Effective for dates of service on or after April 1, 2013, refer to: https://www.bcbsal.org/providers/policies/careCore.cfm

**Name of Policy:**
**Positron Emission Tomography (PET)-Oncologic Applications**

Policy #: 040  
Latest Review Date: February 2013  
Category: Radiology  
Policy Grade: A

**Background/Definitions:**
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

**Medical Necessity** means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Positron emission tomography (PET) scan has many established roles in oncology. Another potential use of PET scanning is early in the course of treatment to assess treatment response, with the intent of altering therapy if the PET scan shows inadequate response.

Positron Emission Tomography (PET) scanning is a highly specialized, non-invasive imaging procedure that is used for measuring the concentrations of positron-emitting radioisotopes within the tissue of living subjects. Radioactive tracers are used to detect active tumor tissue. The radionuclide tracers simultaneously emit two high-energy photons in opposite directions that can be simultaneously detected (referred to as coincidence detection) by a PET scanner, consisting of multiple stationary detectors that encircle the area of interest.

PET scanning differs from CT or MRI scans because it provides information regarding the function of an area of the body rather than just taking an image of it. PET produces cross-sectional images of tumors digesting glucose, providing information on the level of biological activity in a tumor or lesion.

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. A variety of tracers are used for PET scanning, including oxygen-15, nitrogen-13, carbon-11, and fluorine-18. Because of their short half-life, tracers must be made locally, the majority requiring an on-site cyclotron. The radiotracer most commonly used in oncology imaging has been fluorine-18 coupled with fluorodeoxyglucose (FDG), which has a metabolism related to glucose metabolism. FDG has been considered potentially useful in cancer imaging, since tumor cells show increased metabolism of glucose. The most common malignancies studied have been melanoma, lymphoma, lung, colorectal, and pancreatic cancer.

Sodium Fluoride F-18(NaF-18), an early bone scintigraphy agent, has reentered mainstream clinical imaging with the present generations of stand-alone PET and PET/CT hybrid scanners. NaF-18 is a positron-emitting bone-seeking agent, the uptake of which reflects blood flow and remodeling of bone. NaF-18 PET is a highly sensitive imaging modality for detection of benign and malignant osseous abnormalities and is also sensitive for detection of lytic and early marrow-based metastases, by identifying their accompanying reactive osteoblastic changes, even when minimal. Current clinical trials are re-evaluating the use of NaF-18 in light of the technological advances in PET/CT, which have brought unprecedented improvements in the resolution, sensitivity and efficiency of PET, along with integrated multislice CT.

For this policy, PET scanning is discussed for the following 4 applications in oncology.

*Diagnosis:* Diagnosis refers to use of PET as part of the testing used in establishing whether or not a patient has cancer.

*Staging:* This refers to use of PET to determine the stage (extent) of the cancer at the time of diagnosis, before any treatment is given. Imaging at this time is generally to determine whether or not the cancer is localized. This may also be referred to as initial staging.
Restaging: This refers to imaging following treatment in 2 situations. Restaging is part of the evaluation of a patient in whom a disease recurrence is suspected based on signs and/or symptoms. Restaging also includes determining the extent of malignancy following completion of a full course of treatment.

Surveillance: This refers to use of imaging in asymptomatic patients (patients without objective signs or symptoms of recurrent disease). This imaging is completed 6 months or more (12 months or more for lymphoma) following completion of treatment.

Important Note:
This policy only addresses the use of radiotracers detected with the use of dedicated PET scanners. Radiotracers such as FDG may be detected using SPECT cameras, a technique that may be referred to as FDG-single-photon emission computerized tomography (SPECT) imaging.

Policy:
Effective for dates of service on or after April 1, 2013, refer to: https://www.bcbsal.org/providers/policies/careCore.cfm

Effective for dates of service on or after May 15, 2012 through March 31, 2013:
This policy applies to positron emission tomography (PET) scans and PET/computed tomography (CT) scans, i.e., PET scans with or without PET/CT.

KNOWN DIAGNOSIS OF MALIGNANCY
PET scanning for patients with known diagnosis of malignancy (other than the diagnoses listed below) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the following criteria are met:

- To determine optimal anatomic site for biopsy or other invasive diagnostic procedure; or
- Staging and restaging (see Key Points):
  - When standard diagnostic imaging work up (US, CT, MRI) is inconclusive – these imaging reports must be submitted with the request for a PET scan; or
  - Replace conventional imaging when conventional imaging will be inadequate for accurate staging and clinical management will depend upon the stage of disease; or
  - Restaging after completion of therapy to detect residual disease, recurrence, and extent of recurrence.

Routine monitoring of tumor response during treatment (when no change in therapy is planned) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Repeat PET scanning more frequently that every six months, except the indications listed in key points or for specific diagnoses does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.
Request for suspected recurrence should include changes in the clinical status, i.e., new symptoms and/or elevated tumor markers or other laboratory changes, of the patient.

PET scanning for screening and detection of oncology conditions does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Bone Cancer:
- PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in the staging of Ewing sarcoma and osteosarcoma when the results of the PET scan are anticipated to influence treatment decisions.
- PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in the staging of Ewing sarcoma and osteosarcoma when the results of the PET scan are not anticipated to influence treatment decisions.
- PET scanning does not meet and is considered investigational in the staging of chondrosarcoma.

Breast Cancer:
- PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in the staging and restaging of breast cancer when the results of the PET scan are anticipated to influence treatment decisions 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 does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in the staging and restaging of breast cancer when the results of the PET scan are not anticipated to influence treatment decisions 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 does not meet and is considered investigational 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/low suspicion finding on mammography
  - Staging axillary lymph nodes.

Cervical Cancer:
- PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in the initial staging of patients with locally advanced cervical cancer when the results of the PET scan are anticipated to influence treatment decisions.
- PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in the initial staging of patients with locally advanced cervical cancer when the results of the PET scan are not anticipated to influence treatment decisions.
- PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in the evaluation of known or suspected recurrence when the results of the PET scan are anticipated to influence treatment decisions.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in the evaluation of known or suspected recurrence when the results of the PET scan are not anticipated to influence treatment decisions.

Colorectal Cancer:
• PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are anticipated to influence treatment decisions as a technique for:
  o Staging and restaging to detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer, and
  o To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when standard imaging, including CT scan, is negative.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are not anticipated to influence treatment decisions as a technique for:
  o Staging and restaging to detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer, and
  o To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when standard imaging, including CT scan, is negative.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational as a technique to assess the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer.

Esophageal Cancer:
• PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are anticipated to influence treatment decisions in the
  o Staging of esophageal cancer, and
  o Determining response to preoperative induction therapy.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are not anticipated to influence treatment decisions in the
  o Staging of esophageal cancer, and
  o Determining response to preoperative induction therapy.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational in other aspects of the evaluation of esophageal cancer, including but not limited to the following applications:
  o Detection of primary esophageal cancer.

Head and Neck Cancer:
• PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are anticipated to influence treatment decisions in the evaluation of head and neck cancer in the diagnosis of suspected cancer, initial staging of disease, and restaging of residual or recurrent disease during follow up.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are not anticipated to influence treatment decisions in the evaluation of head and neck cancer in the diagnosis of suspected cancer, initial staging of disease, and restaging of residual or recurrent disease during follow up.

Lung Cancer:
• PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are anticipated to influence treatment decisions for any of the following applications:
  o Patients with a solitary pulmonary nodule as a technique to distinguish between benign and malignant disease when prior CT scan and chest x-ray findings are inconclusive or discordant,
  o As staging or restaging technique in those with known non-small cell lung cancer, and
  o To determine resectability for patients with a presumed solitary metastatic lesion from lung cancer.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are not anticipated to influence treatment decisions for any of the following applications:
  o Patients with a solitary pulmonary nodule as a technique to distinguish between benign and malignant disease when prior CT scan and chest x-ray findings are inconclusive or discordant,
  o As staging or restaging technique in those with known non-small cell lung cancer, and
  o To determine resectability for patients with a presumed solitary metastatic lesion from lung cancer.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational in staging of small cell lung cancer.

Lymphoma, Including Hodgkin’s disease:
• PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are anticipated to influence treatment decisions as a technique for staging lymphoma either during initial staging or for restaging at follow-up.
• PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are not anticipated to influence treatment decisions as a technique for staging lymphoma either during initial staging or for restaging at follow-up.

Melanoma:
• PET scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are anticipated to influence treatment decisions as a technique for assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment.
• PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are not anticipated to influence treatment decisions as a technique for assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment.

• PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** as a technique to detect regional lymph node metastases in patients with clinically localized melanoma who are candidates to undergo sentinel node biopsy.

**Ovarian Cancer:**

• PET scanning **meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are anticipated to influence treatment decisions 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 **does not** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are not anticipated to influence treatment decisions 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 **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** in the initial evaluation of known or suspected ovarian cancer in all situations.

**Pancreatic Cancer:**

• PET scanning **meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are anticipated to influence treatment decisions in the initial diagnosis and staging of pancreatic cancer when other imaging and biopsy are inconclusive.

• PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan are not anticipated to influence treatment decisions in the initial diagnosis and staging of pancreatic cancer when other imaging and biopsy are inconclusive.

• PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** as a technique to evaluate other aspects of pancreatic cancer.

**Prostate Cancer:**

• PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational in diagnosis and management of known or suspected prostate cancer.**

**Soft Tissue Sarcoma:**

• PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational 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.

**Testicular Cancer:**

- PET scanning **meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan **are anticipated to influence treatment** decisions in evaluation of residual mass following chemotherapy of stage IIB and III seminomas. *(The PET scan should be completed not sooner than 6 weeks following chemotherapy.)*
- PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan **are not anticipated to influence treatment** decisions in evaluation of residual mass following chemotherapy of stage IIB and III seminomas.
- **Except as noted above for seminoma,** PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** 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
  - Detection of recurrent disease after treatment of testicular cancer

**Thyroid Cancer, Differentiated:**

- PET scanning **meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan **are anticipated to influence treatment** decisions in the restaging of patients with differentiated thyroid cancer when thyroglobulin (Tg) levels are elevated and whole-body I-131 imaging is negative.
- PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan **are not anticipated to influence treatment** decisions in the restaging of patients with differentiated thyroid cancer when thyroglobulin (Tg) levels are elevated and whole-body I-131 imaging is negative.
- PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** in the evaluation of known or suspected differentiated thyroid cancer in all other situations.

**Unknown Primary:**

- PET scanning **meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan **are anticipated to influence treatment** decisions 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 **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the results of the PET scan **are not anticipated to influence treatment** decisions in patients with an unknown primary who meet ANY of the following criteria:
  o In patients with a single site of disease outside the cervical lymph nodes; AND
  o Patient is considering local or regional treatment for a single site of metastatic disease; AND
  o After a negative workup for a occult primary tumor; AND
  o 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 **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigative for other indications in patients with an unknown primary, including, but not limited to the following:
  o As part of the initial workup of an unknown primary;
  o As part of the workup of patients with multiple sites of disease.

Cancer Surveillance:

• PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigative when used as a surveillance tool for patients with cancer or with a history of cancer.
  o A scan is considered surveillance if performed more than six months after completion of cancer therapy (12 months for lymphoma) in patients without objective signs or symptoms suggestive of cancer recurrence.

Other Oncologic Applications:
Other oncologic applications of PET scanning do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

Positron Emission Tomography (PET) scanning using Sodium Fluoride F-18 (NaF-18) does **not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Effective for dates of service July 10, 2010 through May 14, 2012, Positron Emission Tomography (PET) scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the following criteria are met:

**KNOWN DIAGNOSIS OF MALIGNANCY**

Individual consideration will be given for PET scanning for patients with known diagnosis of malignancy (other than the diagnoses listed below) when the following criteria are met:

• To determine optimal anatomic site for biopsy or other invasive diagnostic procedure; or
• Staging and restaging (see Key Points):
o When **standard diagnostic imaging work up** (US, CT, MRI) is **inconclusive** – these imaging reports must be submitted with the request for a PET scan; or

o **Replace conventional imaging** when **conventional imaging** will be **inadequate** for accurate staging and clinical management will depend upon the stage of disease; or

o **Restaging** after completion of therapy to detect residual disease, recurrence, and extent of recurrence.

Routine monitoring of tumor response during treatment (when no change in therapy is planned) **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**Repeat PET scanning** more frequently than **every six months**, except the indications listed in key points or for specific diagnoses **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage. Individual case consideration will be given based on the patient’s medical history.

**Request for suspected recurrence should include changes in the clinical status**, i.e., new symptoms and/or elevated tumor markers or other laboratory changes, of the patient.

**PET scanning for screening and detection of oncology conditions does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**MELANOMA**

- Assessing extranodal spread of malignant melanoma at initial staging or during follow-up treatment.
- In known disease, detection of distal metastases
- Restaging after therapy

PET scanning as a technique to **detect regional lymph node metastases** in patients with clinically localized melanoma that are candidates to undergo sentinel node biopsy **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**BREAST CARCINOMA**

- Must have tissue diagnosis of breast cancer; or
- Magnetic resonance imaging (MRI) is non-diagnostic for breast cancer; and
- Initial staging and restaging (see Key Points); or
- Evaluating response to treatment; or
  - Suspected recurrence as evidenced by:
  - New palpable lesion in axilla or adjacent area
  - Rising tumor markers
  - Changes on other imaging

PET scanning **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:

- Used to establish the diagnosis of breast cancer or to detect the primary lesion unless conventional imaging methods, including MRI, are non-diagnostic; or
• Clarify a finding on mammography, physical examination, or ultrasound; or
• Evaluate axillary nodes

SUSPECTED RECURRENT THYROID CARCINOMA
• Must have tissue diagnosis of thyroid cancer and have been treated by thyroidectomy and/or radioiodine ablation.
• Medullary thyroid cancer
  o Elevated or rising calcitonin
• Indicated for staging and restaging in patients with:
  o Negative I131 and/ or thallium201 scans (whole body), and
  o Thyroglobulin level detectable on hormone replacement therapy; or
  o >2 micro grams/liter after Thyrogen stimulation

HEAD AND NECK CANCERS
• Initial diagnosis is established with tissue diagnosis,
• Evaluation of patient with metastatic cervical lymph node(s) to establish primary site; or
• Staging of patient with known primary head and neck cancer. If diagnosed by needle biopsy – No sooner than 5-7 days thereafter; or
• CT or MRI non-diagnostic for metastasis or nodal disease; or
• Monitor response to therapy.
  o Radiation Therapy – No sooner than 1 month after completion of treatment. (If done too soon may give false positive result.)
  o Surgery – No sooner than 6 weeks after surgery.
  o Chemotherapy – No sooner than 1-2 weeks after completion of first cycle; or
• Evaluation for possible recurrence
  o Stable clinical situation
    ▪ 4-6 months after therapy
    ▪ 1 year after therapy
    ▪ Annually thereafter if requested
• Altered clinical situation

PET/CT is the preferred modality. If a PET alone is performed, CT and/or MRI may be needed for anatomic localization.

SOLITARY PULMONARY NODULE BY CHEST X-RAY (CXR)
• Evaluation of newly discovered solitary pulmonary nodule

(Note---a tissue diagnosis is not a prerequisite for coverage of PET scan for solitary pulmonary nodule.)

Known benign nodules should be followed w/ CXR. Biopsy or CT may be performed for changes or equivocal findings on CXR. Requests due to changes noted on CXR will be given individual consideration.

PET scanning or fusion CT/PET scanning for multiple nodules meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:
- **CT scan** is used for *initial* diagnosis; and
- **Initial CT scan is indeterminate** for *malignant vs. benign* disease.

PET scanning for multiple nodules does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used for indications other than listed above.

**LUNG CARCINOMA**
- Initial staging (see Key Points) of non-small cell lung cancer (after tissue diagnosis has been established); or
- Restaging (see Key Points) after chemotherapy; or
- Monitoring response to treatment (see Key Points) when a change in therapy is anticipated; or
- Increase in CEA

No sooner than 12 weeks after completion of Radiation Therapy unless there is a change in clinical or imaging findings suggestive of recurrence or progression.

**COLORECTAL CARCINOMA**
- Initial staging after tissue diagnosis is established (see key points); or
- Evaluation of response to chemotherapy of hepatic metastases with the *intent of changing* therapy based on the result of the PET scans. If there is no *consideration of a change in therapy, PET or PET/CT scans do not meet* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.
  - No sooner than 4-5 weeks of treatment (about 1 complete cycle);
  - If there is a good response to therapy, there is no need to repeat until the termination of course of therapy unless there is a change in clinical status i.e. increasing CEA; or
- Rising CEA (2 consecutive tests or any significant increase over baseline >2.5 in smoker); or
- Restaging (see Key Points) after completion of therapy; or
- Periodic surveillance not more frequently than every 6 months unless there is a change in clinical status including, but not limited to:
  - Rising CEA;
  - Change on physical examination;
  - Elevation of liver function tests;
  - New findings on chest x-ray.
- Evaluation of radiofrequency ablation or similar procedure of metastases.

**LYMPHOMA / HODGKIN’S DISEASE**
- Initial staging after tissue diagnosis is established; and
- Periodic assessment during chemotherapy;
  - Not more frequently than after 2 cycles; or
- Restaging (see Key Points) after therapy is completed; or
- To determine response to chemotherapy;
May be performed as early as 7 days after the initiation of chemotherapy. Follow-up studies are not needed until completion of the course of chemotherapy, unless there is a change in clinical status; or

- After completion of first line treatment to determine if additional treatment or closer follow-up is needed; or
- Periodic assessment during remission
  - Not more frequently than every 3-12 months for first 2-3 years and then annually up to 5 years.
- New symptoms or findings:
  - Night sweat by history
  - Weight loss as indicated by history or physical examination
  - New enlarged lymph nodes
  - Erythrocyte sedimentation rate (ESR) >30 mm/hr
  - Temperature of 100.4°F (unknown etiology) > one week
  - Suspected metastasis by chest x-ray (CXR), magnetic resonance imaging (MRI), computed tomography (CT)

**ESOPHAGEAL CARCINOMA**
- Initial staging (see Key Points) of known esophageal cancer; or
- Re-evaluation of patients treated with either chemotherapy or radiation therapy; or
- Re-evaluation for suspected recurrence
  - New symptoms or findings of dysphagia, hoarseness, or pain
  - Suspected metastasis by magnetic resonance imaging (MRI), computed tomography (CT)
  - Change in findings on endoscopy
  - Inability to perform endoscopy
  - Lymphadenopathy

**CERVICAL CARCINOMA**
- Initial Staging (see Key Points); or
- Monitor response to therapy; or
- Evaluate for recurrence.

**OVARIAN CARCINOMA**
- Evaluation of recurrence.
- **Does not** meet Blue Cross and Blue Shield of Alabama’s medical criteria for initial staging; or
- Does not replace second look surgery after completion of initial treatment.

**PANCREATIC CARCINOMA**
- Pancreatic mass on CT or MRI
- Abnormal ERCP
- Unexplained jaundice
GASTRIC CARCINOMA
- Must have established tissue diagnosis of gastric cancer; and
- Initial staging (see Key Points); or
- Evaluation of response to chemotherapy; or
- Restaging.

TESTICULAR CARCINOMA
- Must have established tissue diagnosis of germ cell tumor (seminoma or non-seminomatous germ cell tumor); and
- Must be status post chemotherapy (at least 4 weeks since last treatment); and
- Must have ONE:
  - Elevated tumor markers; or
  - Beta HCG; or
  - Alpha Fetoprotein; or
  - Residual mass on CT
Initial staging should be performed with PET/CT if feasible.

If the initial PET scan is negative and the markers remain negative; then no further PET scans are indicated unless the markers turn positive.

If the initial PET scan is negative and the tumor markers remain elevated or rise, follow up PET in 1-3 months is indicated. If the second PET scan is negative, continued surveillance without PET is appropriate.

GASTROINTESTINAL STROMAL TUMOR (GIST TUMOR)
- Must have established tissue diagnosis; and
- Initial staging (see Key Points); or
- Response to chemotherapy (initial evaluation may be as soon as 1 month after initiation of chemotherapy or sooner as indicated by clinical situation in the later case send to physician review); or
- Evaluation for recurrence.

SOFT TISSUE SARCOMA
- Must have an established tissue diagnosis of intermediate or high grade sarcoma; and
- Initial staging (see Key Points); or
- Re-staging (see Key Points) and evaluation for possible local recurrence.

ENDOMETRIAL CARCINOMA
- Must have an established tissue diagnosis; and
- Patient must be status post surgery; and
- Must have elevated tumor markers
  - CA 125 or CEA or CA 19-9

PRIMARY BRAIN TUMOR
- MRI nondiagnostic for tumor extent and surgical resection planned; or
• MRI nondiagnostic for radiation necrosis and an intervention is planned.

MULTIPLE MYELOMA
• Staging or restaging (see key points) in patients with known multiple myeloma

RADIATION THERAPY PLANNING (GROSS TUMOR VOLUME (GTV) & CLINICAL TARGET VOLUME (CTV))
• Ordered by a radiation oncologist prior to initiation of therapy for patients with:
  o Non-small cell lung cancer; or
  o Esophageal cancer; or
  o Head or neck cancer

MEDIASTINAL MASS(ES)
• Suspicious for malignancy on CT scan

Positron Emission Tomography (PET) scanning using Sodium Fluoride F-18 (NaF-18) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Effective for dates of service April 1, 2006 through July 9, 2010, Positron Emission Tomography (PET) scanning meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the following criteria are met:

KNOWN DIAGNOSIS OF MALIGNANCY
Individual consideration will be given for PET scanning for patients with known diagnosis of malignancy (other than the diagnoses listed below) when the following criteria are met:

• To determine optimal anatomic site for biopsy or other invasive diagnostic procedure; or
• Staging and restaging (see Key Points):
  o When standard diagnostic imaging work up (US, CT, MRI) is inconclusive – these imaging reports must be submitted with the request for a PET scan; or
  o Replace conventional imaging when conventional imaging will be inadequate for accurate staging and clinical management will depend upon the stage of disease; or
  o Restaging after completion of therapy to detect residual disease, recurrence, and extent of recurrence.

Routine monitoring of tumor response during treatment (when no change in therapy is planned) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Repeat PET scanning more frequently that every six months, except the indications listed in key points or for specific diagnoses does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage. Individual case consideration will be given based on the patient’s medical history.
Request for suspected recurrence should include changes in the clinical status, i.e., new symptoms and/or elevated tumor markers or other laboratory changes, of the patient.

PET scanning for screening and detection of oncology conditions does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**MELANOMA**
- Assessing extranodal spread of malignant melanoma at initial staging or during follow-up treatment.

PET scanning as a technique to detect regional lymph node metastases in patients with clinically localized melanoma that are candidates to undergo sentinel node biopsy does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**BREAST CARCINOMA**
- Must have tissue diagnosis of breast cancer; or
- Magnetic resonance imaging (MRI) is non-diagnostic for breast cancer; and
- Initial staging and restaging (see Key Points); or

PET scanning does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:
- Used to establish the diagnosis of breast cancer or to detect the primary lesion unless conventional imaging methods, including MRI, are non-diagnostic; or
- Clarify a finding on mammography, physical examination, or ultrasound; or
- Evaluate axillary nodes

**SUSPECTED RECURRENT THYROID CARCINOMA**
- Must have tissue diagnosis of thyroid cancer and have been treated by thyroidectomy and/or radiiodine ablation.
- Indicated for staging and restaging in patients with:
  - Negative I131 and/or thallium201 scans (whole body), and
  - Thyroglobulin level detectable on hormone replacement therapy; or
  - >2 micro grams/liter after Thyrogen stimulation

**HEAD AND NECK CANCERS**
- Initial diagnosis is established with tissue diagnosis,
- Evaluation of patient with metastatic cervical lymph node(s) to establish primary site; or
- Staging of patient with known primary head and neck cancer. If diagnosed by needle biopsy – No sooner than 5-7 days thereafter; or
- CT or MRI non-diagnostic for metastasis or nodal disease; or
- Monitor response to therapy.
  - Radiation Therapy – No sooner than 1 month after completion of treatment. (If done too soon may give false positive result.)
  - Surgery – No sooner than 6 weeks after surgery.
  - Chemotherapy – No sooner than 1-2 weeks after completion of first cycle; or
• Evaluation for possible recurrence.

PET/CT is the preferred modality. If a PET alone is performed, CT and/or MRI may be needed for anatomic localization.

SOLITARY PULMONARY NODULE BY CHEST X-RAY (CXR)
• Evaluation of newly discovered solitary pulmonary nodule; and
• Chest X-ray and computed tomography have failed to distinguish benign from malignant disease, and
• The test results may alter treatment/management

(Note---a tissue diagnosis is not a prerequisite for coverage of PET scan for solitary pulmonary nodule.)

Known benign nodules should be followed w/ CXR. Biopsy or CT may be performed for changes or equivocal findings on CXR. Requests due to changes noted on CXR will be given individual consideration.

PET scanning or fusion CT/PET scanning for multiple nodules meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:
• CT scan is used for initial diagnosis; and
• Initial CT scan is indeterminate for malignant vs. benign disease.

PET scanning for multiple nodules does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used for indications other than listed above.

LUNG CARCINOMA
• Initial staging (see Key Points) of non-small cell lung cancer (after tissue diagnosis has been established); or
• Restaging (see Key Points) after chemotherapy; or
• Monitoring response to treatment (see Key Points) when a change in therapy is anticipated; or
• Increase in CEA

No sooner than 12 weeks after completion of Radiation Therapy unless there is a change in clinical or imaging findings suggestive of recurrence or progression.

COLORECTAL CARCINOMA
• Initial staging after tissue diagnosis is established (see key points); or
• Evaluation of response to chemotherapy of hepatic metastases with the intent of changing therapy based on the result of the PET scans. If there is no consideration of a change in therapy, PET or PET/CT scans do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.
  o No sooner than 4-5 weeks of treatment (about 1 complete cycle);
• If there is a good response to therapy, there is no need to repeat until the termination of course of therapy unless there is a change in clinical status i.e. increasing CEA; or

• Rising CEA (2 consecutive tests or any significant increase over baseline >2.5 in smoker); or

• Restaging (see Key Points) after completion of therapy; or

• Periodic surveillance not more frequently than every 6 months unless there is a change in clinical status including, but not limited to:
  o Rising CEA;
  o Change on physical examination;
  o Elevation of liver function tests;
  o New findings on chest x-ray.

In addition to the above indications, effective for dates of service on or after March 1, 2007:

• Evaluation of radiofrequency ablation or similar procedure of metastases.

LYMPHOMA / HODGKIN’S DISEASE

• Initial staging after tissue diagnosis is established; and

• Periodic assessment during chemotherapy;
  o Not more frequently than after 2 cycles; or

• Restaging (see Key Points) after therapy is completed; or

• To determine response to chemotherapy;
  o May be performed as early as 7 days after the initiation of chemotherapy. Follow up studies are not needed until completion of the course of chemotherapy, unless there is a change in clinical status; or

• After completion of first line treatment to determine if additional treatment or closer follow-up is needed; or

• Periodic assessment during remission
  o Not more frequently than every 3-12 months for first 2-3 years and then annually up to 5 years.

• New symptoms or findings:
  o Night sweat by history
  o Weight loss as indicated by history or physical examination
  o New enlarged lymph nodes
  o Erythrocyte sedimentation rate (ESR) >30 mm/hr
  o Temperature of 100.4°F (unknown etiology) > one week
  o Suspected metastasis by chest x-ray (CXR), magnetic resonance imaging (MRI), computed tomography (CT)

ESOPHAGEAL CARCINOMA

• Initial staging (see Key Points) of known esophageal cancer; or

• Re-evaluation of patients treated with either chemotherapy or radiation therapy; or

• Re-evaluation for suspected recurrence
  o New symptoms or findings of dysphagia, hoarseness, or pain
  o Suspected metastasis by magnetic resonance imaging (MRI), computed tomography (CT)
CERVICAL CARCINOMA
- Initial Staging (see Key Points); or
- Monitor response to therapy; or
- Evaluate for recurrence.

OVARIAN CARCINOMA
- Evaluation of recurrence.
- **Does not** meet Blue Cross and Blue Shield of Alabama’s medical criteria for initial staging; or
- Does not replace second look surgery after completion of initial treatment.

PANCREATIC CARCINOMA
- Pancreatic mass on CT or MRI

GASTRIC CARCINOMA
- Must have established tissue diagnosis of gastric cancer; **and**
- Initial staging (see Key Points); or
- Evaluation of response to chemotherapy; or
- Restaging.

TESTICULAR CARCINOMA
- Must have established tissue diagnosis of germ cell tumor (seminoma or non-seminomatous germ cell tumor); **and**
- Must be status post chemotherapy (at least 4 weeks since last treatment); **and**
- Must have ONE:
  - Elevated tumor markers; or
  - Beta HCG; or
  - Alpha Fetoprotein; or
  - Residual mass on CT.

Initial staging should be performed with PET/CT if feasible.

If the initial PET scan is negative and the markers remain negative, then no further PET scans are indicated unless the markers turn positive.

If the initial PET scan is negative and the tumor markers remain elevated or rise, follow up PET in 1-3 months is indicated. If the second PET scan is negative, continued surveillance without PET is appropriate.

GASTROINTESTINAL STROMAL TUMOR (GIST TUMOR)
- Must have established tissue diagnosis; **and**
- Initial staging (see Key Points); or
- Response to chemotherapy (initial evaluation may be as soon as 1 month after initiation of chemotherapy or sooner as indicated by clinical situation in the later case send to physician review); or
• Evaluation for recurrence.

**SOFT TISSUE SARCOMA**
- Must have an established tissue diagnosis of intermediate or high grade sarcoma; **and**
- Initial staging (see Key Points); **or**
- Re-staging (see Key Points) and evaluation for possible local recurrence.

**ENDOMETRIAL CARCINOMA**
- Must have an established tissue diagnosis; **and**
- Patient must be status post surgery; **and**
- Must have elevated tumor markers
  - CA 125 or CEA or CA 19-9

**PRIMARY BRAIN TUMOR**
- MRI nondiagnostic for tumor extent and surgical resection planned; **or**
- MRI nondiagnostic for radiation necrosis and an intervention is planned.

**MULTIPLE MYELOMA**
- Staging or restaging (see key points) in patients with known multiple myeloma

**RADIATION THERAPY PLANNING (GROSS TUMOR VOLUME (GTV) & CLINICAL TARGET VOLUME (CTV))**
- Ordered by a radiation oncologist prior to initiation of therapy for patients with:
  - Non-small cell lung cancer; or
  - Esophageal cancer; or
  - Head or neck cancer

**MEDIASTINAL MASS(ES)**
- Suspicious for malignancy on CT scan

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members’ contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
As a molecular diagnostic imaging modality, PET can detect rates of biological activity, as contrasted with other imaging modalities such as x-ray films, computed tomography (CT) and magnetic resonance imaging (MRI), which depict the anatomical location of both normal and abnormal structures in the body. Malignancies can cause the abnormalities of blood flow or metabolism before anatomic changes are apparent. Thus, PET can detect disease when anatomic imaging studies are still normal, and may be informative in differentiating benign from
malignant processes. The American College of Radiology’s (ACR) Practice Guideline for the Performance of FDG-PET Scintigraphy in Oncology states that FDG-PET does not work equally well for all tumors. PET evaluation of tissue metabolism can indicate the probable presence or absence of malignancy based on observed differences of biologic activity, whereas anatomic imaging depends on the size and radiographic characteristics of lesions to determine the likelihood of malignancy. Whole body imaging with PET also provides the means to examine all organ systems for both primary and metastatic disease in a single procedure.

The effective radiation dose from a single PET scan is estimated to be about 10 mSv. The effective dose for PET-CT is 20 mSv twice that of a single PET scan, since a whole body CT (up to 8 mSv) is performed in conjunction with PET. Even when more than one PET or PET-CT is performed during follow-up after therapy, the cumulative effective dose is similar to that which would result from a similar number of “dedicated” contrast-enhanced CT scans of the chest, abdomen, and pelvis.

In a recent metaanalysis, FDG-PET imaging was found to have cumulative sensitivity of 96.8% and specificity of 77.8% for identifying malignant lung nodules and masses. FDG-PET may provide a reliable means for noninvasive diagnosis of malignancy in patients with solitary pulmonary nodules that are less than three cm size. It has been shown that a negative FDG-PET study represents less than a 5% probability for cancer in a solitary pulmonary nodule. Because of this high negative predictive value, a pulmonary lung nodule or mass without increased FDG activity is unlikely to be malignant.

Nodules with positive PET should be biopsied or excised. However, PET has a poor positive predictive value, and some nodules with a positive PET will be of infectious, granulomatous, or inflammatory origin.

CT is the method of choice for detecting multiple pulmonary nodules due to metastatic disease.

The use of PET/CT in determining gross tumor volume or clinical target volume in radiation therapy planning has been demonstrated to enhance the precision in coverage of gross tumor volume for non-small cell lung cancer, head and neck cancer, and esophageal carcinoma. Precise delineation of tumor volume and involved lymph nodes is essential to tumor control, survival, and morbidity of treatment.

**Sodium Fluoride F-18 (NaF-18)**

Grant, et al (2008) studied the uses of NaF-18 in skeletal PET scans versus using (99m)Tc-diphosphonate SPECT. They noticed in recent comparative studies that NaF-18 was more accurate than (99m) Tc-diphosphonate in identifying both malignant and benign lesions of the skeleton. Combining NaF-18 PET with other imaging, such as CT, can improve the specificity and overall accuracy of NaF-18 PET and probably will become the routine clinical practice for NaF-18 PET. With the widespread availability of PET scanners and the improved logistics for the delivery of NaF-18 radiopharmaceuticals, prior limitations to the routine use of NaF-18 have largely overcome. They noted that the favorable imaging performance and the clinical utility of NaF-18 PET, compared with (99m) Tc-diphosphonate scintigraphy, supported the reconsideration of NaF-18 as a routine bone-imaging agent.
Hetzel et al (2003) study measured the accuracy, clinical value and cost effectiveness of tomographic bone imaging using NaF-18 PET and single photon emission tomography (SPECT). Previous studies have shown that vertebral bone metastases not seen on planar bone scans may be present on NaF-18 PET or SPECT. A total of 103 patients with initial diagnosis of lung cancer were prospectively examined with planar bone scintigraphy (BS), SPECT of the vertebral column and PET using NaF-18. Receiver operating characteristic (ROC) curve analysis was used for the determination of the diagnostic accuracy. A decision-analysis model and the national charge schedule of the German Hospital Association were used for determination of the cost-effectiveness. Thirteen of 33 patients with bone metastases were false negative on BS, 4 on SPECT and 2 on NaF-18 PET. The area under the ROC curve was 0.771 for BS, 0.875 for SPECT and 0.989 for NaF-18 PET (p < 0.05). As a result of APECT and NaF-18 PET imaging, clinical management was changed in 8 (7.8%) and 10 (9.7%) patients. Compared with BS, the costs per additional correctly diagnosed patient were 1272 Euro with SPECT and 2861 Euro with NaF-18 PET. The threshold for the costs of NaF-18 PET being more cost-effective than SPECT was 345 Euro. Hetzel et al (2003) concluded that routine performance of tomographic bone imaging improves the therapeutic strategy because of detection of otherwise missed metastases. NaF-18 PET is more effective than SPECT but is associated with higher incremental costs.

Definitions:

**Diagnosis:**
The PET results may assist in avoiding an invasive diagnostic procedure, or the PET results may assist in determining the optimal anatomic 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 performed for the purpose of staging, not diagnosis.

**Staging:**
PET is considered medically necessary in situations in which clinical management of the member would differ depending on the stage of the cancer identified and either:

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

The use of PET would potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member.

**Restaging:**
PET is considered for coverage for restaging after completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of recurrence. Use of PET can also be considered covered 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 member.
The appropriate time point for restaging with PET at the conclusion of therapy for the detection of residual or recurrent tumors varies with the type of therapy administered. PET may be performed within four weeks after the completion of chemotherapy, chemoimmunotherapy, or chemohormonal therapy. However, PET is generally not performed until two to three months after radiation or chemoradiation or one to two months after surgery, because acute inflammatory changes that are commonly seen in the first few weeks after radiation or surgery can result in false positive PET scans. False positive PET findings within the first one to two months after surgery are usually located at the site for the surgery. PET evaluation of distant metastatic disease can be reliable during this time.

There are several studies that have demonstrated that tumor restaging with PET can detect and localize disease recurrence in patients who have no symptoms or only mild ones but who have an elevated tumor marker level (e.g., among patients with colorectal cancer with elevated levels of carcinoembryonic antigen). PET can also provide information about whether the detected disease is resectable (e.g., whether it is an isolated pelvic recurrence or involves liver metastases).

### Timing and Role of Restaging with PET

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Timing of Restaging with PET</th>
<th>Dominant Contributions of PET</th>
</tr>
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<tbody>
<tr>
<td>Non-small cell lung cancer</td>
<td>2-6 mo after completion of chemoradiotherapy; 1-2 mo after surgery When recurrent is suspected on the basis of clinical or biochemical findings or by conventional imaging</td>
<td>• Differentiation between persistent or recurrent tumor and fibrosis in patients with residual chest radiographic abnormalities</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>When recurrence is suspected on the basis of clinical or biochemical findings or by conventional imaging</td>
<td>• Selection of biopsy sites for confirmation of suspected recurrence</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>When recurrent is suspected on the basis of clinical or biochemical findings or by conventional imaging</td>
<td>• Determination of actual extent of recurrent (locoregional and distant)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Determination of actual extent of recurrence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Differentiation between metastatic and benign brachial plexopathy</td>
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<tr>
<td></td>
<td></td>
<td>• Detection of recurrence suspected by elevation of carcinoembryonic antigen by distinguishing of viable tumor from fibrosis after therapy</td>
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<tr>
<td></td>
<td></td>
<td>• Determination of actual extent of recurrent disease (isolated vs. disseminated) and resectability of liver metastases</td>
</tr>
<tr>
<td>Cancer Type</td>
<td>Timeframe for Recurrence</td>
<td>Potential Benefits</td>
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<tr>
<td>Esophageal cancer</td>
<td>When recurrent is suspected on the basis of clinical or biochemical findings or by conventional imaging</td>
<td>- More accurate diagnosis of regional and distant recurrence than with conventional imaging (less accurate for peri-anastomotic recurrent)</td>
</tr>
<tr>
<td>Head and Neck cancer</td>
<td>2-6 mo after completion of chemoradiotherapy; 1-2 mo after surgery When recurrent is suspected on the basis of clinical or biochemical findings or by conventional imaging</td>
<td>- More accurate assessment of response to therapy and earlier detection of persistent or recurrent disease (locoregional and distant) than with conventional imaging - Determination of actual extent of recurrence</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>3-4 wk after completion of therapy; 2-3 mo or more after external-beam radiation When recurrence is suspected on the basis of clinical or biochemical findings or by conventional imaging</td>
<td>- Differentiation between viable tumor and necrosis or fibrosis in patients with a residual mass and more accurate differentiation between complete and partial responses than with conventional imaging - Determination of actual extent of lymphoma recurrence</td>
</tr>
<tr>
<td>Melanoma</td>
<td>When recurrence is suspected on the basis of clinical or biochemical findings or by conventional imaging</td>
<td>- More accurate diagnosis of locoregional and distant recurrence than with conventional imaging, except for lung metastases (less sensitive than CT)</td>
</tr>
<tr>
<td>Follicular thyroid cancer</td>
<td>When serum thyroglobulin is elevated (&gt;10 ng per milliliter) and whole-body I scan is negative</td>
<td>- Detection of residual or recurrent disease (locoregional or distant) - Identification of patients for potentially curative surgery vs. palliative treatment</td>
</tr>
</tbody>
</table>

Monitoring:
The purpose of PET for monitoring is to provide an early and accurate assessment of the response to multi-course treatment with the ultimate goal of tailoring therapy according to the information learned from the PET. Although persuasive findings of several studies investigating PET for monitoring the response during the course of therapy, no published reports have clearly demonstrated that PET results were used to alter treatment. Therefore, PET for evaluating tumor response during the planned course of therapy (i.e., when no change in therapy is being contemplated) is not considered for coverage except for breast cancer. Restaging occurs only after a course of treatment is completed.
March 2012 Update:
This update is based on multiple evaluations of positron emission tomography (PET), including TEC Assessments, other systematic reviews, meta-analyses, decision analyses, and cost-effectiveness analyses. From the perspective of evidence-based medicine, overall, the literature on use of PET scanning in oncology is quite limited. There are few rigorous studies that assess the impact of PET on clinical outcomes. The majority of the studies that report on outcomes describe changes in staging and/or treatment that result from the PET scan; however, the studies do not evaluate whether or not these changes result in an improvement in the net health outcome.

A 1997 TEC Assessment considered the use of PET scanning in the evaluation of solitary pulmonary nodules and staging of known lung cancer. A 2006 evidence report by TEC for the Agency for Healthcare Research and Quality (AHRQ) addressed use of PET for staging small cell lung cancer (SCLC). Three 1999 TEC Assessments and one 2000 TEC Assessment considered the use of PET scanning in the evaluation of melanoma, lymphoma, colorectal, and head and neck cancer. TEC Assessments from 2000 and 2002 addressed unknown primaries. One 2001 TEC Assessment, a 2002 decision analysis, and a 2005 systematic review focused on esophageal cancer. Pancreatic cancer was evaluated in a 1999 TEC Assessment and the 2004 Agency for Healthcare Research and Quality (AHRQ) systematic review. The 2004 AHRQ systematic review also focused on ovarian cancer, as well as testicular cancer. Soft tissue sarcoma was the subject of a 2002 AHRQ systematic review. Breast cancer was the focus of two TEC Assessments from 2001 and 2003, a systematic review from 2005, a systematic review from 2007, and a cost-effectiveness analysis from 2005. Several uses of PET were reviewed in National Comprehensive Cancer Network (NCCN) Task Force documents released in 2007 and 2009. Another AHRQ systematic review evaluating use of PET for nine cancers was published in 2008. In the Assessments, PET scanning was considered an adjunct to other imaging methods (i.e., computed tomography [CT], magnetic resonance imaging [MRI], and ultrasonography) often used when previous imaging studies are inconclusive or provide discordant results. In this setting, the clinical value of PET scans is the rate of discordance among imaging techniques and the percentage of time that PET scanning results in the correct diagnosis, as confirmed by tissue biopsy. The Assessments and literature reviews offered the following observations and conclusions:

Bone Cancer
A systematic review and meta-analysis of studies examining the diagnostic accuracy of PET in Ewing sarcoma showed very high estimates of sensitivity and specificity (pooled sensitivity 96%, pooled specificity 92%). Another study of PET in pediatric sarcoma (Ewing sarcoma and osteosarcoma) patients in which PET was used in addition to conventional imaging showed that PET was superior to conventional imaging in detecting lymph node and bone involvement. The most thorough assessment of cancer involvement involved using both PET and conventional tests and produced important changes in therapy decisions.

There are very few studies examining the utility of PET in chondrosarcoma.

Breast Cancer
The 2001 TEC Assessment focused on multiple applications of PET scanning in breast cancer, including characterization of breast lesions, staging axillary lymph nodes, detection of
recurrence, and evaluating response to treatment. The 2003 TEC Assessment re-examined all of the above indications except for its role in characterizing breast lesions.

The bulk of the data regarding PET scanning for breast cancer focuses on its use as a technique to further characterize breast lesions such that patients could avoid biopsy of a mammographically indeterminate or suspicious lesion. The key statistic in this analysis is the false-negative rate, since patients with a false-negative result on a PET scan may inappropriately forego a biopsy and subsequent treatment. The false-negative rate will vary with the underlying prevalence of the disease, but may range from 5.5% to 8.5%. Given the relative ease of breast biopsy, this false-negative rate may be considered unacceptable, and thus patients may undergo biopsy regardless of the results of a PET scan.

A 2005 systematic review and meta-analysis focused on use of PET for detecting recurrence and metastases. The report concluded that PET is a valuable tool; however, it did not compare PET performance with that of other diagnostic modalities, so it is unclear if PET results in different management decisions and health outcomes.

A systematic review published in 2007 on use of PET for staging axillary lymph nodes identified 20 studies. Of these, three studies were rated with the highest quality grade, corresponding to broad generalizability to a variety of patients and no significant flaws in research methods. The remaining studies were more flawed and/or were more narrowly generalizable. The review observed that there was great variability in estimates of sensitivity and specificity from the selected studies and that it is difficult to draw conclusions from the evidence. A National Comprehensive Cancer Network (NCCN) review of PET concluded that PET was useful in staging and restaging regional or distant metastasis when the suspicion was high and other imaging inconclusive.

**Cervical Cancer**
An AHRQ review published in 2008 identified several studies in which PET or PET/CT was used in the staging of advanced cervical cancer and for detection and staging of recurrent disease. The report concluded that the majority of studies supported enhanced diagnostic accuracy, which would improve the selection of appropriate treatment for patients. For recurrent disease, PET identifies additional sites of metastasis which would alter treatment decisions in some cases. For example in a study by Yen et al of 55 patients whose recurrences were initially considered curable with radical surgical treatment, 27 instead underwent palliative therapy based on PET results. An NCCN Task Force Report on PET also identifies several studies that support use of PET for initial staging and identification and staging of recurrent disease.

**Colorectal Cancer**
Two clinical applications of PET scanning were considered in the TEC Assessment:

1. To detect hepatic or extrahepatic metastases and to assess their resectability in patients with colorectal cancer, either as part of initial staging or after primary resection, and
2. To evaluate the presence of postoperative scar versus recurrent disease as a technique to determine the necessity of tissue biopsy.
The body of evidence indicates that PET scanning adds useful information to conventional imaging in detecting hepatic and extrahepatic metastases. In particular, PET can detect additional metastases leading to more identification of non-resectable disease, allowing patients to avoid surgery. The strongest evidence comes from a study that directly assessed the additional value of PET. In a group of 37 patients thought to have solitary liver metastases by conventional imaging, PET correctly upstaged four patients and falsely overstaged one patient. This study and another further found that, when PET is discordant with conventional imaging, PET is correct in 88% and 97%, respectively, of patients. When PET affects management decisions, it is more often used to recommend against surgery.

When used to distinguish between local recurrence and scar, the comparison is between performing histologic sampling in all patients with a suspected local recurrence and avoiding sampling in patients whose PET scans suggest the presence of postoperative scar. The key concern is whether the negative predictive value for PET is sufficiently high to influence decision making, specifically to avoid tissue biopsy when the PET scan is negative. The available studies suggest a probability of false negative results of 8%, making it unlikely that patients and physicians would be willing to forgo histologic sampling and delay potentially curative repeat resection.

Further support for the indication of staging and detection of recurrence of colon cancer was reviewed in an NCCN review on the use of PET scanning. A rising carcinoembryonic antigen (CEA) level is another indication that may be considered medically necessary.

**Esophageal Cancer**
Regarding initial diagnosis, PET is generally not considered a test for detecting primary esophageal tumors, and evidence is lacking on its use to differentiate between esophageal cancer and benign conditions.

A NCCN Task Force Report found studies showing that PET is more sensitive than other diagnostic imaging in detecting stage IV disease with distant lymph node involvement. A meta-analysis described in the report found a 67% pooled sensitivity, 97% specificity, and small added value after conventional staging in detecting distant metastasis.

Another use of PET in esophageal cancer is in determining whether to continue chemotherapy for potential curative resection. The NCCN Task Force Report describes several studies in which response to chemotherapy as defined as a decline in standardized uptake values (SUV) correlated with long-term survival. Patients who do not respond to chemotherapy may benefit by this test by being spared futile and toxic chemotherapy. However, this treatment strategy of PET-directed chemotherapy does not appear to have been validated with randomized clinical trials showing improved overall health outcomes.

**Head and Neck Cancer**
Among the three studies identified in the TEC Assessment that used other diagnostic modalities to attempt to identify a primary tumor in patients with positive cervical lymph nodes, PET found more primary tumors than other modalities in 2 studies and identified similar proportions in one study.

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*Medical Policy #040*
When data from these three studies are pooled, PET was found to identify tumor in 38% of cases and other modalities found tumor in 21% of cases.

When PET is used to initially stage the cervical lymph nodes (i.e., the status of the cervical nodes is unknown), the addition of PET to other imaging modalities increased the proportion of patients who were correctly staged, as confirmed histologically. When compared head to head with other imaging modalities, the pooled data from a variety of studies suggested that PET had a better diagnostic performance compared to CT and MRI.

Of eight studies focusing on the use of PET to detect residual or recurrent disease, five found PET to be more specific and sensitive, two reported mixed or equivalent results, and one reported worse results compared to CT.

**Lung Cancer**

PET scanning may have a clinical role in patients with solitary pulmonary lung nodules in whom the diagnosis is uncertain after prior CT scan and chest x-ray. Patients who are relatively young and have no smoking history are at a relatively low risk for lung cancer, and in this setting the negative predictive value of a PET scan is relatively high. If presented with a negative PET scan and information about the very low probability of undetected malignancy, it is quite likely that some patients would choose to avoid the harms of an invasive sampling procedure (i.e., biopsy).

In patients with known non-small cell lung cancer, the clinical value of PET scanning relates to improved staging information regarding the involvement of mediastinal lymph nodes, which generally excludes patients from surgical excision. The TEC Assessment cited a decision-analysis study that suggested that the use of CT plus PET scanning in staging the mediastinal lymph nodes resulted in fewer surgeries and an average gain in life expectancy of 2.96 days. The gain in life expectancy suggests that avoidance of surgery was not harmful to the patients in that potentially beneficial surgery was not withheld on the basis of false-positive imaging results.

An NCCN report on the use of PET scanning supports an indication for patients who are suspected to have solitary metastases who may be candidates for surgical resection. In such patients the test may detect additional metastases, which would rule out or change the extent of planned surgery.

Six studies of patients with small cell lung cancer (SCLC) reported evidence suggesting that for non-brain metastases, PET added to conventional staging is more sensitive in detecting disease than conventional staging alone. PET may correctly upstage and downstage disease, and studies reported very high occurrence of patient management changes that were attributed to PET.

However, the quality of these studies is consistently poor, and insufficient detail in reporting was the norm, especially with respect to the reference standard. It is not possible from the limited and poor quality evidence that is available to determine whether the use of PET adds value relative to conventional staging tests for SCLC.
Lymphoma, including Hodgkin’s disease
Of the 14 available studies reviewed in the TEC Assessment, three compared PET with anatomic imaging in initial staging and restaging of patients with Hodgkin’s disease and non-Hodgkin’s lymphoma. Two of these studies included data from both diseased and nondiseased sites for PET and CT. Both studies found PET to have better overall diagnostic accuracy than CT. The third study addressed detection of diseased sites only and found PET to have the same sensitivity as use of CT or MRI. Among the 6 studies that reported on concordance between PET and other imaging modalities, PET was discordant with other modalities in 11% to 50%, PET was correct among discordancces in 40% to 75%. PET has been reported to affect patient management decisions in 8–20% of patients in 5 studies mainly by correctly upstaging disease, but also by correctly downstaging disease. Thus when PET is added to conventional imaging, it can provide useful information for selective effective treatment that is appropriate to the correct stage of disease.

Melanoma
Surgical resection for melanoma is limited to those with local disease. Patients with widespread disease are not candidates for resection. Frequently, there is microscopic spread to the proximal lymph nodes. Therefore, patients with a high risk of nodal spread, as assessed by the thickness of the primary melanoma, may be candidates for lymph node sampling, termed sentinel node biopsy. PET scanning has been investigated both as a technique to detect widespread disease as part of an initial staging procedure, and also to evaluate the status of the local lymph nodes to determine the necessity of sentinel node biopsy.

To consider PET a useful alternative to sentinel node biopsy, it must have high sensitivity and specificity when either sentinel node biopsy or lymph node dissection serves as the reference standard. In the only study of this kind, PET had a sensitivity of only 17%, suggesting that PET rarely detects small metastases that can be discovered by sentinel node biopsy. Thus the TEC Assessment concluded that PET is not as beneficial as sentinel node biopsy in assessing regional lymph nodes.

The intent of using PET to detect extranodal metastases is to aid in selecting treatment appropriate to the patient’s extent of disease. For example, surgical resection is typically not appropriate for widespread disease. A prospective blinded study of 100 patients found that PET was much more sensitive and specific than conventional imaging. Another prospective study of 76 patients found that, compared to CT, PET had much higher sensitivity and equivalent specificity. A third comparative study of 35 patients found that PET was much more sensitive than CT. It may be inferred from these studies that PET was usually correct when discordant with other modalities. PET affects management in approximately 18% of patients.

Ovarian Cancer
For primary evaluation, i.e., in patients with suspected ovarian cancer, the ability to rule out malignancy with a high negative predictive value would change management by avoiding unnecessary exploratory surgery. However, available studies suggest that PET scanning has poorer negative predictive value compared to other options, including transvaginal ultrasound (TVUS), Doppler studies, or MRI. Adding PET scanning to TVUS or MRI did not improve results.
Positive predictive value is of greatest importance in evaluating patients with known ovarian cancer, either to detect disease recurrence or progression or monitor response to treatment. While the 2004 AHRQ systematic review suggested that PET may have value for detecting recurrence when CA125 is elevated and conventional imaging does not clearly show recurrence, this had not been demonstrated in an adequately powered prospective study. A 2008 AHRQ systematic review found that the evidence supported the use of PET/CT in detecting recurrent ovarian cancer. The evidence for initial diagnosis and staging of ovarian cancer was still inconclusive.

**Pancreatic Cancer**

Both the 2004 AHRQ systematic review and the 1999 TEC Assessment focused on two clinical applications of PET scanning in patients with known or suspected pancreatic cancer: the use of PET to distinguish between benign or malignant pancreatic masses, and the use of PET as a staging technique in patients with known pancreatic cancer.

In terms of distinguishing between benign and malignant disease, the gold standard is percutaneous or open biopsy. If PET were to be used to allow patients with scans suggesting benign masses to avoid biopsy, a very high negative predictive value would be required. The key statistic underlying the negative predictive value is the false-negative rate. Patients with false-negative results are incorrectly assumed to have benign disease and are thus not promptly treated for pancreatic cancer. Based on the literature review, the negative predictive value ranged between 75% and 92%, depending on an underlying prevalence of disease ranging from 50–75%. The Assessment concluded that this level of diagnostic performance would not be adequate to recommend against biopsy. The 2004 AHRQ report found that PET was sometimes found to be more accurate than other modalities, but the meta-analysis stated that it is unclear whether PET’s diagnostic performance surpasses decision thresholds for biopsy or laparotomy. (12)

In both the TEC Assessment and AHRQ systematic review, there were inadequate data to permit conclusions regarding the role of PET scanning as a technique to stage known pancreatic cancer.

The AHRQ review published in 2008 and NCCN guidelines on pancreatic carcinoma suggest that PET/CT may be useful for staging in certain patients when the standard staging protocol is inconclusive.

**Prostate Cancer**

Both an NCCN Task Force Report and an AHRQ systematic review do not find sufficient evidence to support use of PET for any indication in patients with prostate cancer. Reports show significant overlap between benign prostatic hyperplasia, malignant tumor, local recurrence, and postoperative scarring. PET may have limited sensitivity in detecting distant metastatic disease. The AHRQ report identified only four studies of PET for the indications of restaging and recurrence, none of which addressed the effect of PET on management decisions.

**Soft Tissue Sarcoma**

A 2002 AHRQ systematic review on use of PET for soft tissue sarcoma evaluated five 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 metastases, and evaluating response to therapy.

The review found that PET has low diagnostic accuracy in distinguishing low-grade tumors from benign lesions. PET performs better at differentiating high- or intermediate-grade tumors from low-grade tumors; however, it is unclear whether this will have an impact on management decisions and health outcomes. Evidence is insufficient on the comparative diagnostic performance of PET and alternative diagnostic modalities in the diagnosis of soft tissue sarcoma, detection of locoregional recurrence, detection of distant metastasis, and evaluating response to therapy.

Testicular Cancer
The 2004 AHRQ systematic review found one prospective study and four retrospective studies that generally showed higher sensitivity and specificity for PET over CT. However these studies were small in size and failed to report separate results for patients with seminoma versus those with non-seminoma. Studies also failed to report separate results by clinical stage of disease. Thus, it is unclear whether this evidence translates to changes in patient management and improved health outcomes.

Studies on distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer were flawed in two main ways. First, most studies did not compare the diagnostic accuracy of PET with other imaging modalities. Second, studies that did compare PET and CT did not state a clear threshold for a positive CT test, making study results difficult to interpret. Therefore, it is uncertain whether use of PET leads to different patient management decisions and health outcomes than other imaging modalities.

An AHRQ technology assessment published in 2008 and studies evaluating residual masses in patients after chemotherapy for seminoma support the use of PET. NCCN guidelines support the use of PET for this indication.

Thyroid Cancer, Differentiated
The NCCN Task Force Report on PET reviewed studies which showed that PET can localize recurrent disease when other imaging tests are negative. In addition, PET is a predictor of prognosis in this setting. More metabolically active lesions on PET are strongly correlated with survival.

Unknown Primary
The 2002 TEC Assessment concluded that the TEC criteria were met for the limited indication of the workup and management of patients with unknown primaries and a single site of metastatic disease. Specifically, local or regional therapy may be offered to these patients. In this setting, PET scanning may be used to verify the absence of disseminated disease.

Regarding this application, the TEC Assessment identified four reports, including a total of 47 patients referred for imaging with a single known metastatic site from an unknown primary. In 13 (28%) of these patients, PET scanning identified previously undetected metastases that were
confirmed by biopsy. Therefore, the use of PET can contribute to optimal decision making regarding the appropriateness of local or regional therapy.

**Cancer Surveillance**
The clinical utility for PET scanning in surveillance, i.e., in performing follow-up PET scans in asymptomatic patients to detect early disease recurrence, is not well-studied. (For this policy, a scan is considered a surveillance scan if performed more than 6 months following therapy, but 12 months for lymphoma.) The most recent NCCN publication indicates, “The use of PET as a surveillance tool should only be used in clinical trials.” In addition, the NCCN guidelines for various malignancies often note that PET scans are not recommended in asymptomatic patients. For example the NCCN breast cancer guidelines comment that PET scans (as well as many other modalities) provide no advantage in survival or ability to palliate recurrent disease and are not recommended.

**Other Malignancies**
There are inadequate scientific data to permit conclusions regarding the role of PET scanning in other malignancies.

**September 2012 Update:**

**Lymphoma**
Some single-arm studies that assess outcomes of patients receiving treatment changes based on interim PET/CT scan suggest that some chemotherapeutic regimens can be switched to less-toxic regimes without harm. The conclusions of single-arm studies may be biased by selection and lead-time bias. Imperfect prediction of poor prognosis may lead to some low-risk patients being classified as high risk, improving the group’s survival. Earlier treatment using salvage therapies may result in a lead-time bias, which would also give an apparent survival improvement. Given the potential for selection and lead-time biases, comparative trials would be necessary to determine the efficacy of such a strategy.

In the 2012 update of the NCCN guidelines on Hodgkin lymphoma, several statements were made regarding use of interim PET. For early stage Hodgkin lymphoma (stage I to II favorable disease), interim PET imaging is not considered to be of important prognostic significance. Many patients with positive interim PET, indicating possible nonresponse to therapy, have negative scans at the completion of chemotherapy and a good prognosis.

**Summary**
The utility of PET scanning for the diagnosis and staging of malignancies varies by specific type of cancer. In general, PET scanning can be useful for distinguishing benign from malignant masses in certain circumstances and for increasing the accuracy of staging by detecting additional disease not detected by other imaging modalities. Therefore, PET scanning for diagnosis and staging of malignancies can be considered medically necessary when specific criteria are met for specific cancers, as outlined in the policy statement. For follow-up after the initial diagnosis and staging has been performed, or for tumor surveillance, the clinical utility is uncertain and this use of PET scanning is considered investigational.
Key Words:
PET scans, Positron emission scanning, FDG PET, Sodium Fluoride F-18 (NaF-18)

Approved by Governing Bodies:
In 1997, the U.S. Food and Drug Administration (FDA) Modernization Act (FDAMA) attempted to resolve the controversy regarding positron emission tomography (PET) scans first by establishing FDA authority over the safety and effectiveness of locally manufactured radiotracers and second, by developing streamlined regulations for good manufacturing practices (GMP) with which each PET facility must comply.

The FDA issued a notice in the Federal Register on March 10, 2000, summarizing the regulatory history of PET radiotracers and highlighting its decisions on safety and effectiveness for certain uses of certain PET radiotracers. The FDA conducted a literature review and Advisory Committee meetings to discuss the following uses:
• 18F-FDG for evaluation of glucose metabolism in oncology
• 18F-FDG for evaluation of myocardial hibernation
• 13N-ammonia for evaluation of myocardial blood flow
• 15O-water for assessment of cerebral perfusion

However, only the first three of these were subsequently approved by the FDA. There have been no additional approvals specific to oncologic PET.

A draft guidance document for Current Good Manufacturing Practice (CGMP) requirements was issued on April 1, 2002; though as of October 2003, regulatory procedures had not yet been finalized.

An FDA web page includes various PET-related documents: available online at:
www.fda.gov/cder/regulatory/PET

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan.

Pre-certification requirements: Effective for dates of service on or after November 1, 2007, required when ordered by a provider in a Blue Cross and Blue Shield of Alabama’s Preferred or Participating Network for a patient covered by Blue Cross and Blue Shield of Alabama who will receive outpatient imaging services(s) from a Preferred Medical Doctor (PMD) or Preferred Radiology Participating (PRP) provider.

Exceptions to the Alabama PMD and PRP pre-certification requirement: NASCO, Wal-Mart, Blue Advantage, Flowers Foods, Inc., FEP.
In addition to the above Blue Cross and Blue Shield of Alabama PMD/PRP Network requirement, some self-insured national account groups may require pre-certification for all MRIs effective for dates of service on or after January 1, 2009. Please confirm during your benefit verification process if a pre-certification is required.

**Current Coding:**

**CPT codes:**

78608  Brain imaging, positron emission tomography (PET); metabolic evaluation

78811  Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)

78812  Positron emission tomography (PET) imaging; skull base to mid-thigh

78813  Positron emission tomography (PET) imaging; whole body

78814  Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)

78815  Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh

78816  Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

**HCPCS codes:**

A9580  Sodium Fluoride F-18, Diagnostic, Per Study Dose, Up To 30 Millicuries

G0125  PET imaging regional or whole body; single pulmonary nodule

G0210  PET imaging, whole body; full and partial ring PET scanners only, diagnosis; lung cancer; non-small cell

G0211  PET imaging, whole body; full and partial ring PET scanners only, initial staging; lung cancer; non-small cell (replaced G0126)

G0212  PET imaging, whole body; full and partial ring PET scanners only, re-staging; lung cancer; non-small cell

G0213  PET imaging, whole body; full and partial ring PET scanners only, diagnosis; colorectal cancer

G0214  PET imaging, whole body; full and partial ring PET scanners only, initial staging; colorectal cancer

G0215  PET imaging, whole body; full and partial ring PET scanners only, re-staging, colorectal cancer (replaced G0163)

G0216  PET imaging, whole body, full and partial ring PET scanners only, diagnosis; melanoma

G0217  PET imaging, whole body; full and partial ring PET scanners only, initial staging, melanoma

G0218  PET imaging, whole body; full and partial ring PET scanners only, re-staging, melanoma (replaced G0165)
G0219  PET imaging whole body; melanoma for non-covered indications
G0220  PET imaging, whole body; full and partial ring PET scanners only, diagnosis; lymphoma
G0221  PET imaging, whole body; full and partial ring PET scanners only, initial staging; lymphoma (replaced G0164)
G0222  PET imaging, whole body; full and partial ring PET scanners only, re-staging lymphoma (replaced G0164)
G0223  PET imaging, whole body or regional; full and partial ring PET scanners only, diagnosis; head and neck cancer, excluding thyroid and CNS cancers
G0224  PET imaging, whole body or regional; full and partial ring PET scanners only, initial staging; head and neck cancer, excluding thyroid and CNS cancers
G0225  PET imaging, whole body or regional; full and partial ring PET scanners only, re-staging; head and neck cancer, excluding thyroid and CNS cancers
G0226  PET imaging, whole body; full and partial ring PET scanners only, diagnosis; esophageal cancer
G0227  PET imaging, whole body; full and partial ring PET scanners only, initial staging; esophageal cancer
G0228  PET imaging, whole body; full and partial ring PET scanners only, re-staging; esophageal cancer
G0231  PET, whole body, for recurrence of colorectal or colorectal metastatic cancer; gamma cameras only
G0232  PET, whole body, for staging and characterization of lymphoma; gamma cameras only
G0233  PET, whole body, for recurrence of melanoma or melanoma metastatic cancer; gamma cameras only
G0234  PET, regional or whole body, for solitary pulmonary nodule following CT or for initial staging of pathologically diagnosed non-small cell lung cancer; gamma cameras only
G0235  PET imaging, any site, not otherwise specified
G0252  PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes), not covered by Medicare
G0253  PET imaging for breast cancer, full and partial ring PET scanners only, detection of local regional recurrence or distant metastases, i.e., staging/re-staging after or prior to course of treatment
G0254  PET imaging for breast cancer, full and partial-ring PET scanners only, evaluation of responses to treatment, performed during course of treatment

References:


18. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography to Manage Patients with an Occult Primary Carcinoma and Metastasis outside the Cervical Lymph Nodes. TEC Assessments 2002; Volume 17, Tab 14.


42. Empire Medicare New Jersey Policy X-29J. Positron emission tomography (PET) scans. Empire Medicare Services Local Medical Review Policy.


53. Gennari A, Donati S, Salvadori B, Giogetti A, et al. Role of 2-[18F]-fluordeoxyglucose (FDG) positron emission tomography (PET) in the early assessment of response to


102. Multiple Myeloma, NCCN Clinical practice guidelines on oncology v. 1:2006


139. Spaepen K, Stroobants S, Dupont P, et al. Prognostic value of positron emission tomography (PET) with fluorine – 18 fluorodeoxyglucose ([18] FDG) after first line...


142. Stark P. Computed tomographic and positron emission tomographic scanning of pulmonary nodules.


Policy History:
Medical Review Committee, March 1996
Medical Policy Group, April 1998
Medical Policy Group, July 1998
Medical Policy Group, January 2000
TEC, August 2000
Medical Policy Group, September 2000
Medical Review Committee, September 2000
TEC, 2001
Medical Policy Group, February 2001
MPRM, February 2002
Medical Policy Group, March 2002
Medical Policy Group, April 2002
Available for Comment May 1-June 14, 2002
Medical Policy Group, July 2002
Medical Policy Group, August 2002
Medical Policy Administration Committee, August 2002
Medical Policy Group, September 2002
Medical Policy Administration Committee, September 2002
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Medical Policy Group, November 2002
Medical Policy Administration Committee, November 2002
Available for comment November 19, 2002-January 3, 2003
Medical Policy Group, January 2006 (2)
Medical Policy Administration Committee, February 2006
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Medical Policy Administration Committee, April 2006
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Medical Policy Group, June 2006 (2)
Medical Policy Administration Committee, July 2006
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Medical Policy Administration Committee, February 2007
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Medical Policy Administration Committee, April 2007
Available for comment April 20-June 4, 2007
This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.