



## **Cohere Medicare Advantage Policy – Positron Emission Tomography (PET)/PET-Computed Tomography (CT)**

*Clinical Guidelines for Medical Necessity Review*

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# Important Notices

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## Guideline Information:

**Specialty Area:** Diagnostic Imaging

**Guideline Name:** Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

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# Medical Necessity Criteria

**Service: Positron Emission Tomography (PET)/PET-Computed Tomography (CT)**

## **Benefit Category**

Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.<sup>1,61</sup>

## **Related CMS Documents**

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.<sup>1,57,61-63,69</sup>

- [National Coverage Determination \(NCD\). Positron emission tomography \(FDG\) for oncologic indications \(220.6.17\)](#)
- [National Coverage Determination \(NCD\). Positron emission tomography \(NaF-18\) to identify bone metastasis of cancer \(220.6.19\)](#)
- [Local Coverage Determination \(LCD\). Positron emission tomography \(PET\) scan for inflammation and infection \(L39521\)](#)
- [Billing and Coding: Positron emission tomography \(PET\) scan for inflammation and infection \(A59318\)](#)
- [Local Coverage Determination \(LCD\). Multiple imaging in oncology \(L35391\)](#)

## **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.<sup>57-58</sup>

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.<sup>1-3</sup>

### **Evaluation of Clinical Benefits and Potential Harms**

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of positron emission tomography (PET)/PET computed tomography (CT). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.<sup>64-66</sup>
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.<sup>16</sup> Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.<sup>67</sup>
- Increased healthcare costs and complications from the inappropriate use of additional interventions.<sup>68</sup>

The clinical benefits of using these criteria include:

- Improved diagnostic accuracy: PET imaging, and in particular, PET/CT, has shown greater accuracy in evaluating patients with either known or suspected malignancy than PET or CT alone or PET and CT obtained separately but interpreted together.<sup>2</sup>
- Noninvasive: PET is a noninvasive imaging modality. It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. PET

also utilizes no injected contrast agent, conferring an inherent safety benefit.

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

## **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**<sup>1-3,57,61,62,63</sup>:

- ◆ For initial anti-tumor treatment strategy, CMS continues to cover one FDG PET study for beneficiaries who have cancers that are biopsy-proven or strongly suspected based on other diagnostic testing when the beneficiary's treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for **ANY** of the following therapeutic purposes:
  - To determine whether the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; **OR**
  - To determine the optimal anatomic location for an invasive procedure; **OR**
  - To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor; **OR**

◆ Diagnosis, staging, treatment monitoring/re-staging for **ANY** of the following biopsy-proven or strongly suspected primary cancer/tumor types:

- Adrenal<sup>4</sup>; **OR**
- Anal<sup>5</sup>; **OR**
- Bladder<sup>6</sup>; **OR**
- Bone<sup>7</sup>; **OR**
- Brain/central nervous system<sup>8</sup>; **OR**
- Breast (see Non-Indications below)<sup>1,9-12</sup>; **OR**
- Cervical (see Non-Indications below)<sup>13-14</sup>; **OR**
- Colorectal<sup>15-17</sup>; **OR**
- Endometrial<sup>18-19</sup>; **OR**
- Esophageal<sup>20-21</sup>; **OR**
- Gastric<sup>22</sup>; **OR**
- Gestational trophoblastic neoplasia<sup>23</sup>; **OR**
- Head and neck<sup>24-26</sup>; **OR**
- Lung cancer, non-small cell<sup>27-29</sup>; **OR**
- Lung cancer, small cell<sup>28-29</sup>; **OR**
- Lymphoma<sup>30-31</sup>; **OR**
- Melanoma, cutaneous (see Non-Indications below)<sup>32</sup>; **OR**
- Multiple myeloma<sup>33</sup>; **OR**
- Ovarian<sup>34-36</sup>; **OR**
- Pancreatic<sup>37-38</sup>; **OR**
- Pleural mesothelioma<sup>39</sup>; **OR**
- Prostate (see Non-Indications below)<sup>40-44</sup>; **OR**
- Squamous cell carcinoma of the skin<sup>45</sup>; **OR**
- Soft tissue sarcoma<sup>46-47</sup>; **OR**
- Testes (indicated for seminoma cancers only)<sup>48-49</sup>; **OR**
- Thyroid<sup>50-51</sup>; **OR**
- Vulvar<sup>52</sup>; **OR**

◆ Characterization of solitary pulmonary nodules (SPNs) greater than 8 millimeters in diameter<sup>70</sup>; **OR**

◆ **Prostate-specific membrane antigen (PSMA [using F-18 piflufolastat, F-18 flutufolastat, or Ga-68 PSMA-11]) PET** and the patient has prostate cancer/tumor and **ANY** of the following positive findings<sup>40-44</sup>:

- 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 elevated 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 or other nonsurgical treatment 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 (e.g., Pluvicto) for metastatic castration-resistant prostate cancer; **OR**
- ◆ **F-18 fluciclovine or choline C-11 PET/CT** and **ANY** of the following positive findings<sup>40-44</sup>:
  - 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 elevated 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 or other nonsurgical treatment 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**



- ◆ **Dotatate PET** and the patient has a well-differentiated neuroendocrine tumor and **ANY** of the following<sup>4,53</sup>;
  - Diagnosis with high suspicion of neuroendocrine tumor based on prior imaging (e.g. prior CT), symptoms (e.g. intractable diarrhea) or laboratory values (e.g. High chromogranin levels) ; **OR**
  - Initial staging; **OR**
  - Treatment planning for lutetium Lu-177 Dotatate; **OR**
  - Restaging or treatment monitoring, and **ANY** of the following is **TRUE**<sup>28,36</sup>:
    - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
    - Suspected recurrence/progression; **OR**
    - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy and/or 6-8 weeks since the prior imaging evaluation); **OR**
- ◆ **Positron emission tomography (PET) scan for non-oncologic conditions** is considered appropriate if **ANY** of the following are **TRUE**<sup>59-60</sup>:
  - **ALL** of the following are **TRUE**:
    - MRI and CT are contraindicated or inconclusive; **AND**
    - **ANY** of the following is **TRUE**<sup>62</sup>:
      - ◆ For patients greater than or equal to 18 years of age with fever of unknown origin (FUO) and **ALL** of the following<sup>62</sup>:
        - Fever higher than 38.3 Celsius (101 degrees Fahrenheit); **AND**
        - Present for greater than or equal to 21 days defined by fever on 2 or more occasions with repeating episodes for 2 or more weeks prior to the study; **AND**
        - The patient is not immunocompromised; **AND**

- Investigation including history, physical, laboratory analysis, and standard imaging is non-diagnostic; **AND**
- The patient does not have any conditions that would limit the ability to interpret the PET scan; **OR**
- ◆ For diagnosis of equivocal cases of suspected osteomyelitis or spondylodiscitis (with abnormal radiographs or CT findings and **ALL** of the following:
  - MRI cannot be performed or is non-diagnostic or inconclusive; **AND**
  - The patient does not have any conditions that would limit the ability to interpret the PET (e.g., post-operative or post-traumatic conditions, uncontrolled blood sugars); **AND**
  - Not in conjunction with bone scintigraphy, leukocyte scintigraphy, and or MOAB scintigraphy; **OR**
- Evaluation of cardiac sources of infection or inflammation, as indicated by **ALL** of the following<sup>62</sup>:
  - Documented suspicion on clinical exam and laboratory evaluation; **AND**
  - Non-specific or inconclusive imaging from echocardiography and/or CT; **AND**
  - The patient is being evaluated for **ANY** of the following conditions:
    - ◆ Infective endocarditis with a prosthetic valve; **OR**
    - ◆ Suspected cardiac device infection (pacemaker, defibrillators, LVAD, metallic implants); **OR**
    - ◆ CTA or MRA are inconclusive or nondiagnostic for **ANY** of the following:
      - Aortitis; **OR**
      - Systemic vasculitis; **OR**
      - Vascular graft infection; **OR**

- ◆ Cardiac sarcoidosis with **ANY** of the following:
  - Risk factors (such as systemic sarcoidosis); **OR**
  - Patient less than 60 years old with unexplained, new onset conduction system disease; **OR**
  - Heart failure without explanation; **OR**
  - Idiopathic sustained ventricular tachycardia unexplained by other causes; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
  - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
  - One-time clarifying follow-up of a prior indeterminate finding; **OR**
  - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

## 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**:
- For **oncologic indications** and **ANY** of the following:
    - Whole-body PET or PET/CT for cancer screening purposes only; **OR**
    - Initial diagnosis or staging of axillary lymph nodes in breast cancer<sup>1.9-12</sup>; **OR**
    - Initial diagnosis of cervical cancer related to anti-tumor treatment strategy<sup>1.13-14</sup>; **OR**
    - Initial staging of regional lymph nodes in melanoma<sup>1.32</sup>; **OR**
    - Initial diagnosis and staging of adenocarcinoma of the prostate; **OR**
    - Non-seminomatous tumors of the testes<sup>48-49</sup>; **OR**

- F-18 sodium fluoride (NaF-18) PET for any indication, including identifying bone metastasis of cancer<sup>69</sup>; **OR**
- For **infection/inflammation** and **ANY** of the following:
  - If used as first-line diagnostic test; **OR**
  - If **ANY** of the following tests have already been done or are planned as part of diagnostic evaluation without documented medical necessity:
    - ◆ Labeled WBC scan; **OR**
    - ◆ 67Ga SPECT/CT; **OR**
  - Endocarditis in a native valve; **OR**
  - If used for monitoring response to treatment with the exception of cardiac sarcoidosis; **OR**
  - The use of PET scan for inflammation and infection of other conditions not specifically addressed in the Indications section above will be considered investigational.

\*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.<sup>54</sup>

\*\*\*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.<sup>55-56</sup>

**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 midhigh
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 midhigh

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)
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**Disclaimer:** G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

# 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.<sup>3</sup>

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.<sup>2</sup>

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.<sup>53</sup>



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# Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		
Version 2	November 21, 2024	Added CMS verbiage related to initial tumor treatment strategy; added bullet and reference related to solitary pulmonary nodules