Cohere Medical Policy - Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: August 15, 2024

Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Cohere Medical Policy - Positron Emission Tomography (PET), PET/Computed Tomography (CT)

Date of last literature review: 8/14/2024
Document last updated: 8/15/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positron Emission Tomography (PET), PET/Computed Tomography (CT)

Recommended Clinical Approach

Positron emission tomography (PET) is a non-invasive diagnostic imaging procedure used to evaluate the metabolic activity in tissues. This technology is particularly useful for assessing oncologic, cardiovascular diseases and neurological disorders. Before undergoing a PET scan, patients typically undergo a series of preliminary assessments, including history and physical examination, and often other imaging studies like MRI or CT scans, which guide the need for further metabolic imaging[57-58].

Oncologic positron emission tomography (PET) is considered advanced imaging and best utilized per institutional oncologic protocols and oncologic (e.g., National Comprehensive Cancer Network [NCCN]) and radiological society guidelines including the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), and the American College of Radiology (ACR). The decision to perform oncologic PET is often made at institutional tumor board meetings after multidisciplinary oncology teams review the case. Teams may include oncologic surgeons, radiation oncologists, medical oncologists, pathologists, and radiologists.[1-3]

Medical Necessity Criteria

Indications

➔ **Positron emission tomography (PET) with or without concurrently acquired computed tomography (CT)(PET/CT) using**

fluorodeoxyglucose (FDG) is considered appropriate if **ANY** of the following is **TRUE**[1-3]:

- Diagnosis, staging, treatment monitoring, re-staging, or surveillance of **ANY** of the following primary cancer/tumor types:
  - Adrenal[4]; **OR**
  - Anal[5]; **OR**
  - Bladder[6]; **OR**
  - Bone[7]; **OR**
  - Brain/central nervous system[8]; **OR**
  - Breast[1,9-12]; **OR**
  - Cervical[13-14]; **OR**
  - Colorectal[15-17]; **OR**
  - Endometrial[18-19]; **OR**
  - Esophageal[20-21]; **OR**
  - Gastric[22]; **OR**
  - Gestational trophoblastic neoplasia[23]; **OR**
  - Head and neck[24-26]; **OR**
  - Lung cancer, non-small cell[27-29]; **OR**
  - Lung cancer, small cell[28-29]; **OR**
  - Lymphoma[30-31]; **OR**
  - Melanoma, cutaneous[32]; **OR**
  - Multiple myeloma[33]; **OR**
  - Ovarian[34-36]; **OR**
  - Pancreatic[37-38]; **OR**
  - Pleural mesothelioma[39]; **OR**
  - Prostate (response to therapy and restaging)[40-44]; **OR**
  - Squamous cell carcinoma of the skin[45]; **OR**
  - Soft tissue sarcoma[46-47]; **OR**
  - Testes (indicated for seminoma cancers only)[48-49]; **OR**
  - Thyroid[50-51]; **OR**
  - Vulvar[52]; **OR**
- **F-18 fluciclovine, choline C-11, or prostate-specific membrane antigen (PSMA [using F-18 piflufolastat, F-18 flotufolastat, or Ga-68 PSMA-11]) PET** and the patient has prostate cancer/tumor and **ANY** of the following positive findings[40-44]:

- The patient has been treated with radical prostatectomy and **ANY** of the following is **TRUE**:
    - Serum prostate-specific antigen (PSA) elevation greater than 0.1 ng/ml; **OR**
    - Persistence of PSA (failure to fall to undetectable levels); **OR**
    - Previously undetectable PSA that has been increasing on two or more occasions; **OR**
- The patient has been treated with radiation therapy and **ANY** of the following:
    - An increase of PSA by 2 ng/mL or greater above the lowest post-treatment PSA; **OR**
    - PSA increasing after radiation therapy and the patient is a candidate for salvage local therapy (even if the lowest PSA value is under 2 ng/mL); **OR**
- Initial treatment planning for suspected metastatic disease; **OR**
- Staging for individuals with a diagnosis of unfavorable intermediate-risk, high-risk, or very high-risk prostate cancer; **OR**
- GA-68 PSMA-11 PET/CT before initial treatment with lutetium Lu 177 vipivotide tetraxetan for metastatic castration-resistant prostate cancer; **OR**

◆ **Dotatate PET** and the patient has a well-differentiated neuroendocrine tumor and **ANY** of the following[4,53]:

- Diagnosis; **OR**
- Staging; **OR**
- Restaging; **OR**
- Treatment planning for 177-lutetium Lu Dotatate; **OR**

◆ Repeat imaging of a specific area or structure using the same imaging modality (in the absence of an existing follow-up guideline) is considered appropriate when **ALL** of the following is **TRUE**:

- There is documented clinical necessity; **AND**
- Prior imaging results of the specific area or structure,

obtained using the same imaging modality, must be documented and available for comparison; **AND**

- **ANY** of the following is **TRUE**:
    - A change in clinical status, such as worsening symptoms or the emergence of new symptoms, that may influence the treatment approach; **OR**
    - The requirement for interval reassessment, which may alter the treatment plan; **OR**
    - One-time follow-up of a prior indeterminate finding to assess for interval change; **OR**
    - The need for re-imaging either before or after performing an invasive procedure.

◆ **Positron emission tomography (PET) scan for non-oncologic conditions** is considered appropriate if **ALL** of the following are **TRUE**[59-60]:

- MRI and CT are contraindicated or inconclusive**; AND**
- **ANY** of the following is **TRUE**:
    - For suspected musculoskeletal osteomyelitis, when MRI cannot be performed and CT is nondiagnostic; **OR**
    - Fever of unknown origin (FUO) after clinical (including labs and blood cultures) and other advanced imaging workup (CT or MR) are negative.

Non-Indications

➔ **Positron emission tomography (PET), with or without concurrently acquired computed tomography (CT)(PET/CT)** is not considered appropriate if **ANY** of the following is **TRUE**:

◆ The patient has undergone advanced imaging of the same body part and for the same indication within 3 months, without being

on treatment; **OR**

- **ANY** of the following:
  - Used as an initial screening test in asymptomatic individuals; **OR**
  - Whole-body PET or PET/CT for cancer screening purposes only; **OR**
  - Initial diagnosis or staging of axillary lymph nodes in breast cancer[1,9-12]; **OR**
  - Initial diagnosis of cervical cancer related to anti-tumor treatment strategy[1,13-14]; **OR**
  - Initial staging of regional lymph nodes in melanoma[1,32]; **OR**
  - Non-seminoma tumors of the testes[48-49]; **OR**
  - FDG-PET for the staging of prostate cancer.[40-44]

*NOTE: PET/CT in patients with claustrophobia should be requested at the discretion of the ordering provider.
**NOTE: PET/CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.[54]
***NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for

pediatric patients to limit radiation exposure.[55-56]

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.[55-56]

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.[55-56]

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.[55-56]

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78811	Positron emission tomography (PET) imaging of chest
78812	Positron emission tomography (PET) imaging of skull base to midthigh

78813	Positron emission tomography (PET) imaging of whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging of skull base to midthigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) of whole body
79101	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
A9552	Fluorodeoxyglucose f-18 fdg, diagnostic, per study dose, up to 45 millicuries
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie
A9595	Piflufolastat f-18, diagnostic, 1 millicurie
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9597	Positron emission tomography radiopharmaceutical,

	diagnostic, for tumor identification, not otherwise classified
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie
A9608	Flotufolastat f18, diagnostic, 1 millicurie
A9609	Fludeoxyglucose f18 up to 15 millicuries
A9800	Gallium Ga-68 gozetotide, diagnostic, (Locametz), 1 millicurie
G0219	PET imaging whole body; melanoma for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)

Medical Evidence

Jadvar et al. (2017) published Appropriate Use Criteria for the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), the American Society of Clinical Oncology (ASCO), the American College of Nuclear Medicine (ACNM) the Society for Pediatric Radiology (SPR), and the Canadian Association of Nuclear Medicine (CANM). The group focused on meta-analyses and large individual studies comparing PET or PET/CT with other imaging modalities. It stated that the physician must prioritize which modality to begin with. PET/CT is said to have a strong role in restaging cancers and determining future patient management. Clinical studies cited to support the accuracy of PET/CT in detecting recurrent disease and assessing treatment response.[3]

The American College of Radiology (ACR) published the ACR-ACNM-SNMMI-SPR practice parameter for performing FDG-PET/CT in oncology in 2021. The indications presented in the document include use in the staging of malignancy, monitoring response to therapy, or restaging when the patient has relapsed. Additionally, this imaging modality may help localize the site of the primary tumor in the setting of metastatic disease, clarify indeterminate results, or localize occult disease when testing such as tumor markers indicates neoplastic disease. Finally, FDG-PET/CT may be used to plan treatment goals and to guide biopsy and radiation treatment planning.[2]

Published by the American College of Radiology in 2023, the ACR-ACNM-SNMMI practice parameter for performing Gallium-68 and Copper-64 Dotatate PET/CT imaging for neuroendocrine tumors (NETs). This imaging modality is appropriate for diagnosing, staging, restaging, and assessing treatment response in neuroendocrine tumors. Radiotracers such as those discussed in this practice parameter, which target cell membrane expression of somatostatin receptors (SSTRs), are useful in evaluating well-differentiated NETs compared to anatomical imaging. Fused imaging with computed tomography (PET/CT) in hybrid PET scanners has shown a high level of accuracy in evaluating patients with known or suspected malignancy.[53]

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Clinical Guideline Revision History/Information

Original Date: April 29, 2022		
Review History		
Version 2	8/15/2024	Annual review and policy restructure.