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FEP Medical Policy Manual

FEP 6.01.67 Oncologic Applications of Positron Emission Tomography Scanning (Brain, Melanoma, Unknown Primary)

Annual Effective Policy Date: October 1, 2024

Original Policy Date: September 2024

Related Policies:

6.01.06 - Miscellaneous (Noncardiac, Nononcologic) Applications of Fluorine 18 Fluorodeoxyglucose Positron Emission Tomography
6.01.20 - Cardiac Applications of Positron Emission Tomography Scanning
6.01.51 - Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment
6.01.62 - Oncologic Applications of Positron Emission Tomography Scanning (Breast and Gynecologic)
6.01.64 - Oncologic Applications of Positron Emission Tomography Scanning (Hematologic)
6.01.65 - Oncologic Applications of Positron Emission Tomography Scanning (Lung)
6.01.66 - Oncologic Applications of Positron Emission Tomography Scanning (Thyroid, Neuroendocrine, Head and Neck)

Oncologic Applications of Positron Emission Tomography Scanning (Brain, Melanoma, Unknown Primary)

Description

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Positron emission tomography (PET) scans are based on the use of positron-emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia, or water. The radionuclide tracers simultaneously emit 2 high-energy photons in opposite directions that can be simultaneously detected (referred to as coincidence detection) by a PET scanner, comprising multiple stationary detectors that encircle the area of interest.

OBJECTIVE

The objective of this evidence review is to examine whether the use of positron emission tomography for the diagnosis, staging and restaging, and/or surveillance of various carcinomas improves the net health outcome in individuals with brain cancer, melanoma, cancer of unknown primary, and single-site metastatic disease.

POLICY STATEMENT

Brain Cancer

PET scanning may be considered **medically necessary** in the staging or restaging of brain cancer.

Melanoma

PET scanning may be considered **medically necessary** as a technique for assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment for advanced disease (stage III or IV).

PET scanning is considered **investigational** in managing stage 0, I, or II melanoma.

PET scanning is considered **investigational** as a technique to detect regional lymph node metastases in individuals with clinically localized melanoma who are candidates to undergo sentinel node biopsy.

Cancer of Unknown Primary

PET scanning may be considered **medically necessary** in individuals with a cancer of unknown primary who meet ALL of the following criteria:

- In individuals with a single site of disease outside the cervical lymph nodes, and
- Individual is considering local or regional treatment for a single site of metastatic disease, and
- After a negative workup for an occult primary tumor, and
- PET scan will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment.

PET scanning is considered **investigational** for other indications in individuals with a cancer of unknown primary, including, but not limited to the following:

- As part of the initial workup of a cancer of unknown primary, and
- As part of the workup of individuals with multiple sites of disease.

Cancer Surveillance

PET scanning is considered **investigational** when used as a surveillance tool for individuals with cancer or with a history of cancer. A scan is considered surveillance if performed more than 6 months after completion of cancer therapy (12 months for lymphoma) in individuals without objective signs or symptoms suggestive of cancer recurrence (see Policy Guidelines section).

POLICY GUIDELINES

Patient Selection

As with any imaging technique, the medical necessity of positron emission tomography (PET) scanning depends in part on what imaging techniques are used before or after the PET scanning. Due to its expense, PET scanning is typically considered after other techniques, such as computed tomography (CT), magnetic resonance imaging (MRI), or ultrasonography, provide inconclusive or discordant results. Thus, PET should be considered for the medically necessary indications above only when standard imaging (eg, CT, MRI) is inconclusive or not indicated.

Patient selection criteria for PET scanning may also be complex. Due to the complicated hierarchy of imaging options in individuals with malignancy and complex patient selection criteria, a possible implementation strategy for this policy is its use for retrospective review, possibly focusing on cases with multiple imaging tests, including PET scans.

Use of PET scanning for surveillance as described in the policy statement and policy rationale refers to the use of PET to detect disease in asymptomatic individuals at various intervals. This is not the same as the use of PET for detecting recurrent disease in symptomatic individuals; these applications of PET are considered within tumor-specific categories in the policy statements.

Coding

A PET scan involves 3 separate activities: (1) manufacture of the radiopharmaceutical, which may be on site or at a regional center with delivery to the institution performing PET; (2) actual performance of the PET scanner; and (3) interpretation of the results. There are Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes available to code for PET scans.

When the radiopharmaceutical is provided by an outside distribution center, there may be an additional separate charge, or this charge may be passed through and included in the hospital bill. In addition, an extra transportation charge will be likely for radiopharmaceuticals that are not manufactured on site.

The Centers for Medicare & Medicaid Services added 2 new modifiers in 2009 to facilitate the changes in the Medicare national coverage policy for PET. The modifiers are:

PI - 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, 1 per cancer diagnosis.

PS - 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 anti-tumor strategy.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A number of radiopharmaceuticals have been granted approval by the FDA, to be used with PET for various cancer-related indications, however none are specific to brain cancer, melanoma, cancer of unknown primary, or single-site metastatic disease. Fluorine-18 fluorodeoxyglucose (FDG) is approved for use in suspected or existing diagnosis of cancer, all types.

RATIONALE

Summary of Evidence

Brain Tumors

For individuals who have diagnosed brain tumors and in need of staging or restaging information or who have suspected brain tumor who receive FDG-PET, ^{18}F fluoro-ethyl-tyrosine PET, or carbon 11 (^{11}C) methionine PET, the evidence includes several systematic reviews and meta-analyses. Relevant outcome is test validity. Pooled analyses have shown that PET or PET/CT can be effective in distinguishing brain tumors from normal tissue. Indirect comparisons between the radiotracers ^{11}C-methionine and FDG have shown that ^{11}C-methionine may have better diagnostic performance. Clinical guidelines include PET to inform management decisions that may offer clinical benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic after completing brain cancer treatment who receive FDG-PET, ^{18}F fluoro-ethyl-tyrosine-PET, or ^{11}C-methionine PET, the evidence includes systematic reviews and meta-analyses. Relevant outcome is test validity. Pooled analyses did not support the use of PET for surveillance of brain cancer following treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Melanoma

For individuals who have suspected or diagnosed stage I or II melanoma and in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes a TEC Assessment. Relevant outcome is test validity. Evidence has shown PET and PET/CT are not as beneficial as the reference standard (sentinel node biopsy) for assessing regional lymph nodes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have diagnosed advanced melanoma (stage III or IV) and in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes a TEC Assessment and a meta-analysis. Relevant outcome is test validity. Evidence has shown PET and PET/CT can detect systemic metastases in individuals with advanced melanoma. Clinical guidelines include PET/CT for staging or restaging stage III or IV disease and for surveillance. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic after completing melanoma treatment who receive FDG-PET or FDG-PET/CT, the evidence includes retrospective and observational studies. Relevant outcome is test validity. At the discretion of the physician, imaging surveillance can be considered every 3 to 12 months. Because recurrences usually occur within 3 years, screening asymptomatic individuals beyond 3 to 5 years is not recommended. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Cancer of Unknown Primary and Single-Site Metastatic Disease

For individuals with cancer of unknown primary and single-site metastatic disease who receive FDG-PET or FDG-PET/CT, the evidence includes a TEC Assessment. Relevant outcome is test validity. Studies reviewed in the assessment showed that PET identified previously undetected metastases confirmed by biopsy. Additionally, PET can contribute to the management of individuals with cancer of unknown primary. Clinical guidelines include PET/CT to inform management decisions that may offer clinical benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Current National Comprehensive Cancer Network, American College of Radiology, and other relevant U.S.-based guidelines are summarized in each section of the Rationale.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Medicare coverage policy on positron emission tomography scans, effective for claims with dates of service on and after June 11, 2013, is summarized in Table 1.[10,]

Table 1. National FDG PET Coverage for Oncologic Conditions

FDG PET for Cancers by Tumor Type	Initial Treatment Strategy (formerly "diagnosis" & "staging")	Subsequent Treatment Strategy (formerly "restaging" & "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-cover**	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions *	Cover
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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2024	New policy- Add to Radiology/Interventional Radiology section	Policy created by separating out brain cancer, melanoma, cancer of unknown primary, and single-site metastatic disease indications from policy 6.01.26. Policy revised with literature review through October 13, 2023. No references added. No changes to policy statements.