FEP Medical Policy Manual

FEP 6.01.26 Oncologic Applications of Positron Emission Tomography Scanning

Effective Date: October 15, 2017

Related Policies:
6.01.06 Miscellaneous (Noncardiac, Nononcologic) Applications of 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

Oncologic Applications of Positron Emission Tomography Scanning

Description
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.

FDA REGULATORY STATUS
The FDA website includes various PET-related documents.

As of June 2016, the following radiopharmaceuticals have been granted FDA-approval, to be used with PET for carcinoma-related indications:
- Carbon-11 choline- Suspected prostate cancer recurrence based on elevated blood PSA after therapy and noninformative bone scintigraphy, CT, or MRI
- Fluorine-18 fluorodeoxyglucose- Suspected or existing diagnosis of cancer, all types
- Fluorine-18 fluciclovine- Suspected prostate cancer recurrence based on elevated blood PSA levels after treatment
- Gallium-68 dotatate- Localization of somatostatin receptor positive NETs in adult and pediatric patients

POLICY STATEMENT
All policy statements apply to both positron emission tomography (PET) scans and PET plus computed tomography (CT) scans, i.e., PET scans with or without PET/CT fusion. For the clinical situations indicated that may be considered medically necessary, this assumes that the results of the PET scan will influence treatment decisions. If the results will not influence treatment decisions, these situations would be considered not medically necessary.
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BONE CANCER
PET scanning may be considered **medically necessary** in the staging or restaging of Ewing sarcoma and osteosarcoma.

PET scanning is considered **not medically necessary** in the staging of chondrosarcoma.

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

BREAST CANCER
PET scanning may be considered **medically necessary** in the staging or restaging of breast cancer for the following application:
- Detecting locoregional or distant recurrence or metastasis (except axillary lymph nodes) when suspicion of disease is high and other imaging is inconclusive

PET scanning is considered **not medically necessary** in the evaluation of breast cancer for all other applications, including but not limited to the following:
- Differential diagnosis in patients with suspicious breast lesions or an indeterminate or low suspicion finding on mammography
- Staging axillary lymph nodes
- Predicting pathologic response to neoadjuvant therapy for locally advanced disease

CERVICAL CANCER
PET scanning may be considered **medically necessary** in the initial staging of patients with locally advanced cervical cancer.

PET scanning may be considered **medically necessary** in the evaluation of known or suspected recurrence.

COLORECTAL CANCER
PET scanning may be considered **medically necessary** as a technique for:
- Staging or restaging to detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer, and
- To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when standard imaging, including CT scan, is negative

PET scanning is considered **not medically necessary** as:
- A technique to assess the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer
- A technique contributing to radiotherapy treatment planning

ENDOMETRIAL CANCER
PET scanning is considered **medically necessary** in the:
- Detection of lymph node metastases, and
- Assessment of endometrial cancer recurrence

ESOPHAGEAL CANCER
PET scanning may be considered **medically necessary** in the
- Staging of esophageal cancer, and
- Determining response to preoperative induction therapy

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PET scanning is considered **not medically necessary** in other aspects of the evaluation of esophageal cancer, including but not limited to the following applications:
- Detection of primary esophageal cancer.

**GASTRIC CANCER**
PET scanning may be considered **medically necessary** in the:
- Initial diagnosis and staging of gastric cancer, and
- Evaluation for recurrent gastric cancer after surgical resection, when other imaging modalities are inconclusive.

**HEAD AND NECK CANCER**
PET scanning may be considered **medically necessary** in the evaluation of head and neck cancer in the:
- Initial diagnosis of suspected cancer,
- Initial staging of disease, and restaging of residual or recurrent disease during follow-up, and
- Evaluation of response to treatment

**LUNG CANCER**
PET scanning may be considered **medically necessary** for any of the following applications:
- Patients with a solitary pulmonary nodule as a single scan technique (not dual-time) to distinguish between benign and malignant disease when prior CT scan and chest x-ray findings are inconclusive or discordant,
- As staging or restaging technique in those with known non-small-cell lung cancer, and
- To determine resectability for patients with a presumed solitary metastatic lesion from lung cancer

PET scanning is considered **not medically necessary** in staging of small-cell lung cancer

**LYMPHOMA, INCLUDING HODGKIN DISEASE**
PET scanning may be considered **medically necessary** as a technique for staging lymphoma either during initial staging or for restaging at follow-up

**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 **not medically necessary** in managing stage 0, I, or II melanoma

PET scanning is considered **not medically necessary** as a technique to detect regional lymph node metastases in patients with clinically localized melanoma who are candidates to undergo sentinel node biopsy

**MULTIPLE MYELOMA**
PET scanning is considered **not medically necessary** in all aspects of managing multiple myeloma

**NEUROENDOCRINE TUMORS**
PET scanning is considered **not medically necessary** in all aspects of managing neuroendocrine tumors

**OVARIAN CANCER**
PET scanning may be considered **medically necessary** in the evaluation of patients with signs and/or symptoms of suspected ovarian cancer recurrence (restaging) when standard imaging, including CT scan, is inconclusive
PET scanning is considered **not medically necessary** in the initial evaluation of known or suspected ovarian cancer in all situations.

**PANCREATIC CANCER**
PET scanning may be considered **medically necessary** in the initial diagnosis and staging of pancreatic cancer when other imaging and biopsy are inconclusive.

PET scanning is considered **not medically necessary** as a technique to evaluate other aspects of pancreatic cancer.

**PENILE CANCER**
PET scanning is considered **not medically necessary** in all aspects of managing penile cancer.

**PROSTATE CANCER**
PET scanning with $^{11}$C-choline may be **medically necessary** for evaluating response to primary treatment in prostate cancer.

PET scanning with $^{68}$Gallium is considered **not medically necessary** in all aspects of managing prostate cancer.

PET scanning for all other indications in known or suspected prostate cancer is considered **not medically necessary**.

**RENAL CELL CARCINOMA**
PET scanning is considered **not medically necessary** in all aspects of managing renal cancer.

**SOFT TISSUE SARCOMA**
PET scanning is considered **not medically necessary** in evaluation of soft tissue sarcoma, including but not limited to the following applications:
- Distinguishing between benign lesions and malignant soft tissue sarcoma,
- Distinguishing between low-grade and high-grade soft tissue sarcoma,
- Detecting locoregional recurrence,
- Detecting distant metastasis, and
- Evaluating response to imatinib and other treatments for gastrointestinal stromal tumors.

**TESTICULAR CANCER**
PET scanning may be considered **medically necessary** in evaluation of residual mass following chemotherapy of stage IIB and III seminomas. (The scan should be completed no sooner than 6 weeks after chemotherapy.)

Except as noted above for seminoma, PET scanning is considered **not medically necessary** in evaluation of testicular cancer, including but not limited to the following applications:
- Initial staging of testicular cancer,
- Distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer, and
- Detection of recurrent disease after treatment of testicular cancer.

**THYROID CANCER**
PET scanning may be considered **medically necessary** in the restaging of patients with differentiated thyroid cancer when thyroglobulin levels are elevated and whole-body iodine-131 imaging is negative.
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PET scanning is considered not medically necessary in the evaluation of known or suspected differentiated or poorly differentiated thyroid cancer in all other situations.

UNKNOWN PRIMARY
PET scanning may be considered medically necessary in patients with an unknown primary who meet ALL of the following criteria:

- In patients with a single site of disease outside the cervical lymph nodes, and
- Patient 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 not medically necessary for other indications in patients with an unknown primary, including, but not limited to the following:

- As part of the initial workup of an unknown primary, and
- As part of the workup of patients with multiple sites of disease.

CANCER SURVEILLANCE
PET scanning is considered not medically necessary when used as a surveillance tool for patients 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 patients 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. In patients with melanoma or lymphoma, PET scanning may be considered an initial imaging technique. If so, the medical necessity of subsequent imaging during the same diagnostic evaluation is unclear. 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 also may be complex. For example, it may be difficult to determine from claims data whether a PET scan in a patient with malignant melanoma is being done primarily to evaluate extranodal disease or regional lymph nodes. Similarly, it may be difficult to determine whether a PET scan in a patient with colorectal cancer is being performed to detect hepatic disease or evaluate local recurrence. Due to the complicated hierarchy of imaging options in patients 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 patients at various intervals. This is not the same as the use of PET for detecting recurrent disease in symptomatic patients; these applications of PET are considered within tumor-specific categories in the policy statements.
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**BENEFIT APPLICATION**

Services, drugs, or supplies that are not medically necessary are not covered (See General Exclusion Section of brochure).

**RATIONALE**

### Summary of Evidence

**Bone Sarcoma**

For individuals who have suspected or diagnosed bone sarcoma and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, the evidence includes systematic reviews and meta-analyses of many studies. Relevant outcomes are test accuracy and test validity. Pooled analyses have shown that PET or PET/CT can effectively diagnose and stage bone cancer. PET or PET/CT has high sensitivities and specificities in detecting metastases in bone and lymph nodes; however, the tests have low sensitivity in detecting lung metastases. Clinical guidelines include PET and CT to inform management decisions that may offer clinical benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are asymptomatic after completing bone sarcoma treatment who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Brain Tumors**

For individuals who have diagnosed brain tumors and in need of staging or restaging information or who have suspected brain cancer or are asymptomatic after completing brain cancer treatment who receive $^{18}$F-FDG-PET, $^{18}$F-FET-PET, or $^{11}$C-methionine PET, the evidence includes several systematic reviews and meta-analyses. Relevant outcomes are test accuracy and 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 $^{18}$F-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 a meaningful improvement in the net health outcome.

**Breast Cancer**

For individuals who have diagnosed breast cancer and inconclusive results from other imaging techniques who receive adjunctive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT for staging or restaging, the evidence includes meta-analyses. Relevant outcomes are test accuracy and test validity. While studies included in the meta-analyses report variability in estimates of sensitivity and specificity, $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT may be helpful in situations in which standard staging results are equivocal or suspicious, particularly in patients with locally advanced or metastatic disease. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected or diagnosed breast cancer and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, the evidence includes a TEC Assessment, several systematic reviews, and meta-analyses. Relevant outcomes are test accuracy and test validity. There is no evidence supporting the use of PET in diagnosing breast cancer. The false-negative rates (5.5%-8.5%) using PET in patients with breast cancer can be considered unacceptable, given that breast biopsy can provide more definitive results. PET/CT may be considered for detection of metastases only when results from other imaging techniques are inconclusive. The evidence is insufficient to determine the effects of the technology on health outcomes.
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For individuals who are asymptomatic after completing breast cancer treatment who receive $^{18}$F-FDG PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Cervical Cancer**

For individuals who have diagnosed cervical cancer and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes an Agency for Healthcare Research and Quality (AHRQ) report and a meta-analysis. Relevant outcomes are test accuracy and test validity. Pooled results show that PET can be used for staging or restaging and for detection of recurrent disease. Clinical guidelines include PET and CT to inform management decisions that may offer clinical benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected cervical cancer or who are asymptomatic after completing cervical cancer treatment who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Colorectal Cancer**

For individuals who have diagnosed colorectal cancer and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes a TEC Assessment and several metaanalyses. Relevant outcomes are test accuracy and test validity. Several pooled analyses evaluating staging or restaging using PET or PET/CT resulted in wide ranges of sensitivities and specificities, from the low 60s to the high 90s. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have suspected colorectal cancer or who are asymptomatic after completing colorectal cancer treatment who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, the evidence includes a TEC Assessment and meta-analysis. Relevant outcomes are test accuracy and test validity. Several pooled analyses evaluating the diagnostic accuracy of PET or PET/CT showed a high sensitivity but low specificity. The evidence for the use of PET or PET/CT does not show a benefit over the use of contrast CT in patients with colorectal cancer. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Endometrial Cancer**

For individuals who have diagnosed endometrial cancer in need of staging or restaging information who are asymptomatic after completing endometrial cancer treatment who receive $^{18}$F-FDG-PET or $^{18}$FPET/CT, the evidence includes a systematic review and meta-analysis. Relevant outcomes are test accuracy and test validity. Pooled estimates from the meta-analysis showed high sensitivities and specificities for $^{18}$F-FDG-PET/CT in detecting lymph node metastases and endometrial cancer recurrence following treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Esophageal Cancer**

For individuals who have diagnosed esophageal cancer and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes several meta-analyses. Relevant outcomes are test accuracy and test validity. Pooled estimates have shown high sensitivities and specificities compared to other diagnostic imaging techniques. Clinical guidelines include PET and CT to inform management decisions that may offer clinical benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
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For individuals who have suspected esophageal cancer or who are asymptomatic after completing esophageal cancer treatment who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, the evidence includes meta-analyses. Relevant outcomes are test accuracy and test validity. Pooled analyses showed adequate sensitivities but low specificities. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Gastric Cancer**

For individuals who have suspected or diagnosed gastric cancer and in need of staging or restaging information, who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes several meta-analyses. Relevant outcomes are test accuracy and test validity. Pooled analyses, with sensitivities and specificities ranging from the high 70s to the high 80s, have shown that PET or PET/CT can inform staging or restaging of patients with gastric cancer. 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 a meaningful improvement in the net health outcome.

For individuals who are asymptomatic after completing gastric cancer treatment who receive $^{18}$F-FDGPET or $^{18}$F-FDG-PET/CT, the evidence includes meta-analyses. Relevant outcomes are test accuracy and test validity. Pooled analyses showed low sensitivities and specificities. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Head and Neck Cancer**

For individuals who have suspected or diagnosed head and neck cancer who need staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes a TEC Assessment and several meta-analyses. Relevant outcomes are test accuracy and test validity. In patients with head and neck cancers, PET and PET/CT are better able to detect local and metastatic disease compared with other imaging techniques. Evidence has also shown that $^{18}$F-FDG-PET/CT may be useful in predicting response to therapy. Two meta-analyses calculated the ability of $^{18}$F-FDG-PET or PET/CT to detect residual or recurrent disease during various stages of treatment and another meta-analysis calculated the ability of positive PET or PET/CT results to predict overall survival and event-free survival. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are asymptomatic after completing head and neck cancer treatment who receive $^{18}$FDG-PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Non-Small-Cell Lung Cancer**

For individuals who have suspected non-small-cell lung cancer and inconclusive results from other imaging techniques or who have diagnosed non-small cell lung cancer and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes several meta-analyses. Relevant outcomes are test accuracy and test validity. Pooled analyses have shown that PET and PET/CT have better diagnostic performance compared with conventional imaging techniques. 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 a meaningful improvement in the net health outcome.

For individuals who have suspected non-small-cell lung cancer or who are asymptomatic after completing non-small-cell lung cancer treatment who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Small-Cell Lung Cancer
For individuals with diagnosed small-cell lung cancer and in need of staging or restaging information who receive $^{18}$FDG-PET or $^{18}$F-PET/CT, the evidence includes a systematic review and a meta-analysis. Relevant outcomes are test accuracy and test validity. While the quality of the studies was considered low, PET and PET/CT can be considered for staging or restaging in patients with small-cell lung cancer. 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 a meaningful improvement in the net health outcome.

For individuals who have suspected small-cell lung cancer or who are asymptomatic after completing small-cell lung cancer treatment who receive $^{18}$FDG-PET or $^{18}$F-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Hodgkin and Non-Hodgkin Lymphoma
For individuals who have suspected or diagnosed Hodgkin and non-Hodgkin lymphoma in need of staging or restaging information who receive $^{18}$FDG-PET or PET/CT, the evidence includes a TEC Assessment and several meta-analyses. Relevant outcomes are test accuracy and test validity. PET and PET/CT have been found to provide useful information in the management of Hodgkin and non-Hodgkin lymphoma. The Deauville 5-point scale was developed based on PET results and can be used for staging and treatment response for patients with lymphoma. 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 a meaningful improvement in the net health outcome.

For individuals who are asymptomatic after completing Hodgkin lymphoma treatment who receive $^{18}$FFDG-PET or $^{18}$F-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Melanoma
For individuals who have suspected or diagnosed stage I or II melanoma and in need of staging or restaging information who receive $^{18}$FDG-PET or $^{18}$F-PET/CT, the evidence includes a TEC Assessment. Relevant outcomes are test accuracy and 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 the effects of the technology on health outcomes.

For individuals who have diagnosed advanced melanoma (stage III or IV) and in need of staging for restaging information who receive $^{18}$FDG-PET or $^{18}$F-PET/CT, the evidence includes a TEC Assessment and a meta-analysis. Relevant outcomes are test accuracy and test validity. Evidence has shown PET and PET/CT can detect systemic metastases in patients 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 a meaningful improvement in the net health outcome.

For individuals who are asymptomatic after completing melanoma treatment who receive $^{18}$FDG-PET or $^{18}$F-PET/CT, the evidence includes retrospective and observational studies. Relevant outcomes are test accuracy and test validity. At the discretion of the physician, imaging surveillance can be considered every 3 to 12 months. Since recurrences usually occur within 3 years, screening asymptomatic patients beyond 3 to 5 years is not recommended. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
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Multiple Myeloma
For individuals who have suspected or diagnosed multiple myeloma in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes 2 systematic reviews. Relevant outcomes are test accuracy and test validity. The evidence did not compare PET or PET/CT with other modalities and, therefore, did not provide comparative effectiveness information. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are asymptomatic after completing multiple myeloma treatment who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Neuroendocrine Tumors
For individuals who have suspected or diagnosed neuroendocrine tumors and in need of staging or restaging information who receive $^{18}$F-FDG-PET, $^{18}$F-PET/CT, $^{68}$Ga-PET, or $^{68}$Ga-PET/CT, the evidence includes 2 meta-analyses. Relevant outcomes are test accuracy and test validity. The evidence did not compare PET, PET/CT, Ga-PET, or Ga-PET/CT with other modalities and, therefore, did not provide comparative effectiveness information. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ovarian Cancer
For individuals who have diagnosed ovarian cancer and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes an AHRQ systematic review and several meta-analyses. Relevant outcomes are test accuracy and test validity. Pooled sensitivities and specificities have supported the use of PET and PET/CT for the detection of recurrent ovarian cancer. 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 a meaningful improvement in the net health outcome.

For individuals who have suspected ovarian cancer or who are asymptomatic after completing ovarian cancer treatment who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Pancreatic Cancer
For individuals who have suspected or diagnosed pancreatic cancer and with inconclusive results from other imaging techniques who receive adjunctive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT for staging or restaging, the evidence includes a TEC Assessment and a systematic review. Relevant outcomes are test accuracy and test validity. The evidence has shown that PET and PET/CT do not have a high enough negative predictive value to surpass current standard decision thresholds. Therefore PET or PET/CT should only be considered if results from standard staging methods are inconclusive. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected or diagnosed pancreatic cancer and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes an AHRQ systematic review, a TEC Assessment, and a meta-analysis published after the review and assessment. Relevant outcomes are test accuracy and test validity. The evidence has shown that PET and PET/CT do not have a high enough negative predictive value to surpass current standard decision thresholds. Therefore PET or PET/CT should only be considered if results from standard staging methods are inconclusive. The evidence is insufficient to determine the effects of the technology on health outcomes.

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For individuals who are asymptomatic after completing pancreatic cancer treatment who receive $^{18}$F-FDG PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Penile Cancer**
For individuals who have suspected or diagnosed penile cancer and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes a systematic review and a meta-analysis. Relevant outcomes are test accuracy and test validity. The evidence has shown that PET had a low sensitivity, and no comparisons were made with other modalities. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are asymptomatic after completing penile cancer treatment who receive $^{18}$F-FDG-PET or $^{18}$F-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Prostate Cancer**
For individuals who have suspected or diagnosed prostate cancer and in need of staging or restaging information who receive $^{11}$C-choline PET or $^{11}$C-choline PET/CT, evidence includes several meta-analyses. Relevant outcomes are test accuracy and test validity. Meta-analyses have reported that the choice of radiotracer affects the sensitivity and specificity of the scans, with most evidence showing that the use of $^{11}$C-choline results in the highest sensitivities and specificities compared with $^{18}$F-FDG-PET and $^{11}$C-acetate. Of interest is a single study that investigated the use of PET/CT results to inform patient decisions on radiotherapy treatment plans. The study reported that 40% of the patients altered the extent of the treatment planned based on the PET/CT results. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome. For individuals who are asymptomatic after completing prostate cancer treatment who receive $^{11}$C-choline PET or $^{11}$C-choline PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have suspected or diagnosed prostate cancer and in need of staging or restaging information who receive $^{68}$Ga-PET or $^{68}$Ga-PET/CT, the evidence includes a meta-analysis of small single-institution studies. Relevant outcomes are test accuracy and test validity. The evidence was limited, resulting in estimates with large confidence intervals. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Renal Cell Carcinoma**
For individuals who are diagnosed renal cell carcinoma and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes a systematic review and meta-analysis. Relevant outcomes are test accuracy and test validity. The review concluded that PET has potential to detect metastatic or recurrent lesions in patients with renal cell cancer, but that additional prospective studies are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Soft Tissue Sarcoma**
For individuals who have diagnosed soft tissue sarcoma and in need of staging or restaging information who receive $^{18}$F-FDG-PET or $^{18}$F-PET/CT, the evidence includes an AHRQ systematic review. Another systematic review evaluated PET for assessing response to imatinib. Relevant outcomes are test accuracy and test validity. The review reported that PET had low diagnostic accuracy and there was a lack of studies comparing PET with alternative diagnostic modalities. The evidence is insufficient to determine the effects of the technology on health outcomes.
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For individuals with diagnosed soft tissue sarcoma and in need of rapid reading of activity following imatinib treatment who receive \(^{18}\text{F}\)-FDG-PET or \(^{18}\text{F}\)-PET/CT, the evidence includes a systematic review. Relevant outcomes are test accuracy and test validity. The review concluded that PET/CT can be used to monitor treatment response to imatinib, which can lead to individually adapted treatment strategies. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with soft tissue sarcoma or who are asymptomatic after completing soft tissue sarcoma treatment who receive \(^{18}\text{F}\)-FDG-PET or \(^{18}\text{F}\)-FDG-PET/CT, the evidence includes a systematic review. Relevant outcomes are test accuracy and test validity. The review concluded that there was insufficient evidence on the use of PET for detection of loco-regional recurrence. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Testicular Cancer**

For individuals with diagnosed testicular cancer in need of staging or restaging information who receive \(^{18}\text{F}\)-FDG-PET or \(^{18}\text{F}\)-PET/CT, the evidence includes an AHRQ systematic review and assessment. Relevant outcomes are test accuracy and test validity. Results have shown that PET or PET/CT can evaluate residual masses following chemotherapy for seminoma. Clinical guidelines include PET/CT to inform management decisions that may offer clinical benefit. There is no evidence supporting the use of PET or PET/CT in nonseminoma patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected testicular cancer or who are asymptomatic after completing testicular cancer treatment who receive \(^{18}\text{F}\)-FDG-PET or \(^{18}\text{F}\)-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Thyroid Cancer**

For individuals with diagnosed thyroid cancer and in need of staging or restaging information who receive \(^{18}\text{F}\)-FDG-PET or \(^{18}\text{F}\)-PET/CT, the evidence includes systematic reviews and meta-analyses. Relevant outcomes are test accuracy and test validity. Pooled analyses have shown that PET or PET/CT can effectively detect recurrent differentiated thyroid cancer. 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 a meaningful improvement in the net health outcome.

For individuals who have suspected thyroid cancer or who are asymptomatic after completing thyroid cancer treatment who receive \(^{18}\text{F}\)-FDG-PET or \(^{18}\text{F}\)-FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Unknown Primary and Single-Site Metastatic Disease**

For individuals with unknown primary and single-site metastatic disease who receive \(^{18}\text{F}\)-FDG-PET or \(^{18}\text{F}\)PET/CT, the evidence includes a TEC Assessment. Relevant outcomes are test accuracy and test validity. Studies reviewed in the Assessment showed that PET identified previously undetected metastases confirmed by biopsy. PET can contribute to the management of patients with 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 a meaningful improvement in the net health outcome.

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SUPPLEMENTAL INFORMATION

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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95. Adams HJ, Nievelstein RA, Kwee TC. Outcome of Hodgkin lymphoma patients with a posttreatment $^{18}$F-Fluoro-2-Deoxy-d-Glucose positron emission tomography (FDG-PET)-negative residual mass: systematic review and meta-analysis. Pediatr Hematol Oncol. 2015; 32(8):515-524. PMID 26561044

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POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>New</td>
<td>Policy updated with literature review. References 22-35 added, Policy statements revised with NMN added to breast cancer, colorectal cancer, soft tissue sarcomas and thyroid cancer. Thyroid cancer revised to include both differentiated and poorly differentiated disease, Prostate cancer moved to section on Other Oncologic Applications, also added to this section, are diagnosis of brain tumors, restaging of gastric cancer, staging of multiple myeloma, evaluation of neuroendocrine tumors and staging of inguinal lymph nodes in patients with squamous cell carcinoma of the penis.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Revise Policy</td>
<td>Policy was revised with literature search adding references 37-40, 42-75. PET for gastric cancer as medically necessary for initial work up and staging and for evaluation of recurrent gastric cancer when other imaging modalities are inconclusive.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Revise Policy</td>
<td>Policy revised with literature review; references 1, 42-43, 46, 48-50, 58, 62, 72, 77, 84, and 87 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>Policy revised with literature review through March 23, 2017; references 37,41, 48-50, 59-63, 67, 69-70, 73, 76-80, 85, 94-98, 103, 109-110, 112, 115,119-120, and 126 added. Additional details added to policy statements. The following statements were changed to medically necessary: staging or restaging of brain cancer; evaluation of response to treatment in head and neck cancer; and testing with 11C-choline for evaluating response to primary treatment in prostate cancer. Two additional indications were added.</td>
</tr>
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