Medical Policy

BlueCross BlueShield Kansas
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Title: PET Scanning- Oncologic Applications (Bone and Sarcoma)

Related Policies:	▪ *PET Scanning- Oncologic Applications (Breast and Gynecologic)* ▪ *PET Scanning- Oncologic Applications (Thyroid, Neuroendocrine, Head and Neck)* ▪ *PET Scanning- Oncologic Applications (Hematologic)* ▪ *PET Scanning- Oncologic Applications (Lung)* ▪ *PET Scanning-* Oncologic *(Brain, Melanoma, Unknown Primary)* ▪ PET *Scanning- Oncologic Applications (Genitourinary)* ▪ *PET Scanning: Cardiac Applications* ▪ *PET Scanning: In Oncology to Detect Early Response during Treatment* ▪ *PET Scanning- Oncologic Applications (Gastrointestinal and Pancreatic)* ▪ *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 suspected or diagnosed bone sarcoma 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: • Who are asymptomatic after completing bone sarcoma 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 diagnosed soft tissue sarcoma 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 soft tissue sarcoma and in need of rapid reading of response to imatinib 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 suspected soft tissue sarcoma or who are asymptomatic after completing soft tissue sarcoma 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

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 determine whether the use of positron emission tomography (PET) for the diagnosis, staging and restaging, and/or surveillance improves the net health outcome in individuals with bone and soft tissue sarcoma cancer.

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 bone or soft tissue sarcoma. Fluorine-18 FDG is approved for use in suspected or existing diagnosis of cancer, all types.

POLICY

A. **Bone Sarcoma**
   1. PET scanning may be considered **medically necessary** in the staging or restaging of Ewing sarcoma and osteosarcoma.
   2. PET scanning is considered **experimental / investigational** in the staging of chondrosarcoma.

B. **Soft Tissue Sarcoma**
   1. PET scanning is considered **medically necessary** for evaluating response to imatinib and other treatments for gastrointestinal stromal tumors
   2. PET scanning is considered **experimental / investigational** in evaluation of soft tissue sarcoma, including but not limited to the following applications:
      a. Distinguishing between benign lesions and malignant soft tissue sarcoma
      b. Distinguishing between low-grade and high-grade soft tissue sarcoma
      c. Detecting locoregional recurrence
      d. Detecting distant metastasis

C. PET scanning is considered **medically necessary** for evaluating response to imatinib and other treatments for gastrointestinal stromal tumors.

POLICY GUIDELINES

Patient Selection

As with any imaging technique, the medical necessity of positron emission tomography (PET) scanning depends in part on what imaging techniques are used before or after the PET scanning. Due to its expense, PET scanning is typically considered after other techniques, such as computed tomography (CT), magnetic resonance imaging (MRI), or ultrasonography, provide inconclusive or discordant results. Thus, PET should be considered for the medically necessary indications above only when standard imaging (eg, CT, MRI) is inconclusive or not indicated. Patient selection criteria for PET scanning may also be complex. Due to the complicated hierarchy of imaging options in individuals with malignancy and complex patient selection criteria, a possible implementation strategy for this policy is its use for retrospective review, possibly focusing on cases with multiple imaging tests, including PET scans.

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

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 September 17, 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 an individual 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 an individual 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 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 bone or soft tissue sarcoma.
- Individuals diagnosed with bone or soft tissue sarcoma and need information on the extent of cancer (initial staging upon diagnosis confirmation or restaging following treatment).
- Individuals with bone or soft tissue sarcoma 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

BONE SARCOMA

Systematic Reviews
A meta-analysis (12 studies, N=375) by Zhang et al (2020) evaluated FDG-PET and FDG-PET/CT in the diagnosis and staging of chondrosarcoma, a common type of bone sarcoma.[1,] Six studies used PET/CT, 5 studies used PET, and 1 study utilized both. For differentiating between chondrosarcoma and benign lesions, the pooled sensitivity and specificity of FDG-PET were 84% (95% CI, 46% to 97%) and 82% (95% CI, 55% to 94%), respectively. The sensitivity and specificity for FDG-PET/CT were also found to be high at 94% (95% CI, 86% to 97%) and 89% (95% CI, 82% to 93%), respectively. There was substantial heterogeneity for sensitivity (I^2, 86.90%; 95% CI, 76.8% to 97.0%) and specificity (I^2, 70.32%; 95% CI, 42.57% to 98.07%) among studies. Most included studies were retrospective (75%) and included small sample sizes (n=7 to 95), potentially introducing bias and variability.

A systematic review and meta-analysis (35 studies, N=2171) by Liu et al (2015) evaluated FDG-PET and FDG-PET/CT in the diagnosis, staging, and recurrence assessment of bone sarcoma.[2,] Most selected studies used PET/CT (n=29). Meta-analyses showed high sensitivity (96%; 95% CI, 93% to 98%) and specificity (79%; 95% CI, 63% to 90%) of FDG-PET and FDG-PET/CT to differentiate primary bone sarcomas from benign lesions. For pooled results for detecting recurrence, sensitivity was 92% (95% CI, 85% to 97%) and specificity was 93% (95% CI, 88% to 96%). For pooled results for detecting distant metastases, sensitivity was 90% (95% CI, 86% to 93%) and specificity was 85% (95% CI, 81% to 87%). Subgroup analysis by specific metastatic site revealed that PET alone was less effective in detecting lung metastases than other

metastatic sites (sensitivity, 71%; 95% CI, 52% to 86%; specificity, 92%; 95% CI, 87% to 96%).

A systematic review (13 studies, N=342) and meta-analysis (5 studies, n=279) by Treglia et al (2012) examined the diagnostic accuracy of FDG-PET and FDG-PET/CT in Ewing sarcoma.[3,] The meta-analysis showed high estimates of sensitivity and specificity for FDG-PET and FDG-PET/CT (pooled sensitivity, 96%; pooled specificity, 92%).

GUIDELINES

American College of Radiology

In 2020, the American College of Radiology (ACR) issued an Appropriateness Criteria for primary bone tumors.[4,] For suspected primary bone tumors with evidence of lesions on radiographs and indeterminate or aggressive appearance for malignancy, FDG-PET/CT of the whole body may be appropriate; MRI of area of interest with or without contrast was deemed usually appropriate. Use of FDG-PET/CT was considered usually not appropriate for other diagnostic and staging imaging procedures addressed in the guidance.

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network (NCCN) guidelines for bone cancer (v.1.2025) state that PET/CT may be considered for:[5,]

- Diagnostic workup of individuals with suspected primary bone cancer, including chordoma, Ewing sarcoma, or osteosarcoma,
- Restaging in individuals with Ewing sarcoma or osteosarcoma, and
- Surveillance of individuals with Ewing sarcoma or osteosarcoma (category 2B).

Section Summary: Bone Sarcoma

Evidence for the use of FDG-PET and FDG-PET/CT for the diagnosis and for the staging and restaging of bone sarcoma consists of systematic reviews and meta-analyses. Pooled analyses have shown that PET is effective in the staging of bone sarcoma, including chondrosarcoma. Use of PET has also shown high sensitivities and specificities in detecting metastases in bone and lymph nodes but low sensitivity in detecting lung metastases. The evidence supports the use of FDG-PET and FDG-PET/CT for the diagnosis, staging, and restaging of bone sarcoma.

The evidence does not support the use of FDG-PET and FDG-PET/CT for surveillance of bone sarcoma.

SOFT TISSUE SARCOMA

Systematic Reviews

A systematic review by Treglia et al (2012) evaluated PET for assessing response to imatinib and other treatments for gastrointestinal stromal tumors.[6,] Reviewers included 19 studies. They concluded there was sufficient evidence that PET/CT can be used to monitor response to imatinib treatment, and that the information can be used to adapt treatment strategies. However, the review had the following limitations: it lacked appraisal of the methodologic quality of individual studies and lacked comparison of decision making and outcomes between PET-guided and non-PET-guided management.

An Agency for Healthcare Research and Quality (AHRQ) systematic review by Ioannidis et al (2002) on the use of PET for soft tissue sarcoma evaluated 5 indications: 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.[7,] Reviewers found that PET had low diagnostic accuracy in distinguishing low-grade tumors from benign lesions; however, PET performed better at differentiating high- or intermediate-grade tumors from low-grade tumors. It is unclear whether this would impact management decisions and health outcomes. Evidence was 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 evaluation of treatment response.

Guidelines
Current NCCN guidelines for soft tissue sarcoma (v.2.2024) state that PET/CT may be useful in staging, prognostication, grading, and determining response to neoadjuvant therapy.[8,] PET/CT can be considered as a tool to help differentiate between well-differentiated and de-differentiated liposarcoma and to differentiate between neurofibroma(s) and malignant peripheral nerve sheath tumor.

Section Summary: Soft Tissue Sarcoma
Evidence for the use of PET or PET/CT in individuals with soft tissue sarcoma consists of 2 systematic reviews. Results of the ARHQ review showed that PET or PET/CT had low diagnostic accuracy. Another systematic review reported evidence supporting the use of PET/CT in monitoring response to imatinib treatment.

The evidence does not support the use of FDG-PET and FDG-PET/CT for the diagnosis and staging and restaging of soft tissue sarcoma.

The evidence supports the use of FDG-PET and FDG-PET/CT for rapid reading of response to imatinib therapy.

The evidence does not support the use of FDG-PET and FDG-PET/CT for surveillance of soft tissue sarcoma.

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

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in September 2024 did not identify any unpublished trials that would likely influence this review.

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
A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 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 Bone and Sarcoma was originally part of the Positron Emission Tomography (PET) Scanning: Oncologic Applications medical policy. Oncologic Applications for Bone and Sarcoma has been pulled out and placed into a separate medical policy, Positron Emission Tomography (PET) Scanning: Oncologic Applications (Bone and Sarcoma). The medical policy language was unchanged.

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OTHER REFERENCES

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