Medical Policy

BlueCross BlueShield Kansas
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Title: PET Scanning- Oncologic Applications (Brain, Melanoma, Unknown Primary)

Related Policies:	▪ *PET Scanning- Oncologic Applications (Breast and Gynecologic)* ▪ *PET Scanning- Oncologic Applications (Bone and Sarcoma)* ▪ *PET Scanning- Oncologic Applications (Hematologic)* ▪ *PET Scanning- Oncologic Applications (Lung)* ▪ *PET Scanning- Oncologic (Thyroid, Neuroendocrine, Head and Neck)* ▪ *PET Scanning- Oncologic Applications (Genitourinary)* ▪ *PET Scanning- Oncologic Applications (Gastrointestinal and Pancreatic)* ▪ *PET Scanning: Cardiac Applications* ▪ *PET Scanning: In Oncology to Detect Early Response during Treatment* ▪ *PET Scanning: Miscellaneous (Non-cardiac, Non-oncologic) Applications of Fluorine 18 Fluorodeoxyglucose*

Professional / Institutional
Original Effective Date: October 1, 1997 / September 11, 2004
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Populations	Interventions	Comparators	Outcomes
Individuals: • With diagnosed brain tumor and in need of staging or restaging information	Interventions of interest are: • 18F-FDG-PET • 18F-FET-PET • 11C-methionine PET	Comparators of interest are: • Conventional imaging techniques	Relevant outcomes include: • Test validity
Individuals: • With suspected brain tumor or who are asymptomatic after completing brain tumor treatment	Interventions of interest are: • 18F-FDG-PET • 18F-FET-PET • 11C-methionine PET	Comparators of interest are: • Conventional imaging techniques	Relevant outcomes include: • Test validity
Individuals: • With suspected or diagnosed stage I or II melanoma and in need of staging or restaging information	Interventions of interest are: • ^{18}F-FDG-PET or ^{18}F-FDG-PET/CT	Comparators of interest are: • Conventional imaging techniques	Relevant outcomes include: • Test validity
Individuals: • With diagnosed advanced melanoma (stage III or IV) and in need of staging or restaging information	Interventions of interest are: • 18F-FDG-PET or ^{18}F-FDG-PET/CT	Comparators of interest are: • Conventional imaging techniques	Relevant outcomes include: • Test validity
Individuals: • Who are asymptomatic after completing melanoma treatment	Interventions of interest are: • ^{18}F-FDG-PET or ^{18}F-FDG-PET/CT	Comparators of interest are: • Conventional imaging techniques	Relevant outcomes include: • Test validity
Individuals: • With cancer of unknown primary and single-site metastatic disease	Interventions of interest are: • ^{18}F-FDG-PET or ^{18}F-FDG-PET/CT	Comparators of interest are: • Conventional imaging techniques	Relevant outcomes include: • Test validity

DESCRIPTION

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

The utility of PET scanning for the diagnosis, staging and restaging, and surveillance of malignancies varies by type of cancer. In general, PET scanning can distinguish benign from malignant masses in certain circumstances and improve 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 statements. For follow-up, after initial diagnosis and staging have been performed, there are a few situations in which PET can improve detection of recurrence, and lead to changes in management that improve the net health outcome.

OBJECTIVE

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

BACKGROUND

A variety of tracers are used for positron emission tomography (PET) scanning, including oxygen 15, nitrogen 13, carbon 11 choline, fluorine 18, gallium 68, fluciclovine 18, and copper 64. 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 fluorodeoxyglucose (FDG), which correlates with glucose metabolism. Fluorodeoxyglucose has been considered useful in cancer imaging because tumor cells show increased metabolism of glucose. The most common malignancies studied have been melanoma, lymphoma, lung, colorectal, and pancreatic cancer.

This evidence review focuses on the use of radiotracers detected with dedicated PET scanners. Radiotracers, such as FDG, may be detected using single-photon emission computerized tomography cameras, a technique that may be referred to as FDG-single-photon emission computerized tomography imaging. The use of single-photon emission computerized tomography cameras for PET radiotracers presents unique issues of diagnostic performance and is not considered herein.

REGULATORY STATUS

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

POLICY

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

B. **Melanoma**
   1. PET scanning may be considered **medically necessary** as a technique for assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment for advanced disease (stage III or IV).
   2. PET scanning is considered **experimental / investigational** in managing stage 0, I, or II melanoma.
   3. PET scanning is considered **experimental / investigational** as a technique to detect regional lymph node metastases in individuals with clinically localized melanoma who are candidates to undergo sentinel node biopsy.

C. **Cancer of Unknown Primary**
   1. PET scanning may be considered **medically necessary** in individuals with a cancer of unknown primary who meet **ALL** of the following criteria:
      a. In individuals with a single site of disease outside the cervical lymph nodes; **AND**
      b. Individuals is considering local or regional treatment for a single site of metastatic disease; **AND**
      c. After a negative workup for an occult primary tumor; **AND**
      d. PET scan will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment.
   2. PET scanning is considered **experimental / investigational** for other indications in individuals with a cancer of unknown primary, including, but not limited to the following:
      a. As part of the initial workup of an unknown primary, and
      b. As part of the workup of individuals with multiple sites of disease

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

POLICY GUIDELINES

A. For this policy, PET scanning is discussed for the following 4 applications in oncology.
   1. Diagnosis
      Diagnosis refers to use of PET as part of the testing used in establishing whether a patient has cancer.
   2. Staging

Staging 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 the cancer is localized. This may also be referred to as initial staging.

3. Restaging
   Restaging refers to imaging after treatment in 2 situations.
   a. Restaging is part of the evaluation of a patient in whom a disease recurrence is suspected based on signs and/or symptoms.
   b. Restaging also includes determining the extent of malignancy after completion of a full course of treatment.
4. Surveillance
   Surveillance refers to the 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 for lymphoma) after completion of treatment.

B. **Patient Selection**

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

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

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

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through October 28, 2024.

The review has been informed by multiple evaluations of positron emission tomography (PET), including systematic reviews, meta-analyses, and decision analyses.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That

is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

POSITRON EMISSION TOMOGRAPHY AND POSITRON EMISSION TOMOGRAPHY PLUS COMPUTED TOMOGRAPHY

Clinical Context and Test Purpose

For this evidence review, PET and PET plus computed tomography (CT) scanning is discussed for the following 4 applications in oncology: diagnosis, staging, restaging, and surveillance. Diagnosis refers to the use of PET as part of the testing used in establishing whether a patient has cancer. Staging refers to the use of PET to determine the stage (extent) of cancer at the time of diagnosis before any treatment is given. Imaging during staging is generally to determine whether the cancer is localized. This also may be referred to as initial staging. Restaging refers to imaging after treatment in 2 situations. First, restaging is part of the evaluation of a patient in whom disease recurrence is suspected based on signs and/or symptoms. Second, restaging also includes determining the extent of malignancy after completion of a full course of treatment. Surveillance refers to the use of imaging in asymptomatic individuals (individuals without objective signs or symptoms of recurrent disease). Surveillance is completed 6 months or more (≥12 months for lymphoma) after completion of treatment.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are:

- Individuals who are suspected of having brain cancer, melanoma, cancer of unknown primary, and single-site metastatic disease.
- Individuals diagnosed with brain cancer, melanoma, cancer of unknown primary, and single-site metastatic disease and need information on the extent of cancer (initial staging upon diagnosis confirmation or restaging following treatment).
- Individuals with brain cancer, melanoma, cancer of unknown primary, and single-site metastatic disease. who have completed a round of treatment and may be at risk of recurrence.

Interventions
The test being considered is PET or PET/CT. A PET scan is a nuclear medicine 3-dimensional imaging technique. Radioactive tracers are ingested or injected, and radioactive emissions are detected by an imaging device, allowing observations on blood flow, oxygen use, and metabolic processes around the lesions. When CT is added to PET, the images are superimposed, providing additional anatomic information. The most common radioactive tracer used for oncologic applications is fluorine 18 (^{18}F) fluorodeoxyglucose (FDG). Radiation exposure from PET and PET/CT is considered moderate to high.

Comparators
The comparators of interest are conventional imaging techniques such as ultrasound, magnetic resonance imaging (MRI), and x-rays.

Outcomes
The general outcomes of interest are related to the clinical validity of PET and PET/CT in (1) diagnosing suspected cancers, (2) providing staging or restaging information, and (3) detecting recurrence following cancer treatment. Clinical validity is most often measured by sensitivity, specificity, positive predictive values (PPV), and negative predictive values (NPV). For the clinical utility of PET and PET/CT to be demonstrated, the tests would need to inform treatment decisions that would improve survival and quality of life.

Clinical validity can be measured as soon as results from PET or PET/CT can be compared with results from conventional imaging techniques. Outcomes for clinical utility are long-term, which, depending on the type of cancer, can range from months or a few years for more aggressive cancers to many years for less aggressive cancers.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess the clinical validity of PET and PET/CT, studies should report sensitivity, specificity, PPV, and NPV. Additionally, studies reporting false-positive rates and false-negative rates are informative.
- To assess the clinical utility of PET and PET/CT, studies should demonstrate how results of these imaging techniques impacted treatment decisions and overall management of the patient.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive correct therapy or more effective therapy, avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Most of the evidence on the use of PET scanning in oncology focuses on clinical validity (sensitivity, specificity), and consists mostly of systematic reviews and meta-analyses. There are few rigorous studies assessing the impact of PET on clinical utility. A few studies that have reported on changes in staging and/or treatment that result from the PET scan do not evaluate whether these changes resulted in improvements in the net health outcome. Due to the lack of direct evidence for clinical utility, evidence for clinical validity is presented first, followed by clinical guidelines, which help to outline the indications for which clinical utility is supported.

REVIEW OF EVIDENCE

BRAIN TUMORS

FDG-PET AND ^{18}F-FET PET

Systematic Reviews
A systematic review and meta-analysis by Dunet et al (2016) included studies published through January 2015 in which individuals with suspected primary or recurrent brain tumors underwent both fluorine 18 fluoro-ethyl-tyrosine PET (^{18}F-FET-PET) and FDG-PET.[1,] Four studies (N =109) met the inclusion criteria. All 4 studies included in the meta-analysis had scores greater than 10 in the 15-point QUADAS tool. The ^{18}F-FET PET (pooled sensitivity, 94%; 95% CI, 79% to 98%; pooled specificity, 88%; 95% CI, 37% to 99%) performed better than FDG-PET (pooled sensitivity, 38%; 95% CI, 27% to 50%; pooled specificity, 86%; 95% CI, 31% to 99%) in the diagnosis of brain tumors. Target to background ratios of both FDG and FET were similar in detecting low- and high-grade gliomas.

A systematic review and meta-analysis by Dunet et al (2012) included studies published through January 2011 and assessed the use of ^{18}F-FET PET in detecting primary brain tumors.[2,] Thirteen studies (N=462) were included in the systematic review and 5 (n=224) were included in the meta-analysis. All 5 studies in the meta-analysis had scores above 10 on the 14-point QUADAS scale. The pooled sensitivity for ^{18}F-FET PET in detecting primary brain tumors was 82% (95% CI, 74% to 88%) and pooled specificity was 76% (95% CI, 44% to 92%). Other imaging modalities for diagnosing brain tumors were not included in this analysis, so no conclusions could be made about comparative effectiveness.

FDG-PET AND ^{11}C-METHIONINE PET

Systematic Reviews
A meta-analysis by Zhao et al (2014) compared the diagnostic performance of FDG-PET with carbon 11 (^{11}C) methionine PET in the detection of suspected primary brain tumors and

suspected recurrence of brain tumors following treatment.[3,] The literature search included studies published through February 2013. A total of 24 studies provided data on the use of FDG-PET and 11 studies reported on the use of ^{11}C-methionine PET. The pooled sensitivity and specificity of FDG-PET in detecting primary or recurrent brain tumors were 71% (95% CI, 63% to 78%) and 77% (95% CI, 67% to 85%), respectively. Diagnostic performance was better with ^{11}C-methionine PET, with a pooled sensitivity and specificity of 91% (95% CI, 85% to 94%) and 86% (95% CI, 78% to 92%), respectively.

In another meta-analysis, Deng et al (2013) assessed the ability of ^{11}C-methionine PET and MRI to detect glioma recurrence.[4,] The literature search included articles through March 2012. All selected studies were retrospective cohorts, 11 using ^{11}C-methionine PET (n=244) and 7 using MRI (n=214). Meta-analyses found that the dynamic susceptibility contrast-enhanced MRI (pooled sensitivity, 88%; 95% CI, 82% to 93%; pooled specificity, 85%; 95% CI, 75% to 92%) performed similarly to ^{11}C-methionine PET (pooled sensitivity, 87%; 95% CI, 81% to 92%; pooled specificity, 81%; 95% CI, 72% to 89%) in glioma recurrence detection, with ^{11}C-methionine being slightly less specific.

Guidelines

Current NCCN guidelines for central nervous system cancers (v.3.2024) include these statements:[5,]

- PET can assess metabolism within the tumor and normal tissue by using radio-labeled tracers, which may be useful in differentiating tumor from radiation necrosis, may correlate with tumor grade, or provide an optimal area for biopsy.
- Limitations include the accuracy of interpretations.
- Close follow-up imaging, MR perfusion, MR spectroscopy, PET/CT imaging, and repeat surgery may be necessary if clinically indicated. Educate patients on the uncertainty of imaging as a whole, and the potential need for corollary testing to interpret scans.

Section Summary: Brain Tumors

Evidence for the use of PET to diagnose and stage brain cancer consists of several systematic reviews and meta-analyses. The diagnostic capabilities of PET vary by radiotracer used. There was a direct comparison of radiotracers, with ^{18}F-FET-PET showing better diagnostic accuracy than FDG-PET. An indirect comparison between FDG-PET and ^{11}C-methionine PET showed that ^{11}C-methionine PET performed better, and another indirect comparison of ^{11}C-methionine PET and MRI showed a comparable diagnostic capability between methods. The evidence supports the use of FDG-PET, ^{18}F-FET-PET, and ^{11}C-methionine PET for the diagnosis and staging and restaging of brain tumors.

The evidence does not support the use of FDG-PET, ^{18}F-FET-PET, and ^{11}C-methionine PET for surveillance of brain tumors.

Melanoma

Surgical resection for melanoma is limited to those with local disease. Individuals with widespread disease are not candidates for resection. Frequently, there is a microscopic spread of cancer cells to the proximal lymph nodes. Therefore, individuals 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*. Use of PET scanning has been investigated both as a

technique to detect the widespread disease as part of an initial staging procedure and to evaluate the status of local lymph nodes to determine the necessity of sentinel node biopsy.

To consider PET as a useful alternative to sentinel node biopsy, it must have high sensitivity and specificity when sentinel node biopsy or lymph node dissection serves as the reference standard.

Systematic Reviews
In a meta-analysis of 9 studies (N=623), Rodriquez Rivera et al (2014) reported pooled sensitivity and specificity of FDG-PET for detecting systemic metastases in individuals with stage III cutaneous melanoma of 89% (95% CI, 65% to 98%) and 89% (95% CI, 77% to 95%), respectively.[6,]

In a systematic review of 17 diagnostic studies (N=1155), Schröer-Günther reported a sensitivity ranging between 68% to 87% and specificity ranging between 92% to 98% for stage III and IV melanoma.[7,] In contrast, for stage I and II melanoma, sensitivity ranged between 0% and 67% and specificity ranged from 77% to 100%, highlighting the limited clinical validity in early-stage disease.

Guidelines
Current NCCN guidelines for cutaneous melanoma (v.3.2024) indicate that PET/CT can be used at baseline in stage IV disease to evaluate for distant metastases.[8,] For stage III disease, cross-sectional imaging, including PET/CT can be consider at baseline (category 2B) or to assess specific signs and symptoms (category 2A). Use of PET/CT is not recommended for stage I or II diseases. Also, PET/CT is listed as an option for surveillance screening for recurrence every 3 to 12 months (category 2B) at the physician's discretion. Because most recurrences occur within the first 3 years, routine screening for asymptomatic recurrence is not recommended beyond 3 to 5 years. The guidelines note that the safety of PET/CT is of concern due to cumulative radiation exposure.

Section Summary: Melanoma
Evidence for the use of FDG-PET/CT in the management of individuals with melanoma consists of a meta-analysis and systematic review. In individuals with melanoma, PET can provide information for staging or restaging in individuals with more advanced disease (stage III or higher). The evidence supports the use of FDG-PET and FDG-PET/CT for the diagnosis and staging and restaging of stage III or IV melanoma.

The evidence does not support the use of FDG-PET and FDG-PET/CT for the diagnosis or staging and restaging of stage I or II melanoma.

The evidence supports the use of FDG-PET and FDG-PET/CT for surveillance of melanoma.

Cancer of Unknown Primary
Burglin et al (2017) conducted a systematic review and meta-analysis on the use of PET/CT for the detection of the primary tumor in individuals with extra cervical metastases.[9,] The literature search identified 20 studies (N=1942) published between 2005 and 2016 for inclusion. The QUADAS tool was used to assess the risk of bias. In regard to patient selection and reference standard, the risk of bias was low; however, the risk of bias was high or unclear for most studies

in regard to flow and timing of the index test. The pooled detection rate was 41% (95% CI, 39% to 43%), with large heterogeneity among the studies.

A larger (N=2795) systematic review conducted by Woo et al (2021) included 38 cohort studies (29 of which were retrospective) published through February 2021 assessing the effect of FDG-PET or FDG-PET/CT on patient management.[10,] Study quality was assessed using the QUADAS-2 tool; no studies were judged low risk of bias for all QUADAS-2 domains. A funnel plot analysis did not reveal publication bias (Egger's test p=.98). In pooled analysis, 35% (95% CI 31% to 40%) of individuals undergoing FDG-PET or FDG-PET/CT imaging had a change in management, although the proportions among the individual studies ranged widely from 0% to 73%, and heterogeneity was high when pooled (I^2=82%). The reason for change in management was detection of the primary cancer site in 22% (95% CI, 19% to 28%) of individuals undergoing imaging, and detection of metastatic site(s) in 14% (95% CI 10% to 19%).

No evidence was identified that evaluated the use of FDG-PET for surveillance of individuals with cancer of unknown primary.

Guidelines
Current NCCN guidelines for occult primary cancers (v.2.2025) state that PET has been useful in the diagnosis, staging, and restaging of many malignancies, so it may be warranted in some situations for cancers of unknown primary.[6,11,] However, the exact role of PET/CT remains undetermined. The guideline does not recommend PET/CT for the initial evaluation of cancers of unknown primary individuals, but notes that it can be useful in certain cases, especially when considering local or regional therapy. NCCN also notes that FDG-PET/CT is an alternative in patients with a contraindication to contrast enhancement.

Section Summary: Cancer of Unknown Primary
The evidence supports the use of FDG-PET and FDG-PET/CT for the diagnosis, staging, and restaging of cancer of unknown primary.

SUPPLEMENTAL INFORMATION
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03116412	A Prospective Randomized Multicenter Trial to Assess the Role of Imaging During Follow up After Radical Surgery of Stage IIb-c and III Cutaneous Malignant Melanoma (TRIM)	1300	Dec 2028

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation
78811	Positron emission tomography (PET) imaging; limited area (e.g. Chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (e.g. chest, head/neck)
78815	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh
78816	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body
A9515	Choline C-11 injection, diagnostic, per study dose up to 20 millicuries
A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
A9580	Sodium fluoride F-18, diagnostic, per study dose, up to 30 millicuries
A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
A9598	Positron emission tomography radiopharmaceutical, diagnostic, for non-tumor identification, not otherwise classified
G0235	PET imaging, any site not otherwise specified

REVISIONS	
Posted 01-28-2025 Effective 02-27-2025	Oncologic Applications Brain, Melanoma, Unknown Primary was originally part of the Positron Emission Tomography (PET) Scanning: Oncologic Applications medical policy. Oncologic Applications for Brain, Melanoma, Unknown Primary has been pulled out and placed into a separate medical policy, Positron Emission Tomography (PET) Scanning: Oncologic Applications (Brain, Melanoma, Unknown Primary). The medical policy language was unchanged.

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