blue of california

Medical Policy

Positron Emission Tomography (PET)	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Radiology (Diagnostic/Therapeutic)
Original Policy Date: January 26, 2009	**Effective Date:** October 7, 2011

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Positron emission tomography (PET) is a method of molecular imaging based on positron emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia, or water. Oncologic applications of PET utilizing fluorine-18 coupled with fluorodeoxyglucose (FDG) are

most common. Malignant tumors typically demonstrate an increase in FDG uptake, which allows the detection of metabolic abnormalities indicative of cancer, before anatomic changes occur. Non-oncologic uses of PET, including cardiac, neurologic and infectious/inflammatory, employ different tracer materials. Positron emission tomography in combination with computed tomography (CT), or PET/CT fusion, provides molecular imaging with anatomic registration, and is considered by most to be an improvement over PET imaging alone. This policy makes no distinction between FDG PET, PET and PET/CT, and the terms are used interchangeably throughout the policy.

Policy

I. Oncological Indications

Note: Coverage for positron emission tomography (PET) requires that both General Oncologic and Tumor Specific criteria are satisfied.

II. General Oncologic Criteria

Positron emission tomography may be considered **medically necessary** for the initial treatment of patients with known or suspected solid tumors for **any** of the following indications:

- To determine the potential benefit of an invasive diagnostic or therapeutic procedure
- To determine the optimal anatomic location for an invasive procedure
- To determine the anatomic extent of tumor when the recommended antitumor treatment reasonably depends on the extent of the tumor

III. Tumor Specific Criteria

Brain Cancer

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of brain cancer.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of brain cancer.

Breast Cancer

Positron emission tomography is considered **not medically necessary** for the initial diagnosis of breast cancer and the staging of axillary lymph nodes.

Positron emission tomography (one study) may be considered **medically necessary** for the staging of breast cancer to detect metastatic disease.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of breast cancer.

Cervical Cancer

Positron emission tomography is considered **investigational** for the initial diagnosis of cervical cancer.

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Positron emission tomography (one study) may be considered **medically necessary** for the initial staging of cervical cancer when **both** of the following criteria are met:

- Conventional imaging is negative for extrapelvic metastasis
- Positron emission tomography is utilized for the detection of pretreatment metastases

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of cervical cancer.

Colorectal Cancer

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of colorectal cancer.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of colorectal cancer.

Esophageal Cancer

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of esophageal cancer.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of esophageal cancer.

Head and Neck Cancer

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of head and neck cancers (excluding thyroid and central nervous system (CNS)).

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of head and neck cancers (excluding thyroid and CNS).

Lung Cancer - Non-Small Cell

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of non-small cell lung cancer.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of non-small cell lung cancer.

Lung Cancer - Small Cell

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of small cell lung cancer.

Positron emission tomography is considered **investigational** for the subsequent treatment (restaging and recurrence) of small cell lung cancer.

Lymphoma, Including Hodgkin's Disease

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of lymphoma.

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Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of lymphoma.

Melanoma

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of melanoma, except for the initial staging of regional lymph nodes.

Positron emission tomography is considered **not medically necessary** for the initial staging of regional lymph nodes.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of melanoma.

Myeloma

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of myeloma.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of myeloma.

Ovarian Cancer

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of ovarian cancer.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of ovarian cancer.

Pancreatic Cancer

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of pancreatic cancer.

Positron emission tomography is considered **investigational** for the subsequent treatment (restaging and recurrence) of pancreatic cancer.

Prostate Cancer

Positron emission tomography is considered **not medically necessary** for the initial treatment (diagnosis and staging) of prostate cancer.

Positron emission tomography is considered **investigational** for the subsequent treatment (restaging and recurrence) of prostate cancer.

Soft Tissue Sarcomas

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of soft tissue sarcomas.

Positron emission tomography is considered **investigational** for the subsequent treatment (restaging and recurrence) of soft tissue sarcomas.

Testicular Cancer

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Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of testicular cancer.

Positron emission tomography is considered **investigational** for the subsequent treatment (restaging and recurrence) of testicular cancer.

Thyroid Cancer

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of thyroid cancer.

Positron emission tomography may be considered **medically necessary** for the subsequent treatment (restaging and recurrence) of recurrent or residual thyroid cancer when **all** of the following criteria are met:

- The cancer is of follicular cell origin
- Serum thyroglobulin > 10 nanograms/milliliter (ng/ml)
- Negative I-131 whole-body scan
- Previous treatment with thyroidectomy and radioiodine ablation

Positron emission tomography is considered **investigational** for all other indications in the subsequent treatment (restaging and recurrence) of thyroid cancer.

Other Solid Tumors

Positron emission tomography (one study) may be considered **medically necessary** for the initial treatment (diagnosis and staging) of other solid tumors.

Positron emission tomography is considered **investigational** for the subsequent treatment (restaging and recurrence) of other solid tumors.

Other Cancers

Positron emission tomography (one study) is considered **investigational** for the initial treatment (diagnosis and staging) of all other cancers.

Positron emission tomography is considered **investigational** for the subsequent treatment (restaging and recurrence) of all other cancers.

Unknown Primary

Positron emission tomography may be considered **medically necessary** in patients with an unknown primary cancer who meet **all** of the following criteria:

- Single site of disease outside the cervical lymph nodes
- Local or regional treatment for a single site of metastatic disease is being considered
- Workup for an occult primary tumor is negative
- Positron emission tomography will be used to rule out or detect additional sites of metastatic disease that would eliminate the rationale for local or regional treatment

Positron emission tomography is considered **investigational** for all other indications in patients with an unknown primary including, but not limited to, the following:

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- As part of the initial workup of an unknown primary cancer
- As part of the workup of patients with multiple sites of metastatic disease

Cancer Surveillance

Positron emission tomography is considered **investigational** for surveillance of patients with a history of cancer, but without objective signs or symptoms suggestive of cancer recurrence. (A scan is considered surveillance if performed more than six months after completion of cancer therapy, (more than 12 months for lymphoma))

IV. Non-Oncologic Indications

Cardiac Applications

For patients with suspected coronary artery disease (CAD), a cardiac PET for the evaluation of myocardial perfusion, either at rest or with pharmacological stress, may be considered **medically necessary** to aid in the diagnosis of CAD if **all** of the following criteria are met:

- Patient has three or more Framingham Risk Factors (* listed below)
- Patient has either a echo stress test or exercise tolerance test which did not diagnose coronary artery disease and **one** of the following:
    - Patient is likely to experience attenuation artifact with single-photon emission computed tomography (SPECT) imaging due to factors such as severe obesity (body mass index (BMI) > 35 kilograms/square meter (kg/m^2)), large breasts, breast implants, previous mastectomy, chest wall deformity, or pleural/pericardial effusion
    - Patient had a previous indeterminate SPECT scan due to inadequate findings, technical difficulties with interpretation, or discordant results with previous clinical data

***Framingham Risk Factors:**

Patient is considered to be a high risk for CAD if they have three or more of the following risk factors:

- Age >/= 55
- Diabetic
- Hypertension
- Active history of smoking
- History of low-density lipoprotein (LDL) cholesterol > 130 milligrams/deciliter (mg/dL)
- History of high-density lipoprotein (HDL) cholesterol < 35 mg/dL
- Obesity with BMI > 30 kg/m^2
- Family history of premature or early onset of CAD:
    - Father below age 55
    - Mother below age 65

A cardiac PET for the evaluation of myocardial viability prior to possible percutaneous or surgical revascularization may be considered **medically necessary** when **both** of the following criteria are met:

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- Previous SPECT test for viability is inadequate
- Patient has severe left ventricular dysfunction (LVEF) ≤ 35%

A cardiac PET may be considered **medically necessary** for the diagnosis of cardiac sarcoidosis in patients who are unable to undergo magnetic resonance imaging (i.e., patients with pacemakers, automatic implanted cardioverter-defibrillators, or other metal implants).

A cardiac PET is considered **not medically necessary** for all other indications.

Central Nervous System Applications

Positron emission tomography may be considered **medically necessary** for preoperative assessment of patients with intractable complex partial seizures to localize epileptogenic foci.

Positron emission tomography is considered **investigational** for the differential diagnosis of Alzheimer's disease versus frontotemporal dementia (FTD).

Infectious/Inflammatory Applications

Positron emission tomography may be considered **medically necessary** for the diagnosis of chronic osteomyelitis.

Other Miscellaneous Applications

Positron emission tomography is considered **investigational** for all other indications including, but not limited to, the following:

- Autoimmune disorders with CNS manifestations, including:
  - Systemic lupus erythematosus
  - Behcets syndrome
- Cerebral blood flow in newborns
- Cerebrovascular disease, including:
  - Arterial occlusive disease (arteriosclerosis, atherosclerosis)
  - Carotid artery disease
  - Cerebral aneurysm
  - Cerebrovascular malformations (Arteriovenous malformation (AVM) and Moya Moya disease)
  - Giant cell arteritis
  - Hemorrhage
  - Infarct
  - Ischemia
- Degenerative motor neuron diseases, including:
  - Amyotrophic lateral sclerosis
  - Friedreichs ataxia
  - Olivopontocerebellar atrophy
  - Parkinsons disease
  - Progressive supranuclear palsy

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  - Shy-Drager syndrome
  - Spinocerebellar degeneration
  - Steele-Richardson-Olszewski disease
- Dementias, including:
  - Alzheimer's disease
  - Multi-infarct dementia
  - Presenile dementia
  - Picks disease
- Demyelinating diseases, such as multiple sclerosis
- Developmental, congenital, or inherited disorders, including:
  - Adrenoleukodystrophy
  - Downs syndrome
  - Huntington's disease
  - Kinky-hair disease (Menkes syndrome)
  - Sturge-Weber syndrome (encephalofacial angiomatosis) and the phakomatoses
- Infections, including:
  - Aspergillosis
  - Acquired immunodeficiency syndrome (AIDS)
  - Creutzfeldt-Jakob syndrome
  - Encephalitis
  - Progressive multifocal leukoencephalopathy
  - Progressive rubella encephalopathy
  - Subacute sclerosing panencephalitis
  - Human immunodeficiency virus
- Migraine
- Miscellaneous:
  - Chronic fatigue syndrome
  - Post-traumatic stress disorder
  - Sick building syndrome
- Musculoskeletal diseases:
  - Joint replacement follow-up
  - Spondylodiscitis
- Nutritional or metabolic diseases and disorders, including:
  - Acanthocytes
  - Hepatic encephalopathy
  - Hepatolenticular degeneration
  - Metachromic leukodystrophy

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  - Mitochondrial disease
  - Subacute necrotizing encephalomyelopathy
- Psychiatric disorders, including:
  - Anorexia nervosa
  - Affective disorders
  - Depression
  - Obsessive-compulsive disorders
  - Psychomotor disorders
  - Schizophrenia
  - Tourettes syndrome
- Pulmonary diseases, including:
  - Adult respiratory distress syndrome
  - Diffuse panbronchiolitis
  - Emphysema
  - Obstructive lung disease
  - Pneumonia
- Substance Abuse, including the CNS effects of alcohol, cocaine, or heroin
- Trauma, including brain injury and carbon monoxide poisoning
- Vegetative versus "locked-in" state

Policy Guideline

- The Centers for Medicare and Medicaid Services (2009) added CPT modifiers for use with PET CPT and HCPCS codes.
  - PI - PET or PET/CT to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing, one per cancer diagnosis
  - PS - PET or PET/CT to inform the subsequent treatment strategy of tumors that are biopsy proven or strongly suspected of cancerous tumors when the beneficiary's treating physician determines that the PET study is needed to inform subsequent anti-tumor strategy
- PET Applications:
  - Diagnosis - PET imaging performed when tumor is suspected to avoid an invasive diagnostic procedure or to determine the optimal anatomical site for an invasive diagnostic procedure. In this instance PET imaging is performed for initial diagnosis instead of or prior to tissue biopsy.
  - Initial Staging - PET imaging performed after confirmed diagnosis to determine the extent of tumor. In this instance PET imaging is performed to optimize initial treatment planning prior to therapy.

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  - Restaging - PET imaging performed after the completion of therapy to detect and quantify residual disease. In this instance PET imaging is performed to inform subsequent treatment strategies.
  - Recurrence - PET imaging performed for the detection of a suspected recurrence or to determine the extent of a known recurrence. In this instance PET imaging is performed to determine the potential benefit of subsequent treatment strategies.

- Soft tissue sarcomas include but are not limited to: gastrointestinal stromal tumor (GIST), angiosarcoma, malignant fibrous histiocytoma, malignant schwannoma, malignant peripheral nerve sheath tumor, rhabdomyosarcoma, synovial sarcomaepithelioid sarcoma, fibrosarcoma, leiomyosarcoma, and liposarcoma.
- Other solid tumors include but are not limited to: bladder, bone, gastric, hepatobiliary, kidney, malignant pleural mesothelioma, neuroendocrine (e.g. pheochromocytoma, Merkel cell, carcinoid) testicular, thymic and uterine.
- Other cancers may include leukemia, myelodysplastic syndromes, and basal cell carcinoma.

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review
• History and physical from referring physician including previous treatment and response • Pathology reports, if applicable • Radiological reports, if applicable Post Service • PET report

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available

Click here to view the appendix for this policy

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