



**Cohere Medicare Advantage Policy –
Positron Emission Tomography
(PET)/PET-Computed Tomography (CT)**
Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Diagnostic Imaging

Policy Name: Cohere Medicare Advantage Policy - Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Type: Adult (18+ yo) | Pediatric (0-17 yo)

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Medical Necessity Criteria

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

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁶

- [National Coverage Determination \(NCD\). Positron emission tomography \(FDG\) for oncologic indications \(220.6.17\)](#)¹
- [National Coverage Determination \(NCD\). Positron emission tomography \(NaF-18\) to identify bone metastasis of cancer \(220.6.19\)](#)²
- [Local Coverage Determination \(LCD\). Positron emission tomography \(PET\) scan for inflammation and infection \(L39521\)](#)³
 - [Billing and Coding: Positron emission tomography \(PET\) scan for inflammation and infection \(A59318\)](#)⁴
- [Local Coverage Determination \(LCD\). Multiple imaging in oncology \(L35391\)](#)⁵
 - [Billing and Coding: Multiple Imaging in Oncology \(A56848\)](#)⁶

Description

Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolic activity in tissue. Typically, the patient is injected with a radiotracer, often fluorodeoxyglucose (FDG), which allows a scanner to detect the metabolic activity of cells. This technology is particularly useful for assessing oncologic, cardiovascular, and neurological disorders. Before undergoing a PET scan, the patient often undergoes other imaging studies, including magnetic resonance imaging (MRI) and computed tomography (CT) scans, which guide the need for further metabolic imaging.⁷

PET/CT combines functional and anatomic information and allows for precise tumor staging and evaluation of disease progression, as well as treatment planning, monitoring response to treatment and post-treatment surveillance in at-risk patients.⁸⁻⁹ Oncologic PET is considered advanced imaging and is best used per institutional oncologic protocols and oncological (e.g., National

Comprehensive Cancer Network, NCCN) and radiological society guidelines including those of 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.¹⁰⁻¹¹

Medical Necessity Criteria

Indications

Positron emission tomography (PET) with or without concurrently acquired computed tomography (CT) (PET/CT) is considered appropriate if **ANY** of the following is **TRUE**^{1-6,10-11}:

- One fluorodeoxyglucose (FDG) PET study for initial anti-tumor treatment strategy with **ALL** of the following¹:
 - The patient has cancer(s) that are biopsy-proven or strongly suspected based on other diagnostic testing; **AND**
 - The 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 patient 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 the tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor; **AND**
 - **ANY** of the following oncologic conditions, cancers, or tumor types:
 - Colorectal²³⁻²⁵; **OR**
 - Esophagus²⁸⁻²⁹; **OR**
 - Head and neck (not thyroid, CNS)³²⁻³⁴; **OR**
 - Lymphoma³⁸⁻³⁹; **OR**
 - Non-small cell lung^{35,37}; **OR**
 - Ovary⁴²⁻⁴³; **OR**
 - Brain¹⁶; **OR**
 - Cervix (see non-indications)²¹⁻²²; **OR**
 - Small cell lung³⁶⁻³⁷; **OR**

- Soft tissue sarcoma⁵³⁻⁵⁴; **OR**
- Pancreas⁴⁴⁻⁴⁵; **OR**
- Testes⁵⁵⁻⁵⁶; **OR**
- Thyroid⁵⁷⁻⁵⁸; **OR**
- Breast (see non-indications)¹⁷⁻²⁰; **OR**
- Melanoma (see non-indications)⁴⁰; **OR**
- All other solid tumors; **OR**
- Myeloma⁴¹; **OR**
- All other cancers not listed; **OR**
- Three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for **ANY** of the following oncologic conditions, cancers, or tumor types:
 - Colorectal²³⁻²⁵; **OR**
 - Esophagus²⁸⁻²⁹; **OR**
 - Head and neck (not thyroid, CNS)³²⁻³⁴; **OR**
 - Lymphoma³⁸⁻³⁹; **OR**
 - Non-small cell lung^{35,37}; **OR**
 - Ovary⁴²⁻⁴³; **OR**
 - Brain¹⁶; **OR**
 - Cervix²¹⁻²²; **OR**
 - Small cell lung³⁶⁻³⁷; **OR**
 - Soft-tissue sarcoma⁵³⁻⁵⁴; **OR**
 - Pancreas⁴⁴⁻⁴⁵; **OR**
 - Testes⁵⁵⁻⁵⁶; **OR**
 - Prostate⁴⁷⁻⁵¹; **OR**
 - Thyroid⁵⁷⁻⁵⁸; **OR**
 - Breast¹⁷⁻²⁰; **OR**
 - Melanoma⁴⁰; **OR**
 - All other solid tumors; **OR**
 - Myeloma⁴¹; **OR**
 - All other cancers not listed; **OR**
- Characterization of solitary pulmonary nodule (SPN) greater than 8 millimeters in diameter or greater than 8mm for the solid component of a part-solid nodule⁶⁰; **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 ALL** of the following⁴⁷⁻⁵¹:

- The patient has prostate cancer/tumor; **AND**
- **ANY** of the following:
 - Initial staging if the patient has a diagnosis of unfavorable intermediate-risk, high-risk, or very high-risk prostate cancer; **OR**
 - The patient has been treated with radical prostatectomy and **ANY** of the following:
 - 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**
 - Prior to initiation of androgen deprivation therapy (ADT)⁶²; **OR**
 - Three months following completion of ADT⁶²; **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**
 - Restaging 12 weeks after treatment with Lu177/Pluvicto⁶⁴; **OR**
 - Known metastatic disease and concern for progression on treatment and **ALL** of the following⁶¹⁻⁶³:
 - PSMA imaging will influence treatment plan; **AND**
 - Inconclusive prior imaging; **OR**
- **Dotatate PET** with **ALL** of the following^{12,65-66}:
 - The patient has a well-differentiated neuroendocrine tumor; **AND**
 - **ANY** of the following:
 - Diagnosis ; **OR**
 - Staging; **OR**
 - Restaging; **OR**
 - Treatment planning for Lutetium Lu-177 Dotatate; **OR**
- **Positron emission tomography (PET) scan for non-oncologic conditions** is considered appropriate if **ANY** of the following is **TRUE**⁶⁷⁻⁶⁸:

- The patient is greater than or equal to 18 years of age with fever of unknown origin (FUO) and **ALL** of the following³:
 - 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 following³:
 - 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**
- **Subsequent PET scans for oncological purposes** for **ANY** of the following⁵:
 - Assessment of therapeutic effect after completion of potentially curative therapy, if additional or alternative therapy will be employed for residual or progressive disease; **OR**
 - Assessment of therapeutic effect after localized, non-surgical therapy (e.g., stereotactic radiotherapy, radiofrequency or thermal ablation) of apparently limited or clinically significant lesions; **OR**
 - Suspected recurrence/progression including **ANY** of the following:
 - New symptoms suggestive of tumor recurrence or progression; **OR**
 - New physical findings (e.g., palpable lesion) suspicious for recurrence/progression; **OR**
 - Rising tumor markers or other signs or laboratory values suggestive of paraneoplastic phenomena; **OR**
 - Findings on other imaging that are equivocal or suspicious; **OR**
 - Restaging after documentation of recurrence/progression, if extent of disease will alter therapy or if new baseline needed prior to change in therapy; **OR**

- Evaluating response to treatment, when a change in therapy is contemplated and routine imaging (e.g., CT) does not or is not expected to provide optimal information; **OR**
- Follow-up of indeterminate findings on a clinically indicated PET scan performed for restaging or suspected recurrence/progression, to assess for trends in FDG uptake within suspected lesions over time. Typically no sooner than 3 months after the indeterminate PET scan; **OR**
- PET should be employed instead of or before conventional imaging if **ANY** of the following:
 - Available data suggest that PET is likely to obviate additional advanced imaging tests or invasive procedures or is likely to be more accurate than other modalities in detection or characterization of lesions that would change patient management; **OR**
 - The patient has contrast allergy or other contraindication to contrast administration that renders other modalities less effective; **OR**
 - The patient is being monitored for known disease that either has been previously shown to be characterized on PET than on other modalities or has been shown to be adequately FDG-avid for follow-up with PET and was not previously imaged with other modalities (e.g., bone metastases well visualized on previous PET and either not as well visualized on bone scintigraphy or bone scintigraphy not done); **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**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms in the absence of established guidelines or criteria supporting more frequent imaging⁶⁹; **OR**
- For oncologic indications and **ANY** of the following:
 - As an initial screening test in asymptomatic individuals; **OR**
 - Initial anti-tumor treatment strategy in the diagnosis of breast cancer or initial staging of axillary lymph nodes¹⁷⁻²⁰; **OR**
 - Initial anti-tumor treatment strategy for diagnosis of cervical cancer²¹⁻²²; **OR**
 - Initial anti-tumor treatment strategy for evaluation of regional lymph nodes in melanoma⁴⁰; **OR**
 - Initial anti-tumor treatment strategy in adenocarcinoma of the prostate¹; **OR**
 - Non-seminoma tumors of the testes⁴⁸⁻⁴⁹; **OR**
 - F-18 sodium fluoride (NaF-18) PET for any indication, including identifying bone metastasis of cancer²; **OR**
- For infection/inflammation and **ANY** of the following³:
 - When 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**
 - The use of PET scan for inflammation and infection of other conditions not specifically addressed in the Indications section above will be considered investigational.

^ANOTE: PET/CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

^BNOTE: PET/CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.⁷⁵

^CNOTE: 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.⁷⁰⁻⁷¹

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.⁷⁰⁻⁷¹

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.⁷⁰⁻⁷¹

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.⁷⁰⁻⁷¹

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)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

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.⁷²⁻⁷⁴
- 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. Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁷⁵
- Increased healthcare costs and complications from the inappropriate use of additional interventions.⁷⁶

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.¹⁰
- 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 Evidence

Zamani-Siahkali et al. (2024) conducted a systematic review and meta-analysis of studies investigating FDG-PET in malignant melanoma.²⁷ In their final analysis, which included 100 studies and over 10,000 patients, the authors reported both sensitivity and specificity of FDG-PET in initial detection and regional lymph node and distant metastasis. The authors reported high overall patient-based sensitivity and specificity of FDG-PET at 81% and 92% respectively. However, the authors also noted different sensitivity and specificity values across clinical settings. For example, detection sensitivity was higher in the secondary (90%) compared to the initial (60%) staging setting. Moreover, sensitivity of detection of regional metastasis was low (38%), indicating that FDG-PET may have minimal utility in detecting regional metastasis in melanoma. In contrast, the authors cite other studies reporting much higher sensitivity of sentinel lymph node biopsy and ultrasound imaging in detecting metastases in melanoma.

Jadvar et al. (2017) published appropriate use criteria for PET/CT in response assessment and restaging in cancer patients 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 authors conducted a systematic review of published meta-analyses and large individual studies investigating PET or PET/CT in seven cancer types: breast, colorectal, lymphoma, lung, melanoma, sarcoma, and head and neck. For each of these cancer types, the authors rated the appropriateness of PET/CT in various clinical scenarios. PET/CT was rated as appropriate for several of the scenarios evaluated including restaging for local recurrence or metastases and/or treatment response evaluation in head and neck cancer, breast cancer, sarcoma, melanoma, lymphoma, lung cancer, and colorectal cancer.²⁸

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 included use in the staging of malignancy, monitoring response to

therapy, or restaging after relapse. Additionally, PET/CT may help localize the site of the primary tumor in the setting of metastatic disease, clarify indeterminate results, or localize occult disease. Finally, FDG-PET/CT may be used to plan treatment, including surgery and radiation, and guide biopsy.¹⁰

In 2023 the American College of Radiology published 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.⁶⁵

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Policy Revision History/Information

Original Date: November 21, 2024		
Review History		
Version 2	11/21/2024	Added CMS verbiage related to initial tumor treatment strategy; added bullet and reference related to solitary pulmonary nodules.
Version 3	10/02/2025	<p>Annual review.</p> <p>Edited FDG-PET for oncologic conditions for clarity and ease-of-use.</p> <p>Updated list of approved primary cancer/tumor types for initial anti-tumor treatment strategy and subsequent tumor management in accordance with NCD 220.6.17.</p> <p>Split indications for initial anti-tumor treatment strategy from indications for subsequent tumor management in accordance with NCD 220.6.17.</p> <p>Consolidated F-18 fluciclovine/choline C-11 PET/CT and PSMA indications.</p> <p>Simplified dotatate indications for clarity and ease-of-use.</p> <p>Moved evaluation of cardiac sources of infection or inflammation indications to PET Cardiac policy.</p> <p>Incorporated indications from LCD L35391.</p> <p>Added repeat imaging non-indications.</p> <p>Added description section.</p> <p>Medical evidence - added one reference.</p>