

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

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[Instructions for Use](#)

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Related Medicare Advantage Policy Guideline

- [Positron Emission Tomography \(PET\) Scan \(Including NCDs 220.6-220.6.20\)](#)

Coverage Guidelines

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

Positron Emission Tomography (PET) – General Information

Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolism in normal tissues as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. A radiopharmaceutical is injected into the patient that gives off sub-atomic particles, known as positrons, as it decays. PET uses a positron camera (tomograph) to measure the decay of the radiopharmaceutical. The rate of decay provides biochemical information to on the metabolism of the tissue being studied.

Effective for dates of service on or after March 7, 2013, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their Food and Drug Administration (FDA) approved labeled indications for oncologic imaging.

We emphasize each of the following points:

- Changing the 'restrictive' language of prior PET decisions will not by itself suffice to expand Medicare coverage to new PET radiopharmaceuticals.
- The scope of this change extends only to FDA-approved indications for oncologic uses of PET tracers.
- This change does not include screening uses of PET scanning.

Refer to the [National Coverage Determination \(NCD\) for Positron Emission Tomography \(PET\) Scans \(220.6\)](#).
(Accessed November 9, 2020)

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies are required where applicable. These policies are available at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>.

Positron Emission Tomography (PET) (FDG) for Oncologic Conditions

Positron emission tomography (PET)(FDG) for oncologic conditions may be covered when criteria are met.

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.

Refer to the [NCD for Positron Emission Tomography \(FDG\) for Oncologic Conditions \(220.6.17\)](#) (Accessed November 9, 2020)

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).

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.

Therefore, CMS continues to nationally cover one FDG PET study for member's who have cancers that are biopsy proven or strongly suspected based on other diagnostic testing when the member'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 the member 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.

Initial Anti-Tumor Treatment Strategy Nationally Covered Indications

- 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.
- 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.
- 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

- 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 diagnosis of breast cancer and initial staging of axillary nodes.
- 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.

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

Refer to table for [National FDG PET Coverage for Oncologic Conditions](#) for the summary of the national FDG PET coverage for oncologic conditions effective June 11, 2013.

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.

Positron Emission Tomography (PET) for Other Specific Indications

PET for other specific conditions may be covered when criteria are met. Refer to the following National Coverage Determinations (NCDs):

- [NCD for PET for Perfusion of the Heart \(220.6.1\)](#). (Accessed November 10, 2020)
- [NCD for FDG PET for Dementia and Neurodegenerative Diseases \(220.6.13\)](#). (Accessed November 10, 2020)
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 10, 2020)
For payment rules for NCDs requiring CED, refer to the Coverage Summary titled [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).
- [NCD for FDG PET for Myocardial Viability \(220.6.8\)](#). (Accessed November 10, 2020)
- [NCD for FDG PET for Refractory Seizures \(220.6.9\)](#). (Accessed November 10, 2020)
- [NCD for Positron Emission Tomography \(NaF-18\) to Identify Bone Metastasis of Cancer \(220.6.19\)](#). (Accessed November 10, 2020)

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 10, 2020)

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

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 β) 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 β 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 β 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 β 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 10, 2020)

The list of Medicare approved clinical trials is available at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.html>. (Accessed November 10, 2020)

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

References

National Comprehensive Cancer Network (NCCN). Available at <http://www.nccn.org/>. (Accessed November 10, 2020)

National Oncologic PET Registry (NOPR). Available at <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/National-Oncologic-PET-Registry-NOPR.html>. (Accessed November 10, 2020)

Supporting Information

Important Note: When searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the applicable referenced default policy below for coverage guidelines.

National FDG PET Coverage for Oncologic Conditions		
Accessed June 11, 2013		
FDG PET for Cancers Tumor Type	Initial Treatment Strategy (formerly “diagnosis” and “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	Non-covered	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions**	Cover
Melanoma	Cover with exceptions***	Cover
All other solid tumors	Cover	Cover

National FDG PET Coverage for Oncologic Conditions

Accessed June 11, 2013

FDG PET for Cancers Tumor Type	Initial Treatment Strategy (formerly “diagnosis” and “staging”)	Subsequent Treatment Strategy (formerly “restaging” and “monitoring response to treatment”)
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.

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Policy History/Revision Information

Date	Summary of Changes
05/01/2021	Template Update <ul style="list-style-type: none"> Reformatted policy; transferred content to new template
01/19/2021	Positron Emission Tomography (PET) for Other Specific Indications <ul style="list-style-type: none"> Removed reference link to the National Coverage Determination for <i>FDG PET for Infection and Inflammation (220.6.16)</i>

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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.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

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