Cohere Medicare Advantage Policy - Positron Emission Tomography (PET), Brain

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Positron Emission Tomography (PET), Brain

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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: PET Brain

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.[18-21]

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- National Coverage Determination (NCD) FDG PET for Refractory Seizures 220.6.9.
- National Coverage Determination (NCD) Positron Emission Tomography (FDG) for Oncologic Conditions 220.6.17
- National Coverage Determination (NCD) FDG PET for Dementia and Neurodegenerative Diseases 220.6.13
- Billing and Coding: NCD Coding Article for Positron Emission Tomography (PET) Scans Used for Non-Oncologic Conditions (A53134)
- Billing and Coding: Multiple Imaging in Oncology (A56848)

Recommended Clinical Approach

Two distinct types of positron emission tomography (PET) of the brain are considered for different indications. Utilizing ^{18}FDG (fluorodeoxyglucose) PET/CT imaging enables the assessment of metabolic activity and cerebral function. Specifically, ^{18}F-FDG brain imaging proves valuable across a spectrum of clinical scenarios, such as dementia, seizure disorders, and the detection of new or recurring brain tumors.[1] FDG-PET imaging reveals regional variations in glucose metabolism, serving as a marker for neurodegeneration. These patterns not only signify the existence of neurological decline but also offer insight into the specific cerebral regions and pathways affected by the condition.[2] Amyloid imaging is advised for identifying the presence or absence of abnormal Aß amyloid deposits in individuals experiencing progressive cognitive decline or dementia of unknown cause, where Alzheimer's disease is considered a potential diagnosis.[2]

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) of the brain. 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.[1,17]
- 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.[16] Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.[16]
- Increased healthcare costs and complications from the inappropriate use of additional interventions.[15]

The clinical benefits of using these criteria include:

- Improved diagnostic accuracy: PET imaging, and in particular, FDG PET, can visualize certain pathologies before those conditions are visible on other imaging modalities, such as CT and MRI.[1] PET has also been shown to significantly impact clinical management and decision-making, even among patients with mild symptomatology, which is of particular importance in the context of neurodegenerative conditions.[14]
- Noninvasive: As an imaging modality, PET of the brain is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It 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, ensuring 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), brain** is considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ **Fluorodeoxyglucose (FDG) PET brain** and the patient has **ANY** of the following exam findings[3]:
    - Seizure disorder (epilepsy) refractory to medical therapy for which invasive treatment is considered [1,6,19]; **OR**
    - Tumor, strongly suspected or known, for initial or subsequent treatment strategy[7-8,20]; **OR**
    - Cognitive decline or suspected diagnosis of dementia for differentiation of Alzheimer's dementia and frontotemporal dementia, and the patient has had **ALL** of the following[1-2,4,18]:
      - Evaluation by a physician experienced in the diagnosis and assessment of dementia; **AND**
      - Abnormal cognitive testing (MMSE, MoCA, SLUMS or similar); **AND**
      - Relevant lab values are available (B12, TSH); **AND**
      - Prior MRI or CT imaging of the brain; **OR**
  - ◆ **Single Amyloid PET** is considered appropriate if **ALL** of the following are **TRUE**[9]:
    - Alzheimer's disease following an interdisciplinary evaluation with **ALL** of the following:
      - General medical and neurological examination; **AND**
      - Laboratory testing; **AND**

        - Mental status testing; **AND**
        - Structural neuroimaging; **AND**
        - Imaging is needed to determine the extent of the amyloid build-up prior to treatment with amyloid beta-directed antibodies (e.g., Lecanemab).
    - 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.

* NOTE: MRI is the preferred imaging modality for follow-up imaging following an initial amyloid PET scan.

Non-Indications

- ➔ **Positron emission tomography (PET), brain** is not considered appropriate for **ANY** of the following:
    - PET evaluation of perfusion of the brain.[21]

*NOTE: PET in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

**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.[10-11]

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.[10-11]

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.[10-11]

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.[10-11]

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
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation (this code is non-covered by CMS)

78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)

Medical Evidence

Spano et al. (2023) analyzed the efficacy of PET imaging in cases of cognitive decline, specifically its significance in diagnosing Alzheimer's disease (AD). While FDG PET remains the predominant PET tracer in clinical use, several PET radiotracers enable the observation of underlying pathophysiological processes in AD, including Aβ deposition, tau deposition, synaptic density loss, neuroinflammation, cholinergic cell death, and reduced monoamine neurotransmission. Three FDA-approved 18F-labeled radiopharmaceuticals exist, including florbetaben (NeuraCeq), florbetapir (Amyvid), and flutemetamol (Vizamyl). These assess Aβ deposition, predominantly utilized in clinical trials with limited reimbursement for diagnostic purposes. The advancement of PET radiotracers in routine practice allows clinicians to diagnose and intervene in neurodegenerative diseases effectively.[12]

Quigg et al. (2022) report on using positron emission tomography with fluorine-18 fluorodeoxyglucose (^{18}F-FDG-PET) to map brain glucose metabolism patterns. This imaging modality aids in assessing normal brain function and identifying metabolic abnormalities in various brain disorders. Traditional PET methods cannot distinguish normal from pathological tissue, particularly in conditions such as brain neoplasms or focal epilepsy. The aim is to enhance the functional mapping of metabolic activity within the target organ. Recent technological advancements may broaden dynamic PET across various clinical settings.[13]

Rabinovici et al. (2019) conducted a single-group, multi-center longitudinal study called Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) (ClinicalTrials.gov Identifier: NCT02420756). The study assessed whether amyloid PET scans influence the subsequent management decisions for patients diagnosed with mild cognitive impairment (MCI) or dementia of uncertain origin. Participants (n=11409) at 343 imaging centers underwent amyloid PET. Within 90 days of evaluation, participants diagnosed with MCI or dementia of uncertain origin who underwent amyloid PET scans exhibited alterations in clinical management. Further research is needed to ascertain whether amyloid PET correlates with enhanced clinical outcomes.[14]

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