

## Coverage Summary

### Positron Emission Tomography (PET)/Combined PET-CT (Computed Tomography)

<b>Policy Number:</b> P-003	<b>Products:</b> UnitedHealthcare Medicare Advantage Plans	<b>Original Approval Date:</b> 04/02/2007
<b>Approved by:</b> UnitedHealthcare Medicare Benefit Interpretation Committee		<b>Last Review Date:</b> 11/17/2015
<b>Related Medicare Advantage Policy Guideline:</b> <a href="#">PET Scan</a>		

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*The benefit information in this Coverage Summary is based on existing national coverage policy, however Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.*

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#### **I. COVERAGE**

**Coverage Statement:** PET (FDG) and/or combined PET-CT scans are covered when determined to be medically necessary and specific criteria are met.

**Guidelines/Notes:**

**1. Positron Emission Tomography (PET)**

FDG (2-[F18] fluoro-2-deoxy-D-glucose) Positron Emission Tomography (PET) is a minimally-invasive diagnostic imaging procedure used to evaluate glucose metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. FDG is an injected radionuclide (or radiopharmaceutical) that emits sub-atomic particles, known as positrons, as it decays. FDG PET uses a positron camera (tomograph) to measure the decay of FDG. The rate of FDG decay provides biochemical information on glucose metabolism in the tissue being studied. As malignancies can cause abnormalities of metabolism and blood flow, FDG PET evaluation may indicate the probable presence or absence of a malignancy based upon observed differences in biologic activity compared to adjacent tissues.

The Centers for Medicare and Medicaid Services (CMS) was asked by the National Oncologic PET Registry (NOPR) to reconsider section 220.6 of the National Coverage Determinations (NCD) Manual to end the prospective data collection requirements under Coverage with Evidence Development (CED) across all oncologic indications of FDG PET imaging. The CMS received public input indicating that the current coverage framework of prospective data collection under CED be ended for all oncologic uses of FDG PET imaging.

**Positron Emission Tomography (PET) is covered for specific indications when coverage criteria are met. Refer to the following National Coverage Determinations (NCDs) for specific coverage criteria:**

- a. [NCD for Positron Emission Tomography \(FDG\) for Oncologic Conditions \(220.6.17\)](#) (Accessed November 12, 2015)

1) **Framework**

**Effective for claims with dates of service on and after June 11, 2013**, CMS adopted a coverage framework that ends the prospective data collection requirements by the National Oncologic PET Registry (NOPR) under coverage with evidence development (CED) for all oncologic uses of FDG PET imaging. CMS is making this change for all NCDs that address coverage of FDG PET for oncologic uses addressed in this decision. This decision does not change coverage for any use of PET imaging using radiopharmaceuticals NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium-82 (Rb-82).

Refer to the June 11, 2013 CMS [Decision Memo for Positron Emission Tomography \(FDG\) for Solid Tumors \(CAG-00181R4\)](#). (Accessed November 13, 2015)

Also refer to [NCD for Positron Emission Tomography \(FDG\) for Oncologic Conditions \(220.6.17\)](#). (Accessed November 13, 2015)

2) **Initial Anti-Tumor Treatment Strategy**

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 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.

See [Attachment A - National FDG PET Coverage for Oncologic Conditions](#) for the summary of the national FDG PET coverage for oncologic conditions effective June 11, 2013.

Refer to the June 11, 2013 CMS [Decision Memo for Positron Emission Tomography \(FDG\) for Solid Tumors \(CAG-00181R4\)](#). (Accessed November 13, 2015)

Also refer to [NCD for Positron Emission Tomography \(FDG\) for Oncologic Conditions \(220.6.17\)](#). (Accessed November 13, 2015)

**a. Initial Anti-Tumor Treatment Strategy Nationally Covered Indications**

1. 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.
2. 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.
3. 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.

**b. Initial Anti-Tumor Treatment Strategy Nationally Non-Covered Indications**

1. CMS continues to nationally non-cover initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate.
2. CMS continues to nationally non-cover FDG PET imaging for diagnosis of breast cancer and initial staging of axillary nodes.
3. CMS continues to nationally non-cover FDG PET imaging for initial anti-tumor treatment strategy for the evaluation of regional lymph nodes in melanoma.
4. CMS continues to nationally non-cover FDG PET imaging for the diagnosis of cervical cancer related to initial anti-tumor treatment strategy.

**3) Subsequent 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.

Refer to the June 11, 2013 CMS [Decision Memo for Positron Emission Tomography \(FDG\) for Solid Tumors \(CAG-00181R4\)](#). (Accessed November 13, 2015)

See [Attachment A - National FDG PET Coverage for Oncologic Conditions](#) for the summary of the national FDG PET coverage for oncologic conditions effective June 11, 2013

Also refer to [NCD for Positron Emission Tomography \(FDG\) for Oncologic Conditions \(220.6.17\)](#). (Accessed November 13, 2015)

#### 4) Synopsis of Coverage of FDG PET for Oncologic Conditions

See [Attachment A - National FDG PET Coverage for Oncologic Conditions](#) for the summary of the national FDG PET coverage for oncologic conditions effective June 11, 2013.

Refer to the June 11, 2013 CMS [Decision Memo for Positron Emission Tomography \(FDG\) for Solid Tumors \(CAG-00181R4\)](#). (Accessed November 13, 2015)

Also refer to [NCD for Positron Emission Tomography \(FDG\) for Oncologic Conditions \(220.6.17\)](#). (Accessed November 13, 2015)

**Note: Health Plan Note for Surveillance PET Scans:** For most cancer cases, PET is not covered as a screening test (i.e., testing patients without specific signs and symptoms of disease) and thus is not covered for surveillance of patients treated for cancer in whom there is no clinical reason to suspect recurrent disease. However, some cases may require additional review for medical necessity.

b. [NCD for PET for Perfusion of the Heart \(220.6.1\)](#) (Accessed November 13, 2015)

c. [NCD for FDG PET for Dementia and Neurodegenerative Diseases \(220.6.13\)](#) (Accessed November 13, 2015)

The list of Medicare approved clinical trials is available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/FDG-PET-and-Other-Neuroimaging-Devices-for-Dementia.html>. (Accessed November 13, 2015)

For payment rules for NCDs requiring CED, see the [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

d. [NCD for FDG PET for Infection and Inflammation \(220.6.16\)](#) (Accessed November 13, 2015)

e. [NCD for FDG PET for Myocardial Viability \(220.6.8\)](#) (Accessed November 13, 2015)

f. [NCD for FDG PET for Refractory Seizures \(220.6.9\)](#) (Accessed November 13, 2015)

g. [NCD for Positron Emission Tomography \(NaF-18\) to Identify Bone Metastasis of Cancer \(220.6.19\)](#). (Accessed November 13, 2015)

The list of Medicare approved clinical trials is available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/NaF-18-PET-for-Bone-Metastasis.html>. (Accessed November 13, 2015)

For payment rules for NCDs requiring CED, see the [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

Also see the MLN Matters December 1, 2014)Article #MM6861, February 24, 2011 at <http://www.cms.gov/MLNMattersArticles/downloads/MM6861.pdf>. (Accessed November 13, 2015)

## 2. Combined PET (FDG)-CT

The term FDG refers to 2-deoxy-2-[F-18] fluoro-D-glucose, also known as F-18 fluorodeoxyglucose. The term FDG PET refers to positron emission tomography or to a positron

emission tomogram, depending on context. FDG PET refers to PET imaging utilizing FDG as the radioactive tracer. The term FDG PET includes the use of combined or integrated positron emission tomography/computed tomography using FDG as the radioactive tracer (FDG PET/CT).

*See Section II Background of the CMS [Decision Memo for PET for Initial Treatment Strategy in Solid Tumors and Myeloma \(CAG-00181R3\)](#). (Accessed November 13, 2015)*

### 3. **Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease**

On September 27, 2013, CMS has determined that the evidence is insufficient to conclude that the use of positron emission tomography (PET) amyloid-beta (A $\beta$ ) imaging is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member for Medicare beneficiaries with dementia or neurodegenerative disease, and thus PET A $\beta$  imaging is not covered under §1862(a) (1) (A) of the Social Security Act (“the Act”).

However, there is sufficient evidence that the use of PET A $\beta$  imaging is promising in two scenarios: (1) to exclude Alzheimer’s disease (AD) in narrowly defined and clinically difficult differential diagnoses, such as AD versus frontotemporal dementia (FTD); and (2) to enrich clinical trials seeking better treatments or prevention strategies for AD, by allowing for selection of patients on the basis of biological as well as clinical and epidemiological factors.

Therefore, one PET A $\beta$  scan per patient will be covered through coverage with evidence development (CED), under §1862(a)(1)(E) of the Act, in clinical studies that meet the criteria as outlined in the [NCD for Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease \(220.6.20\)](#) (Accessed November 13, 2015)

*The list of Medicare approved clinical trials is available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.html>. (Accessed November 13, 2015)*

*For payment rules for NCDs requiring CED, [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).*

## II. DEFINITIONS

## III. REFERENCES

National Comprehensive Cancer Network (NCCN). Available at <http://www.nccn.org/>. (Accessed November 13, 2015)

National Oncologic PET Registry (NOPR). Available at [http://www.cancerpetregistry.org/indications\\_facilities.htm](http://www.cancerpetregistry.org/indications_facilities.htm). (Accessed November 13, 2015)

## IV. REVISION HISTORY

11/17/2015 Annual review with no updates.

- 04/21/2015 Guideline #1.c (FDG PET for Dementia and Neurodegenerative Diseases)
- Added reference link to the list of Medicare approved clinical trials.
  - Added reference link to the *Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials* for payment rules for NCDs requiring CED.

Guideline 1.g [Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer]

- Added reference link to the list of Medicare approved clinical trials.
- Added reference link to the *Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials* for payment rules for NCDs requiring CED.

Guideline #3 (Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease)

- Updated the reference information pertaining to the list of Medicare approved clinical trials.
- Added payment information pertaining to NCDs requiring CED.

12/16/2014 Annual review with the following updates:

Guideline 3 (Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease)

- Added reference link to the *NCD for Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease (220.6.20)*
- Updated the reference link to the list of CMS approved clinical trials/clinical research studies

Definitions – removed the definition of Positron Emission Tomography (PET); already defined in Section I

05/20/2014 Guidelines #1 Positron Emission Tomography (PET) - Updated coverage language to align with the updated [NCD for Positron Emission Tomography \(FDG\) for Oncologic Conditions \(220.6.17\)](#). (Version #4; dated 03/17/2014)

12/17/2013 Annual review with no updates.

10/24/2013 Guideline #3 Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease - added applicable guidelines based on the CMS [Decision Memo for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease \(CAG-00431N\)](#). Also added reference links to the CMS approved clinical trials/clinical research studies website and the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

06/24/2013 Updated to include the following changes based on the June 11, 2013 CMS [Decision Memo for Positron Emission Tomography \(FDG\) for Solid Tumors \(CAG-00181R4\)](#):

CMS ended the requirement for coverage with evidence development (CED) for 18F fluorodeoxyglucose positron emission tomography (FDG PET) for oncologic indications which are contained in section 220.6.17 of the Medicare National Coverage Determinations Manual. This removes the requirement for prospective data collection by the National Oncologic PET Registry (NOPR) for those cancers or cancer types that had been covered under CED.

CMS has determined that three FDG PET scans are covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anticancer therapy. Coverage of any additional FDG PET scans (that is, beyond three) used to guide subsequent management of antitumor treatment strategy after completion

of initial anti-tumor therapy will be determined by local Medicare Administrative Contractors. Also added the note “For regions where there are no available Local Coverage Determinations for guidance, refer to nationally recognized guidelines, i.e., MCG™ Care Guidelines.”

- 12/17/2012 Annual review with no updates.
- 04/23/2012 Updated to include the note regarding the coverage for surveillance PET Scans.
- 12/19/2011 Annual review with no updates.
- 04/01/2011 Updated policy to include the note regarding the change in the UHC Medicare reimbursement policy for PET scans performed at NOPR facilities for CED trials. Note approved at the March 28, 2012 UMBIC Preliminary meeting for immediate distribution and posting.
- 02/21/2011 Updated Guidelines # 2 (Combined PET (FDG)-CT) to clarify the coverage of combined PET-CT.
- 10/21/2010 Updated to include the CMS updates effective August 4, 2010 based on the Decision Memo for PET for Initial Treatment Strategy in Solid Tumors and Myeloma (CAG-00181R3).

## V. ATTACHMENT(S)

Attachment A - National FDG PET Coverage for Oncologic Conditions (Effective on or after June 11, 2013)		
FDG PET for Cancers Tumor Type	Initial Treatment Strategy (formerly “diagnosis” & “staging”)	Subsequent Treatment Strategy (formerly “restaging” and “monitoring response to treatment”)
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head and Neck (not thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	Cover
Cervix	Cover with exceptions*	Cover
Small cell lung	Cover	Cover
Soft tissue sarcoma	Cover	Cover
Pancreas	Cover	Cover
Testes	Cover	Cover
Prostate	<b>Non-cover</b>	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions*	Cover

**Attachment A - National FDG PET Coverage for Oncologic Conditions**

(Effective on or after June 11, 2013)

<b>FDG PET for Cancers Tumor Type</b>	<b>Initial Treatment Strategy (formerly “diagnosis” &amp; “staging”)</b>	<b>Subsequent Treatment Strategy (formerly “restaging” and “monitoring response to treatment”)</b>
Melanoma	Cover with exceptions*	Cover
All other solid tumors	Cover	Cover
Myeloma	Cover	Cover
All other cancers not listed	Cover	Cover

\*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.