

Radiology

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Brain Positron Emission Tomography (PET) and PET-CT (MCG ORG: A-0096 AC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
78608	Brain positron emission tomography (PET) imaging; metabolic evaluation
78609	Brain positron emission tomography (PET) imaging; perfusion evaluation
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT), limited area (e.g., brain)
A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose (HCPCS radiopharmaceutical)
A9586, A9601, A9602	Florbetapir, florbetaben, and flutemetamol F-18 amyloid PET radiopharmaceuticals, per study dose (HCPCS)
A9598, A9609, Q9982, Q9983, S8085	Additional diagnostic PET radiopharmaceuticals and related imaging agents (HCPCS)

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding diagnostic radiology services, specifically brain positron emission tomography (PET) and PET-CT for evaluation of suspected autoimmune encephalitis, dementia and mild cognitive impairment, and presurgical epilepsy imaging, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of brain PET imaging and to determine when such imaging is medically necessary.

Brain PET is a high-cost advanced imaging study with focused, evidence-defined indications. In the Medicare Advantage population it is most relevant to the differential diagnosis of dementia, including the selection of candidates for emerging anti-amyloid therapy, and to presurgical localization in focal epilepsy. Because Medicare maintains specific national coverage policy for certain PET applications, appropriate use criteria must work alongside those determinations. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary brain PET and inappropriate approval of imaging performed outside its supported indications.

Potential Clinical Harms:

Brain PET and PET-CT: Inappropriate denial of brain PET for suspected autoimmune encephalitis with limbic involvement and inconclusive or contraindicated MRI could delay diagnosis of a treatable inflammatory brain disorder, allowing progressive and potentially

irreversible neurologic injury. Inappropriate denial for the differential diagnosis of dementia could leave Alzheimer disease undistinguished from frontotemporal dementia or dementia with Lewy bodies when that distinction would change management, including eligibility for antiamyloid therapy. Inappropriate denial of presurgical PET in focal epilepsy could prevent accurate localization of the seizure focus, delaying or precluding potentially curative epilepsy surgery.

Clinical Benefits:

Brain PET and PET-CT: MCG criteria provide validated, indication-specific thresholds drawn from consensus and specialty society guidelines, published evidence, and Cochrane systematic reviews. For dementia and mild cognitive impairment, the criteria require that other clinical and imaging tests have been inconclusive and that results will impact the treatment plan (for example, when antiamyloid therapy is being considered), directly countering the harm of misclassified dementia and inappropriate therapy selection identified above. For suspected autoimmune encephalitis, the criteria require limbic symptoms and inconclusive, negative, or contraindicated MRI before PET, and for epilepsy they require a focal-epilepsy presurgical evaluation, ensuring PET is used where it changes management. By tying imaging to these specific clinical pathways, the criteria mitigate the harms of delayed diagnosis of treatable encephalitis, misclassified dementia, and unlocalized epilepsy.

Reduction of unwarranted variation and overutilization: MCG criteria reserve brain PET for presentations where less costly or less complex evaluation has been inconclusive and where the result will alter management, reducing non-indicated high-cost imaging. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria are unlikely to lead to inappropriate denials because they incorporate indications drawn directly from current specialty society and consensus guidelines and high-quality evidence. Use of these criteria ensures patients receive the most clinically appropriate imaging, and decreases inappropriate denials by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

3. Explanation of Supplementation

Basis for Use:

Original Medicare clinical criteria for brain PET are addressed in part by national coverage policy but are not fully established for every clinical indication, and require supplementation to ensure consistent medical necessity determinations. While Medicare statutes establish the general 'reasonable and necessary' standard and CMS maintains national coverage policy for certain PET applications, the available determinations do not specify the full set of clinical thresholds (e.g., the limbic-symptom and MRI criteria for suspected autoimmune encephalitis, the inconclusive-prior-testing and management-impact criteria for dementia, and the focal-epilepsy presurgical criteria) required to distinguish indicated from nonindicated brain PET across all presentations. Where a national or local coverage determination applies, MCG criteria are used to supplement and do not replace, modify, or supersede it.

Applicable Medicare References:

- Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard
- Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 14: Medical Devices (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)

- Medicare Benefit Policy Manual, Chapter 16: General Exclusions from Coverage (CMS IOM Publication 100-02)
- Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08)
- Code of Federal Regulations: 42 CFR 419.22; 42 CFR 422.101
- National Coverage Determinations: CMS maintains national coverage policy applicable to certain PET imaging applications; applicable NCDs and LCDs are followed first, and MCG criteria are used to supplement and do not replace them. For indications not fully addressed by an NCD or LCD, Original Medicare criteria are not fully established, requiring supplementation.
- Medicare Coverage Database:
<https://www.cms.gov/medicare-coverage-database/search.aspx>

Within the above statutes and regulations, coverage criteria for specific brain PET indications are not fully established, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining:

- Medical necessity and appropriateness of brain PET for suspected autoimmune encephalitis with limbic involvement and inconclusive or contraindicated MRI;
- Medical necessity and appropriateness of brain PET for the differential diagnosis of dementia and mild cognitive impairment, including selection of candidates for anti-amyloid therapy, when prior testing is inconclusive and results will impact management;
- Medical necessity and appropriateness of brain PET for presurgical evaluation of focal epilepsy;
- Appropriate clinical setting and expected course for this advanced imaging service.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of brain PET imaging. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure imaging services are not incorrectly denied when medically appropriate for a particular patient, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials. The added criteria will provide numerous clinical benefits in helping ensure patients receive the appropriate level of care. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Background

Brain Positron Emission Tomography (PET) and PET-CT (MCG ORG: A-0096 AC)

Brain PET and PET-CT are advanced functional imaging studies indicated for suspected autoimmune encephalitis with limbic involvement and inconclusive or contraindicated MRI, for the differential diagnosis of dementia and mild cognitive impairment (including selection of candidates for anti-amyloid therapy) when prior testing is inconclusive and results will impact treatment, and for presurgical imaging in focal epilepsy. This MCG care guideline may overlap CMS guidance located in statutes and regulations; for Medicare Advantage beneficiaries, applicable NCDs, LCDs, and other regulations are followed first, and MCG criteria supplement but do not replace them.

Evidence Summary

Brain Positron Emission Tomography (PET) and PET-CT (MCG ORG: A-0096 AC)

The evidence for the clinical indications in this guideline includes 99 published peer-reviewed articles, 5 specialty society or other evidence-based guidelines, and 4 Cochrane systematic reviews. Key evidence includes:

- For suspected autoimmune encephalitis, a consensus-based diagnostic guideline supports brain PET when limbic symptoms are present and MRI is inconclusive, negative, or contraindicated; the guideline notes this indication demonstrates a net benefit of less than moderate certainty, and the criteria reflect this with specific prerequisite findings.
- For dementia and mild cognitive impairment, specialty society guidance supports PET to distinguish Alzheimer disease from other dementias (e.g., frontotemporal dementia, dementia with Lewy bodies) when other clinical and imaging tests are inconclusive and results will impact the treatment plan, including when anti-amyloid therapy is being considered.
- For focal epilepsy requiring presurgical imaging, the criteria are supported by published evidence establishing PET as a tool for localizing the epileptogenic focus when surgery is contemplated.

Rationale (from MCG)

Use of this MCG care guideline helps the clinician identify patient-specific complex clinical factors that determine the medical necessity and appropriate use of brain PET imaging. The evidence-based clinical criteria assist the clinician in deciding when brain PET is appropriate for a specific neurologic indication, including the prerequisite that less complex evaluation has been inconclusive and that the result will impact management. Use of these evidence-based clinical criteria ensures patients receive the most appropriate care for their specific condition, reduces unnecessary risks, promotes recovery, and provides a standard that can reduce disparities in care. Appropriate use of the evidence-based clinical criteria ensures Medicare patients receive full access to Medicare benefits without risk of delay or decreased access. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Related CMS Coverage Guidance (as cited in MCG 30th Edition):

- Code of Federal Regulations (CFR): 42 CFR 419.22; 42 CFR 422.101
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 6 (Hospital Services Under Part B); Chapter 14 (Medical Devices); Chapter 15 (Covered Medical and Other Health Services); Chapter 16 (General Exclusions from Coverage)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5
- National Coverage Determinations: Applicable CMS national coverage policy for PET imaging; followed first, with MCG criteria used to supplement
- Medicare Coverage Determinations: Medicare Coverage Database: <https://www.cms.gov/medicare-coverage-database/search.aspx>

References with Citation Summary -- Brain Positron Emission Tomography (PET) and PET-CT (MCG ORG: A-0096 AC, 30th Edition)

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