Medical Management Policy

The content of this document is used for WPS plans that do not utilize NIA (National Imaging Associates) review.

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

*PUM 250-0010-1712*

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**Description:**

A positron emission tomography (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 fluordeoxyglucose (FDG), 18F Sodium Fluoride (18F-NaF), Choline C-11, somatostatin receptor imaging Gallium Ga-68 dotatate, or 18F-Fluciclovine for prostate cancer imaging administered as part of the study. Because most cancers are hypermetabolic, compared with standard tissue, cancerous tissue will typically absorb more radioactive substance and appear brighter than normal tissue on the PET images. PET is most commonly utilized in oncologic (cancer/tumor), cardiac, and neurologic conditions.

The PET images are commonly fused to an additional imaging modality, usually computed tomography (CT) or magnetic resonance imaging (MRI), to improve spatial resolution. For the purposes of this policy, future use of the term PET/CT may be used interchangeably with PET/MRI.

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--fluorodeoxyglucose PET is delayed 2 to 3 months after surgical therapy, 2 to 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 for detecting recurrence 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.

To navigate through this policy: Determine if the request is for an oncologic (cancer/tumor) or non-oncologic condition.

1. If the condition is oncologic (cancer/malignancy/tumor), determine if the request is for:
   A. Initial treatment strategy (also known as diagnosis and /or initial staging): Go to Section I.A.
   B. Subsequent treatment strategy (restaging, monitoring of treatment, or suspicion of recurrence after treatment ends): Go to Section I.B.
   C. Detecting recurrence, in the absence of clinical symptoms, laboratory evidence, or imaging evidence of cancer recurrence: Go to Limitations of Coverage.
   D. Other imaging (CT, MRI, nuclear medicine scan, ultrasound) was inconclusive in determining a treatment plan or unable to be performed: Go to Section I.C.

2. If the condition is non-oncologic (not for cancer or suspected cancer), go to Section II. (Note that “Pulmonary Nodule” is listed under non-oncologic conditions)
Indications of Coverage:

- Note: PET for surveillance or remission is considered not medically necessary. Neither somatostatin receptor imaging (Gallium-68 DOTATATE PET) nor FDG PET/CT are recommended for routine surveillance.

- Note: For some indications, the medical necessity of the PET/CT study is dependent upon the choice of radiopharmaceutical that will be used.

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

I. Oncologic PET Scan:

A. Initial Treatment Strategy: PET, with or without simultaneous CT (Positron Emission Tomography-Computed Tomography, PET-CT), for tumor imaging is considered medically necessary for initial evaluation or staging (from diagnosis through initial staging), as indicated by ALL the following (a. through c.):

   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:

         i. PET scan with 18F-FDG

         OR

         ii. 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 B-cell or T-cell)

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

18) Multiple Myeloma

19) Neuroendocrine tumors or carcinoid tumors of the GI tract, pancreas, lung or thymus, or of unknown origin, (also to include pheochromocytoma and paraganglioma), provided other imaging (CT, MRI) is inconclusive or insufficient. If Somatostatin Receptor SPECT scan was already performed, Gallium Ga-68 dotatate scan will be considered not medically necessary, unless the result of the SPECT scan was negative or equivocal.

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

B. **Subsequent Treatment Strategy** for known cancer or neoplasm: **The criteria in both a. and b. below must be met.**

a. PET scan is requested for any one of the following:

1) Restaging or monitoring response to *active* treatment *or*

2) Monitor response to current chemotherapy when considering change in chemotherapy *or*

3) After surgery or completion/cessation of radiation therapy to evaluate for residual disease *or*

4) 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

**AND**

b. The primary cancer is one of the following:

1) Brain tumor or cancer with new signs and symptoms indicative of a recurrence of cancer or as a short term follow up adjunct to brain MRI to distinguish scarring/fibrosis from residual tumor

2) Brain tumor follow up after surgery and/or recently completed treatment to differentiate scarring/fibrosis from residual or recurrent tumor, when MRI is inconclusive
3) Breast cancer. **Either of the following:**
   
   a) PET scan with 18F-FDG
   
   **OR**
   
   b) 18F-NaF when current bone scan is inconclusive

4) Cervical cancer

5) Colorectal cancer (anal, rectal, and or appendiceal)

6) Esophageal cancer and gastro-esophageal junction cancer

7) Head and neck cancer (not including brain)

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

9) Lymphoma (all types)

10) Medullary thyroid cancer when calcitonin levels are elevated (greater than 150 pg/ml) postoperatively

11) Melanoma

12) Multiple Myeloma

13) Neuroendocrine cancer (e.g. carcinoid, pheochromocytoma, etc.) includes PET scan with Gallium Ga-68 dotatate (NETSPOT). Note: If Somatostatin Receptor SPECT scan was already performed for subsequent treatment, Gallium Ga-68 dotatate scan will be considered not medically necessary, unless the results of the SPECT scan were negative or equivocal.

14) Ovarian cancer

15) Thyroid cancer provided one of the following (a., b., or c. below) is met:
   
   a) Cell type is papillary, follicular, or Hurthle cell thyroid cancer and all of the following:
      
      i. Individual had thyroidectomy AND radiodine ablation initially
      ii. Whole body I-131 scan is negative
      iii. Stimulated serum thyroglobulin is greater than 2ng/ml
   
   b) Medullary thyroid cancer and calcitonin level is less than 150 pg/ml post-operatively
c) Anaplastic thyroid cancer at 3 to 6 months after initial treatment and thereafter at 3 to 6 months provided there is persistent structural disease.

16) Vaginal/Vulvar Cancer

17) Soft Tissue Sarcoma

C. **Other Imaging (CT, MRI, Nuclear Medicine Scan, Ultrasound) is Inconclusive in Determining a Treatment Plan or Unable to be Performed** AND the primary cancer is one of the following:

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

   **OR**

   d) PET scan with 18F-Fluciclovine (Axumin)

5) Testicular cancer

6) Cancer of unknown primary

II. **Non-oncologic (not related to cancer/malignancy) PET Scan**

A. Coronary Disease. When criteria in MCG Myocardial Perfusion Imaging, Pharmacologic Stress ACG: A-0079(AC) are met, **or** criteria in MCG Myocardial Perfusion Imaging, Exercise Stress A-0078 (AC) are met (but neither myocardial perfusion imaging nor stress echocardiography are expected to provide optimal imaging), **or** when **either** of the following (a. or b.) are met:
a. PET scan of the coronary arteries/heart is medically necessary when one of the following is present:

1) Previous myocardial perfusion imaging (MPI)/ single photon emission computed tomography (SPECT), cardiac MRI, or stress echocardiography is inconclusive or deemed inadequate due to factors interfering with imaging (e.g., due to large body habitus, obesity with body mass index greater than 40, very large breasts)

2) Pre-operative/pre-procedural evaluation for suspected hibernating myocardium with known severe coronary artery disease and ejection fraction less than 40%

3) In patients less than 55 years old with known complex coronary artery disease who will require frequent coronary ischemia evaluation or who have other comorbidity requiring frequent significant radiation exposure

4) Strong suspicion of balanced ischemia on other testing and further noninvasive (non-angiographic) coronary artery evaluation is required

5) Sarcoidosis

6) Infective endocarditis

7) Following radiation therapy to the left chest or anterior chest, to be approved at 5 year intervals after initiation of radiation therapy

8) Documented anomalous coronary arteries

9) For diagnosis and/or surveillance of aortitis

10) Post cardiac transplantation, annually for the first five years, then contingent on transplant coronary vasculopathy

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 (body mass index greater than 40), large breasts, breast implants, chest wall deformity, prior mastectomy, or pericardial/pleural effusion.

2) The PET scan is ordered following an inconclusive SPECT (single photon emission computed tomography) scan or stress echocardiogram, when the results are uninterpretable or discordant with other clinical data/imaging.

3) Repeat testing in an individual with new or worsening symptoms, with a prior negative result greater than one year ago.
B. Cognitive impairment or dementia when ALL of the following (a. through f.) are met:

a. Documentation of cognitive decline over time.

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 as well as exclusion of vascular or traumatic causes of cognitive impairment.

d. Documentation of how results will impact treatment.

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

f. Formal neuropsychological testing showed mild cognitive impairment.

C. Epilepsy and 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.)

D. Solitary Pulmonary Nodule (SPN) equal to or greater than 8mm in size. Either:

a. The PET/CT scan is requested for a suspicious pulmonary nodule found on a recent CT. When there are multiple pulmonary nodules, at least one nodule must be equal to or greater than 8 mm

or

b. Repeat PET scan for SPN: The PET/CT scan is requested to assess stability or change at least 90 or more days after a previous negative or inconclusive PET scan.

Limitations of Coverage:

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

B. If requested/used for a condition/diagnosis other than is listed in the Indications of Coverage, it will be denied as experimental or investigative.

C. If requested/used for a condition/diagnosis that is listed in the Indications of Coverage; but the criteria are not met, it will be denied 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 considered 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. Surveillance PET scanning of neuroendocrine tumors is considered not medically necessary.

H. Repeat PET/CT to assess stability or change of a solitary pulmonary nodule within less than 90 days of a negative or inconclusive PET scan is considered not medically necessary.

I. A PET scan for any of the following conditions is considered experimental / investigational and unproven to affect health outcomes 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; unless prior CT/MRI suggest lymphomatous involvement

2) AML- acute myelogenous leukemia; unless clinical suspicion of extramedullary disease

3) BCC- Basal cell carcinoma of the skin

4) Breast Cancer- initial diagnosis (initial treatment strategy) of axillary lymph nodes (also PET imaging, initial diagnosis and/or surgical planning for breast cancer)

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

8) Paget’s Disease

9) PET imaging, any site, not otherwise specified

10) Prostate Cancer-Initial treatment strategy

J. PET scan using 18F-NaF tracer without current, inconclusive bone scan is considered not medically necessary.
K. If a PET scan with either 18F-FDG, 18F-NaF, Ga-68 dotatate, 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 reports

**WPS Review History**

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