Medical Affairs Policy

**Service:** PET Scan (Positron Emission Tomography)

*PUM 250-0010*

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<td>Prior Authorization Needed</td>
<td>Yes</td>
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**Disclaimer:** This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by the organization may not utilize Medical Affairs medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. The organization uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG to assist in administering health benefits. This medical policy and MCG guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG, email medical.policies@wpsic.com.

**Description:**

A PET scan is a “high technology” radiology imaging method used to evaluate differences in structure or organ function and metabolism. The PET scan shows molecular function and activity, which is not available with other imaging methods. The PET scanner detects signals from a radioactive substance/tracer, such as (the most commonly used tracer) Fluorine-18 fluorodeoxyglucose (FDG), 18F Sodium Fluoride (18F-NaF), Choline C-11, and Gallium Ga-68 dotatate (NETSPOT) administered as part of the study. Many types of cancerous tissue will absorb more radioactive substance and appear brighter than normal tissue on the PET images. PET is most commonly utilized in oncologic, cardiac, and neurologic conditions.

This policy is based on review of the guidelines and recommendations of: Magellan Healthcare (National Imaging Association), MCG, American College of Radiology (ACR) Appropriateness Criteria, Hayes, UpToDate, and The National Comprehensive Cancer Network (NCCN).

For the purposes of this policy, diagnosis, staging, restaging, monitoring, and surveillance are defined as follows:

**Diagnosis:** The PET is performed prior to a pathology-confirmed diagnosis of a malignancy but the results of the PET may inform the need for an invasive diagnostic procedure or the PET results will determine the optimal anatomic location for performing an invasive diagnostic procedure.

**Staging** (also known as Initial Treatment Strategy and Initial Anti-tumor Treatment Strategy):
The PET is performed after a pathology report has confirmed the presence of a malignancy, but prior to any treatment being performed. PET is indicated when the clinical management of the patient would be altered depending on the stage of the cancer and: either staging of cancer is inconclusive after completed standard diagnostic evaluation [(computed tomography (CT), magnetic resonance imaging (MRI) and/or ultrasound (US))] or when PET would replace one or more conventional imaging studies when those studies are inadequate for treatment management.

Restaging or monitoring (also known as Subsequent Treatment Strategy): The PET is performed for restaging or monitoring response to active treatment, and/or a single evaluation after completion/cessation of therapy not to be performed within 4 weeks of completion of therapy (ideally FDG PET is delayed 2-3 months after surgical therapy, 2-3 months after radiation therapy if locoregional assessment is the imaging goal), and/or evaluation for suspicion of recurrence due to new or changing signs/symptoms.

Surveillance / Remission: The PET is performed to assess for possible changes in status when there are no signs or symptoms of active cancer changes and the patient is not on any active treatment. The PET scan is for the purpose of detecting recurrence, in the absence of clinical symptoms, laboratory evidence, or imaging evidence of cancer recurrence.

To navigate through this policy: Determine if the request is for an oncologic or non-oncologic condition.

1. If the condition is oncologic, determine if the request is for:
   a. initial treatment strategy (aka diagnosis and/or initial staging): Go to Section A.1.
   b. subsequent treatment strategy (restaging, monitoring of treatment, or suspicion of recurrence after treatment ends): Go to Section A.2.
   c. detecting recurrence, in the absence of clinical symptoms, laboratory evidence, or imaging evidence of cancer recurrence: Go to Limitations of Coverage.

2. If the condition is nononcologic Go to Section B.
   Note that “Pulmonary Nodule” is listed under non-oncologic conditions.

Indications of Coverage:

➢ Note: PET for surveillance or remission is considered not medically necessary.

PET or PET/CT scan is considered medically necessary for any of the following conditions when the indicated condition specific criteria are met:
A. Oncologic PET Scan:

1. Initial Treatment Strategy: PET, with or without simultaneous CT (PET-CT), for tumor imaging is considered medically necessary for initial evaluation or staging (from diagnosis through initial staging), as indicated by ALL of the following:

   a. Additional imaging information is required to assess one or more of the following:
      1) Anatomic extent of tumor if results will result in optimal antitumor therapy
      2) Appropriateness of patient for invasive diagnostic or therapeutic procedure
      3) Optimal anatomic location for invasive procedure or biopsy
   b. PET scan has not been performed (scan is prior to the initiation of treatment for this malignancy)
   c. Solid tumor malignancy, biopsy proven or strongly suspected, is one or more of the following:
      1) Adrenal cancer
      2) Bladder Cancer (urinary)
      3) Brain or spinal cord cancer
      4) Breast cancer (does not include initial treatment strategy of axillary lymph nodes). Either of the following:
         a) PET scan with 18F-FDG
         OR
         b) 18F-NaF when current bone scan is inconclusive
   5) Cervical cancer
   6) Chronic Lymphocytic Leukemia (CLL). Note: PET/CT is generally not useful in CLL and SLL (Small Lymphocytic Leukemia) but, is considered medically necessary to direct nodal tissue sampling when high-grade histologic transformation is suspected.
7) Colorectal cancer (includes anal, rectal, and/or appendiceal)

8) Esophageal or gastroesophageal junction cancer

9) Gallbladder or extra-hepatic bile duct cancer

10) Gastric (stomach) cancer

11) Head and neck cancer (non-thyroid, non-central nervous system)

12) Kidney (renal) cancer

13) Liver (hepatocellular carcinoma) and intra-hepatic bile duct

14) Lung cancer, non-small cell type (includes squamous cell/epidermoid cancer, adenocarcinoma, and large cell/undifferentiated carcinoma)

15) Lung cancer, small cell type

16) Lymphoma (Hodgkin’s or Non-Hodgkin’s)

17) Melanoma (does not include initial treatment of regional lymph nodes)

18) Multiple Myeloma

19) Neuroendocrine cancer (e.g. carcinoid, pheochromocytoma, etc.) includes PET scan with Gallium Ga-68 dotatate (NETSPOT)

20) Osteosarcoma or Ewing sarcoma

21) Ovarian cancer

22) Pancreatic cancer

23) Paraneoplastic syndrome

24) Penile cancer

25) Pleural mesothelioma, malignant

26) Skin cancer- non-melanoma, non-basal cell carcinoma

27) Small intestine cancer

28) Soft tissue sarcoma including gastrointestinal stromal tumors (GIST)
29) Testicular cancer (includes seminoma)
30) Thymus cancer
31) Thyroid cancer
32) (Cancer of) Unknown primary origin
33) Uterine Cancer (includes leiomyosarcoma)
34) Vulvar Cancer

2. Subsequent Treatment Strategy for known cancer or neoplasm when a) is met and either b) or c) are met:

   a. PET scan is requested for any one of the following:
      1) Restaging or monitoring response to active treatment
      2) Single evaluation to be performed after completion/cessation of therapy (must be scheduled greater than 4 weeks after completion of therapy) to evaluate for residual disease
      3) Suspicion of recurrence well after completion of treatment. Suspicion is based on: new or changing signs and symptoms, abnormal laboratory tests or abnormal imaging studies
   b. The primary cancer is one of the following:
      1) Breast cancer. **Either of the following:**
         a) PET scan with 18F-FDG
         OR
         b) 18F-NaF when current bone scan is inconclusive
      2) Cervical cancer
      3) Colorectal cancer (anal, rectal, and or appendiceal)
      4) Esophageal cancer and gastro-esophageal junction cancer
      5) Head and neck cancer (not including brain)
6) Lung cancer (non small-cell only)

7) Lymphoma

8) Medullary thyroid cancer when calcitonin levels are elevated postoperatively

9) Melanoma

10) Multiple Myeloma

11) Neuroendocrine cancer (e.g. carcinoid, pheochromocytoma, etc.) includes PET scan with Gallium Ga-68 dotatate (NETSPOT)

12) Ovarian cancer

13) Thyroid cancer provided all of the following are met:
   a) Cell type is papillary, follicular, or Hurthle cell origin
   b) Patient had thyroidectomy AND radioiodine ablation initially
   c) Current whole body I-131 scan is negative

c. The primary cancer is one of the following AND other imaging (CT, MRI, Nuclear Medicine scan, Ultrasound) is inconclusive in determining a treatment plan or unable to be performed

1) Brain cancer with metastasis outside the brain

2) Lung cancer-small cell only

3) Pancreatic cancer

4) Prostate cancer One of the following:
   a) PET scan with 18F-FDG

   OR

   b) PET scan with 18F-NaF when current bone scan is inconclusive

   OR
c) PET scan with Choline C-11

5) Soft tissue Sarcoma

6) Testicular cancer

7) Cancer of unknown primary

B. Non-oncologic PET Scan

1. Coronary Disease. Either of the following:

   a. Evaluation of myocardial viability prior to possible percutaneous or surgical revascularization when both of the following are present:

      1) Previous single photon emission computed tomography/myocardial perfusion imaging (SPECT/MPI) for viability is inadequate or inconclusive

      2) Patient has severe left ventricular dysfunction; left ventricular ejection fraction (LVEF) ≤35%

   b. Coronary artery disease is known or suspected. The PET at rest and/or with pharmacologic stress, is ordered for medical or surgical treatment planning AND one of the following is documented:

      1) The PET scan is ordered in place of, but not in addition to, a nuclear cardiac imaging scan in an individual with conditions that may cause suboptimal SPECT imaging due to attenuation difficulties. Conditions may include but are not limited to: morbid obesity (BMI>40), large breasts, breast implants, chest wall deformity, prior mastectomy, or pericardial/pleural effusion.

      2) The PET scan is ordered following an inconclusive SPECT scan (when the results are uninterpretable or discordant with other clinical data/imaging).

2. Dementia when ALL of the following are met:

   a. Documentation of cognitive decline of at least six months, including date of reported onset of symptoms.

   b. Documentation of objective assessment of mental status by neurodiagnostic testing such as: Montreal Cognitive Assessment (MoCA) or other mental status exam showing at least mild cognitive impairment; or a change in mental status with score of less than 26 on the mini-mental status exam (MMSE).
c. A baseline evaluation has been completed to exclude other treatable causes of neurologic symptoms. The evaluation includes completion of basic metabolic work up (such as Complete Blood Count, Liver Function Tests, Thyroid tests) and adjustment of any medications as appropriate.

d. Documentation of how results will impact treatment.

e. The exam must be ordered by a specialist in the field of dementia or neurology

3. Epilepsy. The PET scan is ordered for pre-surgical evaluation to localize / identify a focus of refractory seizure activity for individuals with intractable epilepsy (defined as poor or no response to 2 or more anticonvulsant medications at maximal dose.)

4. Solitary Pulmonary Nodule (SPN) ≥ 8mm in size. Either:

   a. The PET/CT scan is performed for a suspicious pulmonary nodule found on a recent CT. When there are multiple pulmonary nodules, at least one nodule must be ≥ 8 mm

   b. Repeat PET scan for SPN: The PET/CT scan is performed to assess stability or change ≥ 90 days after a negative or inconclusive PET scan.

**Limitations of Coverage:**

A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.

B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

D. If used in conjunction with a clinical trial, the PET scan is subject to medical necessity review and all other conditions and terms of the policy or health plan.

E. A PET scan for initial treatment strategy (formerly diagnosis and initial staging) of axillary lymph nodes associated with breast cancer is not medically necessary.

F. A PET scan for routine **surveillance** in an asymptomatic individual without documentation of signs of recurrence (such as new or changing signs and symptoms, abnormal laboratory tests, or abnormal imaging studies) is not medically necessary. NOTE: PET as a surveillance tool should only be used in clinical trials and therefore
would be considered part of the experimental process of the trial. Refer to member health plan / certificate language for clinical trial coverage.

G. Repeat PET/CT to assess stability or change of a **solitary pulmonary nodule** within 90 days of a negative PET scan is not medically necessary.

H. A PET scan for the diagnosis of brain cancer or brain tumor is considered not medically necessary.

I. A PET scan for any of the following conditions is considered experimental / investigational as there is insufficient peer-reviewed scientific literature supporting the usefulness and effectiveness of PET scan in individuals with these diagnoses:
   1) ALL- acute lymphoblastic leukemia
   2) AML- acute myelogenous leukemia
   3) BCC- Basal cell carcinoma of the skin
   4) Breast Cancer- initial diagnosis of axillary lymph nodes
   5) Infection and/or inflammation: chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin
   6) Initial treatment strategy (formerly evaluation) of regional **lymph nodes** in Melanoma
   7) Neurofibromatosis (not a cancer)
   8) Paget’s Disease (not a cancer)
   9) Prostate Cancer-Initial treatment strategy
   10) PET scan using 18F-NaF tracer without current, inconclusive bone scan is considered not medically necessary.
   11) If a PET scan with either 18F-FDG, 18F-NaF, Ga-68 dototate, or Choline C-11 is indicated, performing **more than one** PET scan (using a different tracer for each scan) is considered not medically necessary.

**Documentation Required:**

- Office Notes
- PET scan report
- Other imaging reports
- Pathology report

References:


11. Milliman Care Guidelines 21st ed. Ambulatory Care. Tumor Imaging Positron Emission Tomography (PET) and PET-CT.


15. UpToDate. Neuroendocrine neoplasms of unknown primary site. Literature review current through: Jan 2017. | This topic last updated: Dec 22, 2016


**WPS Review History**

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Approved by the Medical Director