><strong>Cover (PI) – diagnosis codes: 153.0-153.9, 154.0-154.3, 154.8</strong></td>
<td><strong>Cover (PS) – diagnosis codes: 153.0-153.9, 154.0-154.3, 154.8</strong></td>
</tr>
<tr>
<td>Esophagus</td>
<td><strong>Cover (PI) – diagnosis codes: 150.0-150.5, 150.8, 150.9</strong></td>
<td><strong>Cover (PS) – diagnosis codes: 150.0-150.5, 150.8-150.9</strong></td>
</tr>
<tr>
<td>Head &amp; Neck (not Thyroid, CNS)</td>
<td><strong>Cover (PI) – diagnosis codes: 140.0-140.6, 140.8-140.9, 141.0-141.6, 141.8, 142.0-142.2, 142.8, 142.9, 143.0-143.1, 143.8, 143.9, 144.0-144.1, 144.8, 144.9, 145.0-145.6, 145.8, 145.9, 146.0-146.9, 147.0-147.3, 147.8, 147.9, 148.0-148.3, 148.8, 148.9, 149.0-149.1, 149.8, 149.9, 160.0-160.5, 160.8, 160.9, 161.0-161.3, 161.8, 161.9, 195.0</strong></td>
<td><strong>Cover (PS) – diagnosis codes: 140.0-140.6, 140.8-140.9, 141.0-141.6, 141.8, 142.0-142.2, 142.8, 142.9, 143.0-143.1, 143.8, 143.9, 144.0-144.1, 144.8, 144.9, 145.0-145.6, 145.8, 145.9, 146.0-146.9, 147.0-147.3, 147.8, 147.9, 148.0-148.3, 148.8, 148.9, 149.0-149.1, 149.8, 149.9, 160.0-160.5, 160.8, 160.9, 161.0-161.3, 161.8, 161.9, 195.0</strong></td>
</tr>
<tr>
<td>Lymphoma</td>
<td><strong>Cover (PI) – diagnosis codes: 200.00-200.88, 201.00-201.98, 202.00-202.38, 202.50-202.98</strong></td>
<td><strong>Cover (PS) – diagnosis codes: 200.00-200.88, 201.00-201.98, 202.00-202.38, 202.50-202.98</strong></td>
</tr>
<tr>
<td>Non-Small Cell Lung</td>
<td><strong>Cover (PI) – diagnosis codes: 162.0-162.5, 162.8, 162.9, 518.89</strong></td>
<td><strong>Cover (PS) – diagnosis codes: 162.0-162.5, 162.8, 162.9</strong></td>
</tr>
<tr>
<td>Ovary</td>
<td><strong>Cover (PI) – diagnosis codes: 183.0-183.9</strong></td>
<td><strong>Cover (PS) – diagnosis codes: 183.0-183.9</strong></td>
</tr>
<tr>
<td>Brain</td>
<td><strong>Cover (PI) – diagnosis codes: 191.0-191.9</strong></td>
<td><strong>CED (PSQ0) – diagnosis codes: 191.0-191.9</strong></td>
</tr>
<tr>
<td>Cervix</td>
<td><em><em>Cover w/exception</em> (PI) - diagnosis codes: 180.0-180.1, 180.8, 180.9</em>*</td>
<td><strong>Cover (PS) - diagnosis codes: 180.0-180.1, 180.8, 180.9</strong></td>
</tr>
<tr>
<td>Small Cell Lung</td>
<td><strong>Cover (PI) – diagnosis codes: 162.0-162.5, 162.8, 162.9, 518.89</strong></td>
<td><strong>CED (PSQ0) – diagnosis codes: 162.0-162.5, 162.8, 162.9</strong></td>
</tr>
<tr>
<td>Soft Tissue Sarcoma</td>
<td><strong>Cover (PI) – diagnosis codes: 171.0-171.9, 176.0-176.5, 176.8, 176.9</strong></td>
<td><strong>CED (PSQ0) – diagnosis codes: 171.0-171.9, 176.0-176.5, 176.8, 176.9</strong></td>
</tr>
<tr>
<td>Testes</td>
<td><strong>Cover (PI) – diagnosis codes: 186.0, 186.9</strong></td>
<td><strong>CED (PSQ0) – diagnosis codes: 186.0, 186.9</strong></td>
</tr>
<tr>
<td>Breast (female and male)</td>
<td><em><em>Cover w/exception</em> (PI) - diagnosis codes: 174.0-174.6, 174.8, 174.9, 175.0, 175.9</em>*</td>
<td><strong>Cover – (PS) diagnosis codes: 174.0-174.6, 174.8, 174.9, 175.0, 175.9</strong></td>
</tr>
<tr>
<td>Melanoma</td>
<td><em><em>Cover w/exception</em> (PI) - diagnosis codes: 172.0-172.9</em>*</td>
<td><strong>Cover (PS) - diagnosis codes: 172.0-172.9</strong></td>
</tr>
<tr>
<td>Prostate</td>
<td><strong>Non-Cover</strong></td>
<td><strong>CED (PSQ0) – diagnosis code: 185</strong></td>
</tr>
<tr>
<td>Thyroid</td>
<td><strong>Cover – (PI) diagnosis codes: 193</strong></td>
<td><em><em>Cover w/exception or CED</em> (PS or PSQ0) - diagnosis codes: 193</em>*</td>
</tr>
<tr>
<td>Myeloma</td>
<td><strong>Cover – (PI) diagnosis codes: 203.00-203.12</strong></td>
<td><strong>Cover – (PS) diagnosis codes: 203.00-203.12</strong></td>
</tr>
</tbody>
</table>
### Table 1: FDG PET Coverage for Solid Tumors and Myeloma

<table>
<thead>
<tr>
<th>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>Colorectal</td>
<td>cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Esophagus</td>
<td>cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Head &amp; Neck (not thyroid or CNS)</td>
<td>cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Non-small cell lung</td>
<td>cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Ovary</td>
<td>cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Brain</td>
<td>cover</td>
<td>CED</td>
</tr>
<tr>
<td>Cervix</td>
<td><strong>Cover with exception</strong>*</td>
<td>Cover</td>
</tr>
<tr>
<td>Small Cell Lung</td>
<td>cover</td>
<td>CED</td>
</tr>
<tr>
<td>Soft Tissue Sarcoma</td>
<td>cover</td>
<td>CED</td>
</tr>
<tr>
<td>Pancreas</td>
<td>cover</td>
<td>CED</td>
</tr>
<tr>
<td>Testes</td>
<td>cover</td>
<td>CED</td>
</tr>
<tr>
<td>Breast (Male and Female)</td>
<td><strong>Cover with exception</strong>*</td>
<td>Cover</td>
</tr>
<tr>
<td>Melanoma</td>
<td><strong>Cover with exception</strong>*</td>
<td>Cover</td>
</tr>
<tr>
<td>Prostate</td>
<td><strong>Non-Cover</strong></td>
<td>CED</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Cover</td>
<td><strong>Cover with exception</strong>*</td>
</tr>
<tr>
<td>All other solid tumors</td>
<td>Cover</td>
<td>CED</td>
</tr>
<tr>
<td>Myeloma</td>
<td>Cover</td>
<td>CED</td>
</tr>
<tr>
<td>All other cancers not listed</td>
<td>Cover</td>
<td>CED</td>
</tr>
</tbody>
</table>

**Cervix:** Non-covered for the initial diagnosis of cervical cancer related to initial treatment strategy. All other indications for initial treatment strategy are covered.

**Breast:** Non-covered for initial diagnosis and/or staging of axillary lymph nodes. Covered for initial staging of metastatic disease. All other indications for initial treatment are covered.

**Melanoma:** Non-covered for initial staging of regional lymph nodes. All other indications for initial treatment strategy are covered.

**Thyroid:** Covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radiiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other indications for subsequent treatment strategy are CED.
Cancers and indications that are reimbursable by Medicare are NOT eligible for entry in the National Oncologic PET Registry (NOPR). Cancers and indications that are specifically excluded for Medicare reimbursement are also not eligible for entry in the NOPR. [www.cancerpetregistry.org/indications.htm](http://www.cancerpetregistry.org/indications.htm)

- **C** = covered – Not eligible for entry in the NOPR
- **NC** = non-covered nationally – Not eligible for entry in the NOPR
- **NOPR** = covered only with entry in the NOPR

### Table 2: Cancers and Indications Eligible for Entry in the NOPR

<table>
<thead>
<tr>
<th>INDICATIONS</th>
<th>INITIAL TREATMENT STRATEGY (formerly Diagnosis and initial Staging)</th>
<th>Subsequent Treatment Strategy (includes Treatment Monitoring, Restaging and Detection of Suspected Recurrence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lip, oral cavity, and pharynx (140-149)</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Esophagus (150)</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Stomach (151)</td>
<td>C</td>
<td>NOPR</td>
</tr>
<tr>
<td>Small intestine (152) (For carcinoid, see Neuroendocrine tumor below)</td>
<td>C</td>
<td>NOPR</td>
</tr>
<tr>
<td>Colon (153) and rectum (154)</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Anus (154) (Considered distinct from rectum; see footnote 1)</td>
<td>C</td>
<td>NOPR</td>
</tr>
<tr>
<td>Liver and intrahepatic bile ducts (155)</td>
<td>C</td>
<td>NOPR</td>
</tr>
<tr>
<td>Gallbladder and extrahepatic bile ducts (156)</td>
<td>C</td>
<td>NOPR</td>
</tr>
<tr>
<td>Pancreas (157)</td>
<td>C</td>
<td>NOPR</td>
</tr>
<tr>
<td>Retroperitoneum and peritoneum (158)</td>
<td>C</td>
<td>NOPR</td>
</tr>
<tr>
<td>Nasal cavity, ear, and sinuses (160)</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Larynx (161)</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Lung, non-small cell (162)</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Lung, small cell (162)</td>
<td>C</td>
<td>NOPR</td>
</tr>
<tr>
<td>Pleura (163)</td>
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<tr>
<td>Thymus, heart, mediastinum (164)</td>
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<td>Bone/cartilage (170)</td>
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<td>Connective/other soft tissue (171)</td>
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<tr>
<td>Melanoma of skin (172) (Nasopharyngeal, ocular and vulvar/vaginal melanomas are coded)</td>
<td>C/NC²</td>
<td>C</td>
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<tr>
<td>Condition</td>
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<tr>
<td>based on those anatomic locations; PET not covered for regional nodal staging—see footnote 2)</td>
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<tr>
<td>Non-melanoma skin (173)</td>
<td>C</td>
<td>C/N^2,3</td>
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<td>Female breast (174) (PET not covered for diagnosis of breast masses or for axillary nodal staging—see footnotes 2 and 3)</td>
<td>C</td>
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<tr>
<td>Male breast (175) (PET not covered for diagnosis of breast masses or for axillary nodal staging—see footnotes 2 and 3)</td>
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<td>C/N^2,3</td>
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<td>Kaposi's sarcoma (176)</td>
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<td>Uterus, unspecified (179)</td>
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<td>Cervix (180) (PET not covered for diagnosis of cervical cancer—see footnote 4)</td>
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<td>Placenta (181)</td>
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<td>Uterus, body (182)</td>
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<td>Ovary (183.0)</td>
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<td>Uterine adnexa (183.2-183.9)</td>
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<td>C/N^4</td>
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<tr>
<td>Other and unspecified female genitalia (184) (Includes vulvar/vaginal melanoma)</td>
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<td>C/N^4</td>
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<tr>
<td>Prostate (185)</td>
<td>NC</td>
<td>C/N^4</td>
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<tr>
<td>Testis (186)</td>
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<td>C/N^4</td>
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<td>Penis and other male genitalia (187)</td>
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<td>C/N^4</td>
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<tr>
<td>Bladder (188)</td>
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<td>C/N^4</td>
</tr>
<tr>
<td>Kidney and other urinary tract (189)</td>
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<td>Eye (190) (Includes ocular melanoma)</td>
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<td>Primary Brain (191)</td>
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<td>Other and unspecified nervous system (192)</td>
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<td>Thyroid (193) (Covered for subsequent treatment strategy only if specific requirements met—see footnote 5;</td>
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<td>Other endocrine glands and related structures (194)</td>
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<td>Metastatic cancer / cancer of unknown primary origin (196-199)</td>
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<td>Myeloma (203)</td>
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<td>Neuroendocrine tumor (209)</td>
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<td>All other solid tumors</td>
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<tr>
<td>All other cancers not listed herein</td>
<td>NOPR</td>
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**FOOTNOTES**

1 Some Medicare contractors include anal cancer in their local coverage of “colorectal cancer”; for PET facilities served by those carriers, PET for subsequent treatment evaluation of anal cancer would be a covered indication.

2 PET is non-covered for initial staging of axillary lymph nodes in patients with breast cancer and of regional lymph nodes in patients with melanoma, but is covered for detection of distant metastatic disease in high-risk patients with breast cancer or melanoma.

3 PET is non-covered for “diagnosis” of breast cancer to evaluate a suspicious breast mass. However, PET is covered for initial treatment strategy evaluation of a patient with axillary nodal metastasis of unknown primary origin or in a patient with a paraneoplastic syndrome potentially caused by an occult breast cancer.

4 PET is non-covered for diagnosis of cervical cancer, but is covered for initial staging of cervical cancer.

5 To qualify as a covered indication for subsequent treatment strategy evaluation, thyroid cancer must be of follicular cell origin and been previously treated by thyroidectomy and radiiodine ablation and the patient must have a serum thyroglobulin > 10 ng/mL and a negative whole-body I-131 scan. Patients who do not qualify for this covered indication (e.g., because the tumor is of other than follicular cell origin, the thyroglobulin is not elevated, or I-131 whole-body imaging was not performed or is positive) can be entered on NOPR.

**IMPORTANT NOTES**

- The scientific evidence concerning the clinical utility of FDG-PET is generally less robust for cancers and indications that are currently covered by Medicare only in the NOPR than for cancers and indications that are currently covered without the requirement for clinical data submission to the NOPR. For this reason, Medicare has conditioned coverage of FDG-PET under the NOPR on the collection of clinical data. These data will be used to help determine the clinical utility of FDG-PET for ClinicalTrials.gov Identifier NCT00868582 Version: November 30, 2009 (Page last revised November 30, 2009)

Conditionally covered cancers and indications. The billing physician remains responsible for documenting medical necessity, which is required for the coding and billing of both covered and NOPR-eligible PET studies. Eligibility for the NOPR does not constitute a clinical management recommendation for the use of PET for the conditionally covered cancers and indications, by either the Medicare program or NOPR investigators. Referring and interpreting physicians are thus advised to refer to the published literature to better understand the potential limitations of FDG-PET for NOPR-eligible uses.
The research study design is appropriate to answer the research question being studied. Therefore, does the addition of NaF-18 PET and/or FDG PET study imaging lead to:

- A change in patient management to more appropriate palliative care; or
- A change in patient management to more appropriate curative care; or
- Improved quality of life; or
- Improved survival?

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.

b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56.
g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the www.ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

CMS PET Scans Index: http://www.cms.gov/mcd/index_list.asp?list_type=ncd
I. PET Scans (220.6) at:
http://www.cms.gov/mcd/viewncd.asp?ncd_id=220.6&ncd_version=4&basket=ncd%3A220%2E6%3A4%3APositron+Emission+Tomography+%28PET%29+%28SPECT%29

II. NCD for Single Photon Emission Computed Tomography (SPECT) (220.12)

III. PET for Perfusion of the Heart (220.6.1) at:

IV. FDG PET for Dementia and Neurodegenerative Diseases (220.6.13) at:

V. FDG PET for Infection and Inflammation (220.6.16) at:

VI. Positron Emission Tomography (FDG) for Oncologic Conditions (220.6.17) at:

VII. FDG PET for Myocardial Viability (220.6.8) at:

VIII. FDG PET for Refractory Seizures (220.6.9) at:

IX. PET (NaF-18) to Identify Bone Metastasis of cancer (220.6.19) at:

REFERENCES


POLICY HISTORY

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<td>October 1, 2005</td>
<td>Origination</td>
<td>Policy revised to conform with the changes established by Center for Medicare &amp; Medicaid Services (CMS) dated April 3, 2009; whereas, CMS’s NCD applies to PET scans used to support initial diagnosis and subsequent treatment strategies for breast, cervical, colorectal, esophageal, head and neck, lymphoma, melanoma, non-small lung, and thyroid tumors. CMS expanded PET coverage for subsequent follow-up imaging for cervical cancer, ovarian cancer or myeloma. All other cancers, PET coverage for subsequent treatment strategy evaluation still requires participation in an approved coverage with evidence development (CED) program. Initial Treatment strategy was formerly “diagnosis” and “staging” and Subsequent Treatment strategy was formerly “restaging and “monitoring” response to treatment when a change in treatment is anticipated.</td>
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<tr>
<td>April 28, 2008</td>
<td>Yearly Review</td>
<td>Policy revised to add more detailed explanation of coverage and have all</td>
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<tr>
<td>August 27, 2009</td>
<td>Revised</td>
<td>Policy revised to conform with the changes established by Center for Medicare &amp; Medicaid Services (CMS) dated April 3, 2009; whereas, CMS’s NCD applies to PET scans used to support initial diagnosis and subsequent treatment strategies for breast, cervical, colorectal, esophageal, head and neck, lymphoma, melanoma, non-small lung, and thyroid tumors. CMS expanded PET coverage for subsequent follow-up imaging for cervical cancer, ovarian cancer or myeloma. All other cancers, PET coverage for subsequent treatment strategy evaluation still requires participation in an approved coverage with evidence development (CED) program. Initial Treatment strategy was formerly “diagnosis” and “staging” and Subsequent Treatment strategy was formerly “restaging and “monitoring” response to treatment when a change in treatment is anticipated.</td>
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<td>June 10, 2010</td>
<td>Revised</td>
<td>Policy revised to conform with the changes established by Center for Medicare &amp; Medicaid Services (CMS) dated April 3, 2009; whereas, CMS’s NCD applies to PET scans used to support initial diagnosis and subsequent treatment strategies for breast, cervical, colorectal, esophageal, head and neck, lymphoma, melanoma, non-small lung, and thyroid tumors. CMS expanded PET coverage for subsequent follow-up imaging for cervical cancer, ovarian cancer or myeloma. All other cancers, PET coverage for subsequent treatment strategy evaluation still requires participation in an approved coverage with evidence development (CED) program. Initial Treatment strategy was formerly “diagnosis” and “staging” and Subsequent Treatment strategy was formerly “restaging and “monitoring” response to treatment when a change in treatment is anticipated.</td>
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of PET Studies in one policy.

New to the policy under the indication section is the addition of Positron Emission Tomography with NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer.

New tables added to the policy:
- Table 1: FDG PET Coverage for Solid Tumors and Myeloma updated showing the new changes in coverage and CED.
- Table 2: Cancers and Indications Eligible for Entry in the NOPR
- Table with ICD-9 CM® for FDG PET Scans for Oncological Conditions
- APPENDIX A- CLINICAL STUDIES FOR WHICH CMS WILL PROVIDE COVERAGE

Modifiers added to the policy: PI, PS and QO.

New Tracer code added to the policy:

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<tr>
<td>A9580</td>
<td>Sodium Fluoride F-18, Diagnostic, per study dose, up to 30 Mil</td>
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<td>September 15, 2010</td>
<td>Spot review</td>
<td>Section: B. Subsequent Anti-tumor Treatment Strategies Page 4, Should now read MCS will not consider FDG PET imaging for subsequent anti-tumor treatment strategy for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non small cell lung, thyroid, ovarian cancer, cervical cancer and myeloma. Deletion: “and all other cancers not listed herein, unless the FDG PET is provided under Coverage with Evidence Development (CED) (See Table 1&amp;2).”</td>
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<td>September 29, 2011</td>
<td>Yearly Review</td>
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Medical Policy Department
Clinical Affairs Division

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