BlueCross BlueShield of Louisiana

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Positron Emission Tomography (PET) Oncology Applications

Policy # 00105
Original Effective Date: 01/28/2002
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Cardiac applications of positron emission tomography (PET) scanning are considered in medical policy 00103.

Note: Miscellaneous applications of positron emission tomography (PET) scanning are considered in medical policy 00104.

Note: This policy only addresses the use of radiotracers detected with the use of dedicated PET scanners. Radiotracers such as fluorodeoxyglucose (FDG) may be detected using single photon emission computed tomography (SPECT) cameras, a hybrid PET/SPECT procedure that may be referred to as FDG-SPECT or molecular coincidence.

For this policy, PET scanning is discussed for the following four 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 two 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.

Coverage Eligibility
The following apply to the listed oncologic applications of PET scanning:

Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

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Based on review of available data, the Company considers the use of PET scans for oncology applications to be either **eligible for coverage** or **investigational*** as indicated below:

Bone Cancer

Eligible for Coverage

Staging When used in the staging of Ewing sarcoma and osteosarcoma may be **eligible for coverage.**

Investigational

Staging When used in the staging of chondrosarcoma is considered **investigational.***

Brain Cancer

Eligible for Coverage

Diagnosis When utilized to differentiate scar tissue or tumor necrosis from active disease following radiation or chemotherapy the use of PET scanning may be **eligible for coverage.**

Investigational

Diagnosis When used for diagnosis (other than described above) PET scanning is considered **investigational.***

Staging When used for staging of brain cancer PET scanning is considered **investigational.***

Restaging When used for restaging of brain cancer PET scanning is considered **investigational.***

Breast Cancer

Eligible for coverage

Staging When used in the staging of breast cancer may be **eligible for coverage** for the following application:

- Detecting locoregional or distant recurrence or metastasis (except axillary lymph nodes).

Restaging When used in restaging breast cancer may be **eligible for coverage** for the following application:

- Detecting locoregional or distant recurrence or metastasis (except axillary lymph nodes).

Investigational

All other applications of PET scans in the evaluation of breast cancer are considered **investigational*** including, but not limited to, the following:

- Differential diagnosis in patients with suspicious lesions or an indeterminate/ low suspicion on mammography;
- Staging axillary lymph nodes.

Cervical Cancer

Eligible for Coverage

Staging When used in the staging of cervical cancer PET scans may be **eligible for coverage.**

Restaging When used in the restaging of cervical cancer PET scans may be **eligible for coverage.**

PET scanning in the evaluation of known or suspected recurrence of cervical cancer may be **eligible for coverage.**

Colorectal Cancer

Eligible for Coverage

Diagnosis When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- Avoiding an invasive diagnostic procedure, or
- Determining the optimal anatomical location to perform an invasive diagnostic procedure.

Staging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- To detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer; or
- Cancer stage remains in doubt after completion of a standard diagnostic workup; or
- PET 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 patient, or
- Clinical management would differ depending on the cancer stage.

Restaging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- To detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer; or
- Detecting residual disease (after completion of treatment), or
- Detecting suspected recurrence (example: rising carcinoembryonic antigen [CEA] levels; clinical signs/symptoms suspicious for recurrence); or
- Determination of the extent of known recurrence.

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Investigational

Differentiation When used as a technique to assess the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer PET scanning is considered **investigational.***

Esophageal Cancer

Eligible for Coverage

Diagnosis When PET results may assist in the following situations PET scanning may be **eligible for coverage:**

- To avoid an invasive diagnostic procedure; or
- To determine the optimal anatomical location to perform an invasive diagnostic procedure.

Staging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- Staging of esophageal cancer; or
- Staging of esophageal cancer when the stage of the cancer remains in doubt after completion of a standard diagnostic workup.

Restaging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- Restaging after the completion of treatment; or
- Detection of residual disease, suspected recurrence, or to determine the extent of a known recurrence.

Investigational

Diagnosis When used in the evaluation and detection of primary esophageal cancer PET scanning is considered **investigational.***

Head and Neck Cancers (excluding CNS and Thyroid)

Eligible for Coverage

Diagnosis When PET results may assist in the following situation PET scanning may be **eligible for coverage**:

- In the evaluation of head and neck cancer in the diagnosis of suspected cancer.

Staging When PET results may assist in the following situation PET scanning may be **eligible for coverage**:

- In the evaluation of head and neck cancer in the initial staging of disease.

Restaging When PET results may assist in the following situation PET scanning may be **eligible for coverage**:

- In the evaluation of head and neck cancer in the restaging of residual or recurrent disease during follow-up.

Investigational
When used for applications not discussed above, PET scanning for the evaluation of head and neck cancer is considered **investigational***.

Lung Cancer/Solitary Pulmonary Nodule

Eligible for Coverage

Diagnosis When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- Solitary Pulmonary Nodule - In patients with a solitary pulmonary nodule to distinguish between benign and malignant disease when prior CT and chest x-ray findings are inconclusive or discordant; or
- Lung Cancer - To determine resectability for patients with a presumed solitary metastatic lesion from lung cancer; or
- Lung Cancer -To distinguish between benign and malignant disease when prior CT scan and chest x-ray findings are inconclusive or discordant.

Staging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- In clinical situations in which the stage of cancer remains in doubt after completion of a standard diagnostic workup; or
- As staging technique in those with known non-small cell lung cancer.

Restaging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- As a restating technique in those with known non-small cell lung cancer; or
- For restaging after the completion of treatment; or
- For the purpose of detecting residual disease; or
- For detecting suspected recurrence; or
- To determine the extent of a known recurrence.

Investigational

Staging When used as a technique in the staging of small cell lung cancer PET scanning is **investigational.***

Lymphoma, including Hodgkin's Disease

Eligible for Coverage

Diagnosis Only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal

anatomical 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. Positron emission tomography scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma should be rare.

Staging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- For staging lymphoma during initial staging; or
- In clinical situations in which the stage of the cancer remains in doubt after completion of a standard diagnostic workup.

Restaging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- For restaging at follow-up; or
- For the purpose of detecting residual disease; or
- For detecting suspected recurrence; or
- To determine the extent of a known recurrence; or
- For restaging after the completion of treatment.

Investigational
When used for applications not discussed above, PET scanning for the evaluation of lymphoma is considered **investigational***.

Melanoma
Eligible for Coverage

Diagnosis When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- Only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical 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. Positron emission tomography scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of melanoma should be rare; or
- As a technique for assessing extranodal spread of malignant melanoma at initial staging.

Restaging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- For assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment; or

- For the purpose of detecting residual disease; or
- For detecting suspected recurrence; or
- To determine the extent of a known recurrence.

Investigational
When used for applications not discussed above PET scanning for the evaluation of melanoma is considered **investigational.***

When used as a technique in the evaluation of regional nodes PET scanning is considered **investigational.***

Multiple Myeloma
Eligible for Coverage
Staging

- To assess extent of disease at time of diagnosis

Restaging

- Restaging after completion of treatment
- Detection of residual disease, suspected recurrence, or to determine the extent of a known recurrence.

Ovarian Cancer
Eligible for Coverage
Diagnosis When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- Avoiding an invasive diagnostic procedure, or
- Determining the optimal anatomical location to perform an invasive diagnostic procedure.

Staging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- For staging ovarian cancer during initial staging; or
- In clinical situations in which the stage of the cancer remains in doubt after completion of a standard diagnostic workup.

Restaging When PET results may assist in the following situations PET scanning may be **eligible for coverage**:

- For restaging at follow-up; or
- For the purpose of detecting residual disease; or
- For detecting suspected recurrence; or
- To determine the extent of a known recurrence; or

- For restaging after the completion of treatment.

Pancreatic Cancer

Eligible for Coverage

Diagnosis When used as a technique in the initial diagnosis of pancreatic cancer when other imaging and biopsy are inconclusive PET scanning may be **eligible for coverage.**

Staging When used as a technique for staging of pancreatic cancer when other imaging and biopsy are inconclusive PET scanning may be **eligible for coverage.**

Investigational

When used as a technique to evaluate other aspects of pancreatic cancer PET scanning is considered **investigational.***

Prostate Cancer

Investigational

Diagnosis When used in diagnosis and management of known or suspected prostate cancer PET scanning is considered **investigational***.

Soft Tissue Sarcoma

Investigational

PET scanning 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; or
- Distinguishing between low grade and high grade soft tissue sarcoma; or
- Detecting locoregional recurrence; or
- Detecting distant metastasis.

Testicular Cancer

Eligible for Coverage

Restaging When used as a technique in evaluation of residual mass following chemotherapy of stage IIB and III seminomas PET scanning may be **eligible for coverage**.

Note: The PET scan should be completed not sooner than 6 weeks following chemotherapy.

Investigational

Except as noted above for seminoma, PET scanning is **investigational*** in evaluation of testicular cancer, including but not limited to the following applications:

- Initial staging of testicular cancer; or

- Distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer; or
- Detection of recurrent disease after treatment of testicular cancer.

Thyroid Cancer, Differentiated

Eligible for Coverage

Diagnosis When used as a technique in the diagnosis of patients with differentiated thyroid cancer when thyroglobulin (Tg) levels are elevated and whole-body I-131 imaging is negative PET scanning may be **eligible for coverage**

Restaging When used as a technique for restaging patients with differentiated thyroid cancer when thyroglobulin (Tg) levels are elevated and whole-body I-131 imaging is negative PET scanning may be **eligible for coverage**

Investigational

When used as a technique in the evaluation of known or suspected differentiated thyroid cancer in all other situations PET scanning is considered **investigational.***

Unknown Primary

Eligible for Coverage

Diagnosis When used in patients with an unknown primary who meet all of the following criteria PET scanning may be **eligible for coverage:**

- 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
- 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.

Investigational

Diagnosis PET scanning is considered **investigational*** in evaluation of unknown primary, including but not limited to the following applications:

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

Cancer Surveillance

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

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Other Oncologic Applications
PET scanning for other oncologic applications is considered **investigational*.**

Background/Overview

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

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, some tracers must be made locally using an onsite cyclotron. The radiotracer most commonly used in oncology imaging has been fluorine-18 coupled with FDG, which has a metabolism related to glucose metabolism. Fluorodeoxyglucose has been considered 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.

As with any imaging technique, the medical necessity of PET scanning depends in part on what imaging techniques are used either before or after the PET scanning. Due to its expense, PET scanning is typically considered after other techniques, such as CT, magnetic resonance imaging (MRI) or ultrasonography (US) provide inconclusive or discordant results. In patients with melanoma or lymphoma, PET scanning may be considered an initial imaging technique. If so, the medical necessity of subsequent imaging during the same diagnostic evaluation is unclear.
The patient selection criteria for PET scanning may also be complex. For example, it may be difficult to determine from claims data whether a PET scan in a patient with malignant melanoma is being done primarily to evaluate extranodal disease or the regional lymph nodes. Similarly, it may be difficult to determine whether a PET scan in a patient with colorectal cancer is being performed to detect hepatic disease or evaluate local recurrence.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In 1997, the U.S. FDA Modernization Act (FDAMA) attempted to resolve the controversy regarding 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:

- ^{18}F-FDG for evaluation of glucose metabolism in oncology
- ^{18}F-FDG for evaluation of myocardial hibernation
- ^{13}N-ammonia for evaluation of myocardial blood flow

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- ^{15}O-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.

Centers for Medicare and Medicaid Services (CMS)
Medicare has issued a detailed medical policy regarding oncologic applications of PET scans, which requires documentation on what tests come before and after the PET scan.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 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 2 TEC Assessments from 2001 and 2003, a systematic review from 2005, a systematic review from 2007, and a cost-effectiveness analysis from 2005. In the Assessments, PET scanning was considered an adjunct to other imaging methods (i.e., CT, MRI, and US) 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, 3 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. An 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 (20) 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: 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 4 patients and falsely overstaged 1 patient. This study and another further found that, when PET is discordant with conventional imaging, PET is correct in 88% and 97% 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 histological 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.

Esophageal Cancer

Regarding 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.

Regarding staging, 9 studies addressed staging of locoregional lymph nodes. Given concerns about study quality and inconsistent results, the available evidence on locoregional lymph nodes was considered inadequate to support conclusions about this application of PET scanning. While the studies on detection of distant disease suggest better diagnostic performance for PET over CT, the available body of evidence is small. Only 1 study clearly avoided verification bias, only 1 clearly interpreted PET blind to the reference standard, and none clearly interpreted the reference standard blind to PET. A 2002 decision analysis found that PET used along with endoscopic ultrasound achieved a higher number of quality-adjusted life-years (QALYs) than 5 other diagnostic strategies; however, it did not address the potential impact of study quality concerns on estimates of the relative diagnostic accuracy of different imaging modalities. Thus, the findings of the decision analysis are in question.

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Regarding evaluation of treatment response, the 2001 TEC Assessment identified only 1 small study of 14 patients. While PET found evidence of response not shown on CT, these data are insufficient to permit conclusions regarding the value of PET in evaluating response to treatment. A 2005 systematic review and meta-analysis compared CT, endoscopic ultrasound, and FDG PET for assessing response to neoadjuvant therapy. It found 7 PET studies, 4 of which provided diagnostic accuracy data. While the report suggested that PET has better diagnostic accuracy than CT, findings were based on 4 small studies, none of which made direct comparisons between PET and CT. The authors also did not address the influence of study quality characteristics on diagnostic accuracy. Furthermore, whether neoadjuvant therapy is beneficial for esophageal cancer is still under investigation, so this report does not demonstrate that use of PET in assessing response to neoadjuvant therapy improves health outcomes.

Head and Neck Cancer
Among the 3 studies 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 1 study. When data from these 3 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 8 studies focusing on the use of PET to detect residual or recurrent disease, 5 found PET to be more specific and sensitive, 2 reported mixed or equivalent results, and 1 reported worse results compared to CT.

Lung Cancer
Positron emission tomography 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.

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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. Positron emission tomography 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, 3 compared PET with anatomic imaging in initial staging and restaging of patients with Hodgkin's disease (HD) 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 discordances in 40% to 75%. Positron emission tomography 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. Positron emission tomography 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. Positron emission tomography affects management in approximately 18% of patients.

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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 2 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.
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 4

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 5 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 1 prospective study and 4 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 2 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.

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Regarding this application, the TEC Assessment identified 4 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.

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 eligible for coverage when specific criteria are met for specific cancers, as outlined in the coverage 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.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Oncologic Applications of PET Scanning", 6.01.26, 2:2014.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography for Non-CNS Cancers. TEC Assessments 1997; Volume 12, Tab 2.
3. Seidenfeld J, Samson D, Aronson N. Management of Small Cell Lung Cancer. Evidence Report. Publication No. 06-E016. Rockville, MD: Agency for Healthcare Research and Quality. July 2006.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography in Melanoma. TEC Assessments 1999; Volume 14, Tab 27.
5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography in Lymphoma. TEC Assessment 1999; Volume 14, Tab 26.
6. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography in Colorectal Cancer. TEC Assessments 1999; Volume 14, Tab 25.
7. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography in Head and Neck Cancer. TEC Assessments 2000; Volume 15, Tab 4.
8. 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.

9. Wallace MB, Nietert PJ, Earle C et al. An analysis of multiple staging management strategies for carcinoma of the esophagus: Computed tomography, endoscopic ultrasound, positron emission tomography, and thoracoscopy/laparoscopy. Ann Thorac Surg 2002; 74(4):1026-32.
10. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography for Evaluating Esophageal Cancer. TEC Assessments 2001; Volume 16, Tab 21.
11. Westerterp M, van Westreenen HL, Hoekstra OS et al. Esophageal cancer: CT, endoscopic US, and FDG PET for assessment of response to neoadjuvant therapy – systematic review. Radiology 2005; 236(3):841-51.
12. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography in Pancreatic Cancer. TEC Assessments 1999; Volume 14, Tab 28.
13. Matchar DB, Kulasingam SL, Havrilesky L. Positron Emission Testing for Six Cancers (Brain, Cervical, Small Cell Lung, Ovarian, Pancreatic and Testicular), (Technology Assessment). Rockville, MD: Agency for Healthcare Research and Quality. February 2004.
14. Ioannidis JPA, Lau J. FDG-PET for the Diagnosis and Management of Soft Tissue Sarcoma (Technology Assessment). Rockville, MD: Agency for Healthcare Research and Quality. April 2002.
15. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Positron Emission Tomography in Breast Cancer. TEC Assessments 2001; Volume 16, Tab 5.
16. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG Positron Emission Tomography for Evaluating Breast Cancer. TEC Assessments 2003; Volume 18, Tab 14.
17. Isasi CR, Moadel RM, Blaufox D. A meta-analysis of FDG-PET for the evaluation of breast cancer recurrence and metastases. Br Cancer Res Treatment 2005; 90(2):105-12.
18. Sloka JS, Hollett PD, Mathews M. Cost-effectiveness of positron emission tomography in breast cancer. Mol Imaging Biol 2005; 7(5):351-60.
19. Sloka JS, Hollett PD, Matthews M. A quantitative review of the use of FDG-PET in the axillary staging of breast cancer. Med Sci Monit 2007; 13(3):RA37-RA46.
20. Podoloff DA, Advani RH, Allred C et al. NCCN task force report: positron emission tomography (PET)/computed tomography (CT) scanning in cancer. J Natl Compr Canc Netw 2007; 5(suppl 1):S1-22.
21. Podoloff DA, Ball DW, Ben-Josef E et al. NCCN task force: clinical utility of PET in a variety of tumor types. J Natl Compr Canc Netw 2009; 7(suppl 2):S1-26.
22. Ospina MB, Horton J, Seida J et al. Positron emission tomography for nine cancers (bladder, brain, cervical, kidney, ovarian, pancreatic, prostate, small cell lung, testicular). Technology Assessment Report Project ID: PETC1207. Agency for Healthcare Research and Quality. December 2008.
23. Treglia G, Salsano M, Stefanelli A et al. Diagnostic accuracy of (18) F-FDG-PET and PET/CT in patients with Ewing sarcoma family tumours: a systematic review and a meta-analysis. Skeletal Radiol 2012; 41(3):249-256.
24. Völker T, Denecke T, Steffen I et al. Positron emission tomography for staging of pediatric sarcoma patients: results of a prospective multicenter trial. J Clin Oncol 2007; 25(34):5435-41.
25. Yen TC, See LC, Chang TC et al. Defining the priority of using 18F-FDG PET for recurrent cervical cancer. J Nucl Med 2004; 45(10):1632-9.
26. Becherer A, De Santis M, Karanikas G et al. FDG PET is superior to CT in the prediction of viable tumour in post-chemotherapy seminoma residuals. Eur J Radiol 2005; 54(2):284-8.
27. Testicular Cancer. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. V.1.2010. Available online at: http://www.nccn.org/professionals/physician_gls/PDF/testicular.pdf .
28. Breast Cancer. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. V.1.2010. Available online at: http://www.nccn.org/professionals/physician_gls/PDF/breast.pdf .
29. CMS National Coverage Decision (April 2009). Available online at: http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=218& .

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	78811, 78812, 78813, 78814, 78815, 78816
HCPCS	A9552, A9580, G0219, G0235, G0252
ICD-9 Diagnosis	140.0 thru 140.9, 150.0 thru 150.9, 160.0 thru 162.9, 170.0 thru 172.9, 174.0 thru 175.9, 180.0 thru 180.9, 183.0, 186.0 thru 186.9, 193, 195.0, 197.0, 201.0 thru 201.9, 202.0 thru 202.8
ICD-9 Procedure	92.01, 92.02, 92.03, 92.04, 92.05, 92.09

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10/18/2001	Medical Policy Committee review
11/12/2001	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy
10/05/2004	Medical Director review
12/14/2004	Medical Policy Committee review. Format revision. Coverage eligibility criteria for Unknown Primary and Thyroid Cancer added.
01/31/2005	Managed Care Advisory Council approval
07/19/2005	Omission corrected: Melanoma, Staging and Restaging for the purpose of detecting disease was corrected to reflect policy intent: “for the purpose of detecting residual disease”.
10/10/2005	Medical Director review
10/18/2005	Medical Policy Committee review. Format revision. Coverage eligibility criteria for Thyroid Cancer updated and Cervical Cancer added.
10/27/2005	Quality Care Advisory Council approval
12/20/2005	Medical Policy Committee review. Coverage eligibility coverage changes: The terms Staging and Restaging have been substituted for “differentiation” for Colorectal Cancer indications. Use of PET in the restaging of colorectal cancer was added; “To detect recurrence of colorectal cancer in patients with rising CEA levels and/or in patients who present with signs and symptoms of recurrence”. Appendix 1 Table 1 removed from the policy.
02/23/2006	Quality Care Advisory Council approval

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08/09/2006 Medical Policy Committee approval. PET for follicular and papillary thyroid cancer is now eligible for coverage to detect recurrent thyroid cancer or metastasis when Tg and 131 scans are non-diagnostic.
12/06/2006 Medical Director review
12/20/2006 Medical Policy Committee approval. Coverage eligibility updated:

Breast Cancer changed from:

Diagnosis
- *in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical 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 and/or Restaging
- *in clinical situations in which the stage of the cancer remains in doubt after completion of standard diagnostic workup or for restaging after the completion of treatment; or*
- *for the purpose of detecting residual disease; or*
- *for detecting suspected recurrence; or*
- *to determine the extent of a known recurrence.*

Changed To:

Staging (before any treatment)
- *As an adjunct to standard imaging modalities in the staging of breast cancer with distant metastases, excluding staging of axillary lymph nodes.*
- *Restaging (after treatment has been completed)*
- *As an adjunct to standard imaging in the restaging of loco-regional recurrence or metastases*

Treatment Response Monitoring
- *For women with locally advanced and metastatic breast cancer, when a change in therapy is anticipated.*

Colorectal Cancer changed from:

Diagnosis
- *as a technique to detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer.*

Restaging
- *to assess the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer.*
- *to detect recurrence of colorectal cancer in patients with rising CEA levels and/or in patients who present with signs and symptoms of recurrence.*

Changed To:

Diagnosis-when PET results may assist in
- *Avoiding an invasive diagnostic procedure, or*
- *Determining the optimal anatomical location to perform an invasive diagnostic procedure*
- *The diagnosis has not been confirmed by tissue biopsy*

Staging
- *The cancer stage remains in doubt after completion of a standard diagnostic workup.*
- *PET 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 patient, or*
- *Clinical management would differ depending on the cancer stage*

Restaging for the purpose of
- *Detecting residual disease (after completion of treatment),or*
- *Detecting suspected recurrence (ex: rising CEA levels; clinical signs/symptoms suspicious for recurrence)*
- *Determination of the extent of known recurrence*

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	Potentially replacing one or more conventional imaging studies, when it is expected that information from these studies will be insufficient for clinical management of the patient.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. No change to coverage eligibility. Decided not to differentiate between small cell and non small cell lung cancer.
08/06/2008	Medical Director review
08/20/2008	Medical Policy Committee approval. No change to coverage eligibility.
08/06/2009	Medical Policy Committee approval
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
01/01/2010	Coding revision
08/05/2010	Medical Policy Committee review
08/18/2010	Medical Policy Implementation Committee approval. Coverage eligibility extensively updated.
12/08/2011	Medical Policy Committee review
12/21/2011	Medical Policy Implementation Committee approval. Revised the ovarian cancer coverage so that diagnosis, staging and restaging is covered for certain situations.
12/06/2012	Medical Policy Committee review
12/19/2012	Medical Policy Implementation Committee approval. Added that bone cancer in the staging of Ewing Sarcoma and osteosarcoma may be eligible for coverage, but is investigational in the staging of chondrosarcoma. Reworded the eligible for coverage statements for breast cancer. Added that PET scanning may be eligible for coverage in the evaluation of known or suspected recurrence of cervical cancer. Reworded coverage for head and neck cancer to be more liberal. Prostate cancer given a separate section as investigational. All other oncologic applications are remain investigational, but examples of some investigational applications were removed.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Added coverage for staging and restaging of multiple myeloma.
05/01/2014	Medical Policy Committee review
05/21/2014	Medical Policy Implementation Committee approval. Deleted “when suspicion of disease is high and other imaging is inconclusive” from the Eligible for Coverage statements for breast cancer staging and restaging.

Next Scheduled Review Date: 05/2015

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B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

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A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

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