Molina Clinical Policy
Brain PET: Policy No. 655

Last Approval: 8/09/2023
Next Review Due By: August 2024

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 which makes detecting local tumors or tumors in close proximity to this system extremely 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.

Seizure

- Pre-surgical evaluation for refractory seizures

Dementia

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

1. 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. Not demented OR diagnosis of Alzheimer disease dementia based on NIA-AA criteria for probable AD dementia.
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.
4. Documentation of confirmation of underlying amyloid beta pathology through LP for CSF (cerebrospinal fluid) or a reason why LP cannot be done.
5. Documentation member is not currently being treated or has historically been treated with 2 or more Alzheimer's drug therapies [Donepezil (Aricept), Galantamine (Razadyne), Rivastigmine (Exelon), Memantine (Namenda), donepezil and memantine (Namzaric)].
6. Documentation within medical record member does not have ANY of the following:
   a. Member does NOT have any medical or neurological condition (other than Alzheimer's Disease) that might be a contributing cause of the subject's cognitive impairment.
   b. Member has NOT had a Cerebrovascular (CVA) or Transient Ischemic Attack (TIA) or unexplained loss of consciousness in the past 1 year.
   c. Member does not have the presence of diabetes mellitus that cannot be controlled or managed.
   d. Member does NOT have clinically significant unstable psychiatric illness in past 6 months.
   e. Member does NOT have uncontrolled hypertension.
   f. Member does NOT have a history or known seropositivity for human immunodeficiency virus (HIV).
   g. Member does NOT have a history of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within the past one year.
   h. Member does NOT have impaired renal or liver function.
   i. Member has NOT had a significant systematic illness or infection in past 30 days.
   j. Member does NOT have relevant brain hemorrhage, bleeding disorder and cerebrovascular abnormalities.
   k. Member does NOT have any contraindications to brain magnetic resonance imaging (MRI) or PET scans.
   l. Member is NOT currently taking blood thinners (except for aspirin at a prophylactic dose $\leq$ 325mg/day).
   m. Member does NOT have a recent history (within last year) of alcohol or substance use disorder OR use of illicit narcotic medication.

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.

SUMMARY OF MEDICAL EVIDENCE

None.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	Description
78608	Brain PET

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

08/09/2023	Policy reviewed, criteria changes 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 re: 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.

REFERENCES

1. Albert MS, DeKosky ST, Dickson D, et al. The diagnosis of mild cognitive impairment due to Alzheimer's disease: Recommendations from the National Institute on Aging-Alzheimer's Association Workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimer's Dement. 2011 May;7(3):270-9. doi: 10.1016/j.jalz.2011.03.008. PMID: 21514249.
2. American College of Radiology (ACR). ACR appropriateness criteria. Accessed July 2023. https://www.acr.org/.
3. Ballard C, Gauthier S, Corbett A, Brayne C, Aarsland D, Jones E. Alzheimer's disease. Lancet. 2011 Mar 19;377(9770):1019-31. doi: 10.1016/S0140-6736(10)61349-9. PMID: 21371747.
4. Chen W. Clinical applications of PET in brain tumors. Journal of Nuclear Medicine, 2007, 48, 1468-1481. doi: 10.2967/jnumed.106.037689.
5. ClinicalTrials.gov. 221AD302 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (EMERGE). Updated September 2, 2021. Accessed July 2023. http://clinicaltrials.gov.
6. ClinicalTrials.gov. 221AD301 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (ENGAGE). Updated September 2, 2021. Accessed July 2023. http://clinicaltrials.gov.
7. Expert Panel on Neurological Imaging, Lee RK, Burns J, Ajam AA, Broder JS, Chakraborty S, et al. ACR appropriateness criteria seizures and epilepsy. J Am Coll Radiol. 2020 May;17(5S):S293-S304. doi: 10.1016/j.jacr.2020.01.037.
8. Folstein MF, Folstein SE, McHugh PR. MMSE Mini-Mental State Examination. https://www.parinc.com/ Accessed July 2023.
9. Knight Alzheimer Disease Research Center (ADRC). Clinical Dementia Rating (CDR®) Dementia Staging Instrument. Accessed July 2023. https://knightadrc.wustl.edu/professionals-clinicians/cdr-dementia-staging-instrument/.
10. Kuzniecky RI. Neuroimaging of epilepsy: Therapeutic implications. NeuroRx. 2005 Apr;2(2):384-93. doi: 10.1602/neurorx.2.2.384.
11. O'Bryant SE, Waring SC, Cullum CM, et al. Staging dementia using Clinical Dementia Rating Scale Sum of Boxes scores: A Texas Alzheimer's Research Consortium study. Arch Neurol. 2008;65(8):1091-1095. doi: 10.1001/archneur.65.8.1091.
12. Widjaja E, Raybaud C. Advances in neuroimaging in patients with epilepsy. Neurosurg Focus. 2008 Sep;25(3):E3. doi: 10.3171/FOC/2008/25/9/E3.