Molina Clinical Policy Brain PET: Policy No. 655

Last Approval: 08/14/2024 Next Review Due By: August 2025



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Positron emission tomography (PET) scans are based on the principal of nuclear technology. Most brain PET scans are considered metabolic PET which are performed using the radiotracer FDG (Flourine-18-deoxyglucose) – a lab created molecule similar to glucose. A less common type of brain PET scan is an Amyloid PET which uses a radiotracer that binds to amyloid deposits in the brain and is sometimes requested in the evaluation of dementia. The PET scanner is comprised of cylindrical "detectors" which detect gamma rays being emitted from the radioisotope. Computers interpret this data and transform it into an image.

Attenuation is a term used to describe the loss of detectable photons. The reasons for increased or decreased detection of the photons are extremely complicated but can be due to many factors such as different tissue densities, body surface, and body habitus. Today's scanners predominantly use computed tomography (CT) to address the issue of attenuation. (All PET scans employ some type of attenuation correction). A CT is routinely performed to produce a map of different tissue densities within the body which can be used to correct for differences in photon absorption.

Glucose is utilized for cellular metabolism. Using a radiolabeled glucose molecule (FDG), cells with higher metabolism will have increased uptake of the FDG molecule compared to surrounding tissue. Many tumor cells have increased metabolism and show increased FDG uptake. Other processes with increased rates of metabolism such as infection, inflammation, and sites of active tissue repair (surgical or traumatic wounds, fractures, chemotherapy) also have higher uptake of FDG. Conversely, all cancers are not rapidly growing and in addition some types of tumors do not have high concentrations of the transport molecule needed for uptake of FDG; these would show low FDG avidity on PET.

Some tissues have a higher physiologic metabolism when compared to others. Increased FDG uptake is normally seen in brain tissue, laryngeal muscles, salivary glands, thymic tissue, breast, heart, liver, uterus, testes, brown fat cells, and bone marrow. Colonic activity is known to be extremely variable in location and intensity and can make interpretation difficult. Uptake can be falsely low in small lesions, generally less than 1cm. Finally, FDG is excreted from the body in the urine. This means there is expected increased uptake in the renal collecting system and bladder, making detecting local tumors or tumors close to this system very difficult.

COVERAGE POLICY

Brain Tumor

- Inconclusive imaging findings and PET will be used to clarify the need for biopsy or change in therapy
- Post treatment evaluation to determine residual tumor versus radiation necrosis

<u>Seizure</u>

Pre-surgical evaluation for refractory seizures

Dementia

 Early onset Alzheimer screening for administration of monoclonal antibodies directed against aggregated forms of amyloid beta

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- NOTE: CMS GUIDELINES FOR FDG PET for Dementia and Neurodegenerative Diseases is NOT
 COVERED for ANY of the following:
 - Patient with presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible, or probable Alzheimer's disease, clinically typical fronto-temporal dementia, dementia of Lewy bodies, or Creutzfeldt-Jakob disease) for which CMS has not specifically indicated coverage.

Required Medical Information for Alzheimer's Disease

- Documentation of a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease based on National Institute on Aging-Alzheimer's Association (NIA-AA) diagnostic criteria. These are: A concern regarding cognition reported by the patient or informant or observed by the clinician. Objective evidence of impairment in one or more cognitive domains that is not explained by age or education. Preservation of independence in functional abilities.
- 2. Documentation of brain magnetic resonance imaging (MRI) within that last 12 months
- 3. Documentation of Clinical Dementia Rating Scale (CDR) Global Score of 0.5 OR Mini-Mental State Examination (MMSE) score between 24-30 OR Montreal Cognitive Assessment (MoCA) score 24-30

The above medical necessity recommendations are used to determine the best diagnostic study based on a patient's specific clinical circumstances. The recommendations were developed using evidence-based studies and current accepted clinical practices. Medical necessity will be determined using a combination of these recommendations as well as patient's individual clinical or social circumstances.

- Tests that will not change treatment plans should not be recommended.
- Same or similar tests recently completed need a specific reason for repeat imaging.

All other indications for Brain PET are **not covered**.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

08/14/2024	Policy reviewed. Removed select documentation requirements for Alzheimer's Disease including cerebrospinal fluid testing or contraindication, treatment with two or more Alzheimer's drug therapies, and absence of a number of contraindications. IRO Peer Review on July 24, 2024, by a practicing physician board-certified in Radiology.
08/09/2023	Policy reviewed, criteria updated to include any monoclonal antibodies directed against amyloid beta.
08/10/2022	Policy reviewed, no changes to coverage criteria. Updated Reference section.
08/11/2021	Policy reviewed, updated criteria with reference to CMS guidelines for FDG PET for Dementia and Neurodegenerative Diseases.
12/09/2020	Policy reviewed, no changes to coverage criteria.
12/10/2019	Policy reviewed, no changes to coverage criteria.
12/13/2017	New policy.

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