Radiologic Diagnostic Procedures

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Instructions for Use

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Related Policies
None

Coverage Guidelines

Diagnostic radiologic procedures are covered when Medicare criteria are met.

Notes:
- Radiology prior authorization programs exist for some markets for MRIs, MRAs, PET scans, and nuclear medicine studies. Reference materials are available at UnitedHealthcare Radiology Prior Authorization and Notification.
- For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.

Diagnostic X-Rays

For coverage guidelines, refer to the:
- Medicare Benefit Policy Manual, Chapter 15, §10 – Supplementary Medical Insurance (SMI) Provisions.
- Medicare Benefit Policy Manual, Chapter 15, §80 – Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests.
- Medicare Benefit Policy Manual, Chapter 15, §80.4 – Coverage of Portable X-Ray Services Not Under the Direct Supervision of a Physician.

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. (Accessed December 11, 2023)

X-Ray, Radium, and Radioactive Isotope Therapy

For coverage guidelines, refer to the Medicare Benefit Policy Manual Chapter 15, §90 – X-Ray, Radium and Radioactive Isotope. (Accessed December 11, 2023)

Bone (Mineral) Density Studies/Mass Measurements

Bone (mineral) density studies/mass measurements are covered when Medicare coverage criteria are met.

Refer to the:

- National Coverage Determination (NCD) for Bone (Mineral) Density Studies (150.3).
- Medicare Benefit Policy Manual, Chapter 15, §80.5 – Bone Mass Measurements (BMMs).
- Medicare Preventive Services-MLN Educational Tool at https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html.

Local Coverage Determinations (LCDs/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/search.aspx. (Accessed December 11, 2023)

Computerized Tomography (CT Scan)

For coverage guidelines, refer to NCD for Computerized Tomography (220.1).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

For states/territories with no LCDs/LCAs, for uses of CT scans not specifically addressed by the National Coverage Determination (NCD) for Computerized Tomography (220.1), refer to the following for coverage guidelines:

- **For regions/states/territories involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program**, refer to the UnitedHealthcare Medicare Advantage Plans Radiology and Cardiology Clinical Guidelines at https://www.uhcprovider.com/en/prior-auth-advance-notification/radiology-prior-authorization.html.
- **For regions/states/territories not involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program**, refer to the nationally recognized guidelines, i.e., InterQual® guidelines.

(Accessed December 11, 2023)

Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)

Multi-detector (multi-detector-row/multi-slice) computed cardiac tomography (MDCT) is also known as cardiac computed tomographic coronary angiography (CCTA) or computed tomography of the heart and coronary arteries.

Medicare does not have an NCD for CCT and CCTA. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Cardiac Computed Tomography and Coronary Computed Tomography Angiography.

For states/territories with no LCD/LCAs, refer to the following for coverage guidelines:

- **For regions involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program**, refer to the UnitedHealthcare Medicare Advantage Plans Radiology and Cardiology Clinical Guidelines at https://www.uhcprovider.com/en/prior-auth-advance-notification/radiology-prior-authorization.html.
- **For regions not involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program**; refer to the nationally recognized guidelines, i.e., InterQual® guidelines.

Note: After checking the Cardiac Computed Tomography and Coronary Computed Tomography Angiography table and the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines. (Accessed December 11, 2023)

Single Photon Emission Computed Tomography (SPECT)

For coverage guidelines, refer to the NCD for Single Photon Emission Computed Tomography (SPECT) (220.12).

Notes:

- Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.
- **For states/territories with no LCDs/LCAs, for uses of SPECT not specifically addressed by the National Coverage Determination (NCD) for SPECT (220.12)**, refer to the following for coverage guidelines:
  - **For regions/states/territories involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program**, refer to the UnitedHealthcare Medicare Advantage Plans Radiology and Cardiology Clinical Guidelines at https://www.uhcprovider.com/en/prior-auth-advance-notification/radiology-prior-authorization.html.
  - **For regions/states/territories not involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program**, refer to the nationally recognized guidelines, i.e., InterQual® guidelines.

(Accessed December 11, 2023)

Magnetic Resonance Imaging (MRI)

For coverage guidelines, refer to the NCD for Magnetic Resonance Imaging (220.2).

Notes:

- Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.
- **For states/territories with no LCDs/LCAs, for uses of MRI not specifically addressed by the National Coverage Determination (NCD) for MRI (220.2)**, refer to the following for coverage guidelines:
  - For regions/states/territories involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program, refer to the UnitedHealthcare Medicare Advantage Plans Radiology and Cardiology Clinical Guidelines at https://www.uhcprovider.com/en/prior-auth-advance-notification/radiology-prior-authorization.html.
  - For regions/states/territories not involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program, refer to the nationally recognized guidelines, i.e., InterQual® guidelines.
- The list of Medicare approved clinical trials is available at https://www.cms.gov/medicare/coverage/evidence.
- For payment rules for NCDs requiring CED, refer to the Medicare Managed Care Manual, Chapter 4, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).

(Accessed December 11, 2023)

Magnetic Resonance Angiography (MRA) (MRI for Blood Flow)

For coverage guidelines, refer to the NCD for Magnetic Resonance Imaging (220.2).

Notes:

- Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.
- **For states/territories with no LCDs/LCAs, for uses of MRA not specifically addressed by the National Coverage Determination (NCD) for MRI (220.2)**, refer to the following for coverage guidelines:
  - **For regions/states/territories involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program** refer to the UnitedHealthcare Medicare Advantage Plans Radiology and Cardiology Clinical Guidelines at https://www.uhcprovider.com/en/prior-auth-advance-notification/radiology-prior-authorization.html.
  - **For regions/states/territories not involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program**, refer to the nationally recognized guidelines, i.e., InterQual® guidelines.

(Accessed December 11, 2023)

Positron Emission Tomography

Positron emission tomography (PET) (FDG) for oncologic conditions may be covered when criteria are met. For up to three PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy, refer to the NCD for Positron Emission Tomography (FDG) for Oncologic Conditions (220.6.17). Coverage of more than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy, Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Positron Emission Tomography (PET) (FDG).

For greater than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy, for states/territories with no LCDs/LCAs refer to the UnitedHealthcare Medicare Advantage Plans Radiology and Cardiology Clinical Guidelines at https://www.uhcprovider.com/en/prior-auth-advance-notification/radiology-prior-authorization.html.

Note: After checking the Positron Emission Tomography (PET) (FDG) table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

PET for other specific conditions may be covered when criteria are met. Refer to the following National Coverage Determinations (NCDs):

- NCD for PET for Perfusion of the Heart (220.6.1).
- NCD for FDG PET for Dementia and Neurodegenerative Diseases (220.6.13).
- The list of Medicare approved clinical trials is available at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/FDG-PET-and-Other-Neuroimaging-Devices-for-Dementia.html.
- For payment rules for NCDs requiring CED, refer to the Medicare Managed Care Manual, Chapter 4, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).
- NCD for FDG PET for Myocardial Viability (220.6.8).
- NCD for FDG PET for Refractory Seizures (220.6.9).
- NCD - Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (220.6.19).

(Accessed December 11, 2023)

Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease

Medicare does not have a National Coverage Determination (NCD) for beta amyloid positron emission tomography. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

UnitedHealthcare considers an amyloid PET scan [including, but not limited to, florbetapir F18 (Amyvid), florbetaben F18 (Neuraceq) flortaucipir F18 injection (Tauvid), flutemetamol F18 (Vizamyl)] reasonable and medically necessary for members with a clinical diagnosis of mild cognitive impairment due to Alzheimer disease or mild Alzheimer Dementia who are being considered for enrollment in a clinical trial/registry of Food and Drug Administration (FDA) approved monoclonal antibodies [(e.g., aducanumab (Aduhelm) or lecanemab-irmab (Leqembi)].

Note: Effective October 13, 2023, CMS removed NCD for Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease (220.6.20) from Publication 100-03, the NCD Manual, ending coverage with evidence development (CED) for positron emission tomography (PET) beta amyloid imaging and permitting Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act. (Accessed December 11, 2023)

Computed Tomographic Colonography (CTC) for Screening Purposes

Refer to the Coverage Summary titled Gastroesophageal and Gastrointestinal (GI) Services and Procedures.

Definitions

Diagnostic Services: A service is “diagnostic” if it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology

and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury. Refer to the Medicare Benefit Policy Manual, Chapter 6, §20.4.1 Diagnostic Services Defined. (Accessed December 11, 2023)

Supporting Information

Positron Emission Tomography (PET)(FDG) Accessed December 11, 2023				
LCD/LCA ID	**LCD/LCA Title**	**Contractor Type**	**Contractor Name**	**Applicable States/Territories**
L35391 (A56848)	Multiple Imaging in Oncology (L35391)	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
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Cardiac Computed Tomography (CCT) and Cardiac Computed Tomography Angiography (CCTA) Accessed December 11, 2023				
LCD/LCA ID	**LCD/LCA Title**	**Contractor Type**	**Contractor Name**	**Applicable States/Territories**
L33947 (A56451)	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	Part A and B MAC	CGS Administrators, LLC	KY, OH
L33559 (A56737)	Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	Part A and B MAC	National Government Services, Inc.	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L33423 (A56691)	Cardiac Computed Tomography & Angiography (CCTA)	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L35121 (A57552)	Coronary Computed Tomography Angiography (CCTA)	Part A and B MAC	Wisconsin Physicians Service Insurance Corporation	IN, IA, KS, MI, MO, NE
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Clinical Evidence

Alcolea D, et al. (2019) reported participants had mild cognitive impairment (n = 35), AD dementia (n = 12), other dementias or neurodegenerative diseases (n = 41), or were cognitively normal controls (n = 6). Levels of Aβ1-42 were standardized to certified reference material. Amyloid scans were assessed visually and through automated quantification. We determined the cutoffs of CSF biomarkers that optimized their agreement with 18 F-Florbetapir PET and evaluated concordance between markers of the amyloid category. Aβ1-42, tTau and pTau (but not Aβ1-40) and the ratios with Aβ1-42 had good diagnostic agreement with 18 F-Florbetapir PET. As a marker of amyloid pathology, the Aβ1-42/Aβ1-40 ratio had higher agreement and better correlation with amyloid PET than Aβ1-42 alone. CSF biomarkers measured with the Lumipulse G System show good agreement with amyloid imaging in a clinical setting with heterogeneous presentations of neurological disorders. Combination of Aβ1-42 with Aβ1-40 increases the agreement between markers of amyloid pathology.

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is insufficient to conclude that the use of positron emission tomography (PET) amyloid-beta (Aβ) imaging is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member for Medicare beneficiaries with dementia or neurodegenerative disease, and thus PET Aβ imaging is not covered under §1862(a)(1)(A) of the Social Security Act ("the Act").

However, there is sufficient evidence that the use of PET Aβ imaging is promising in two scenarios: (1) to exclude Alzheimer's disease (AD) in narrowly defined and clinically difficult differential diagnoses, such as AD versus frontotemporal dementia (FTD); and (2) to enrich clinical trials seeking better treatments or prevention strategies for AD, by allowing for selection of patients on the basis of biological as well as clinical and epidemiological factors.

Clinical Practice Guidelines

The Society of Nuclear Medicine and Molecular Imaging (SNMMI)

The goal of this standard/guideline is to assist nuclear medicine practitioners in recommending, performing, interpreting, and reporting the results of brain PET imaging that depicts β-amyloid (Aβ) deposition in the brain (referred to as amyloid PET hereafter).

Appropriate-use criteria for amyloid PET have been published recently by the SNMMI and Alzheimer's Association joint task force. The appropriate-use criteria emphasize that amyloid PET is currently most likely to be helpful when the patient has objectively confirmed cognitive impairment, when the cause of cognitive impairment remains uncertain after a comprehensive evaluation by a dementia expert, when the differential diagnosis includes AD dementia, and when knowledge of the presence or absence of Aβ pathology is expected to increase diagnostic certainty or alter patient management.

The use of amyloid PET is considered appropriate when any of the following is true: the patient has persistent or progressive unexplained mild cognitive impairment (MCI); the core clinical criteria for possible AD are satisfied but there is an unclear clinical presentation – either an atypical clinical course or an etiologically mixed presentation; or the patient has progressive dementia and the age of onset was atypically early (usually defined as ≤ 65 y).

The use of amyloid PET is considered inappropriate when any of the following is true: the patient meets the core clinical criteria for probable AD and had a typical age of onset, there is a need to determine the severity of dementia, the patient is asymptomatic and either has a family history of AD or has been shown to carry the ε4 allele of apolipoprotein E, the patient has a cognitive complaint that has not been confirmed on clinical examination, a test in lieu of genotyping is needed for a patient who is a suspected autosomal dominant mutation carrier, the patient is asymptomatic, or the imaging is to be performed for nonmedical reasons (e.g., legal, insurance coverage, or employment screening).

References

Alcolea D, et al. Agreement of amyloid PET and CSF biomarkers for Alzheimer's disease on Lumipulse. Annals of Clinical and Translational Neurology 2019; 6(9): 1815-1824.

Centers for Medicare and Medicaid Services (CMS) Amyloid PET. Refer to the following website for more information: https://www.cms.gov/medicare/coverage/evidence/amyloid-pet#:~:text=Amyloid%20PET%20imaging%20uses%20a,Vizamyl%E2%84%A2%20(flutemetamol%20F18). Accessed December 11, 2023.

Centers for Medicare and Medicaid Services (CMS) National Coverage Analysis (NCA). Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease.

Centers for Medicare and Medicaid Services (CMS) Prospective Study on Anti-Amyloid-β Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Coverage of Evidence Development (The Anti-Aβ mAb CED Study). Refer to the following website for more information: https://www.cms.gov/files/document/ced-study-description.pdf. Accessed December 11, 2023.

Minoshima S, Drzezga AE, Barthel H, et al. SNMMI Procedure Standard/EANM Practice Guideline for Amyloid PET Imaging of the Brain 1.0. J Nucl Med. 2016 Aug;57(8):1316-22.

Policy History/Revision Information

Approval Date	Summary of Changes
12/13/2023	**Template Update** • Updated *Instructions for Use*

Approval Date	Summary of Changes
	Coverage Guidelines ***Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)*** • Revised language pertaining to states/territories with no Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) for regions not involved in the UnitedHealthcare Radiology Prior Authorization and Notification Program; replaced reference link to the WPS LCD for Coronary Computed Tomography Angiography (CCTA) (L35121) with instruction to refer to the nationally recognized guidelines (i.e., InterQual®) ***Magnetic Resonance Imaging (MRI)*** • Updated reference link to the list of Medicare-approved clinical trials ***Positron Emission Tomography*** • Modified content heading • Added language to indicate: ○ For up to three PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy, refer to the NCD for Positron Emission Tomography (FDG) for Oncologic Conditions (220.6.17) ○ For coverage of more than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy, LCDs/LCAs exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the policy] for Positron Emission Tomography (PET) (FDG) ○ For greater than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Medicare Advantage Plans Radiology and Cardiology Clinical Guidelines at https://www.uhcprovider.com/en/prior-auth-advance-notification/radiology-prior-authorization.html ○ After checking the Positron Emission Tomography (PET) (FDG) table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the UnitedHealthcare Medicare Advantage Plans Radiology and Cardiology Clinical Guidelines for coverage guidelines Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease • Revised language to indicate: ○ Medicare does not have a National Coverage Determination (NCD) for beta amyloid positron emission tomography; Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist ○ UnitedHealthcare considers an amyloid positron emission tomography (PET) scan [including, but not limited to, florbetapir F18 (Amyvid), florbetaben F18 (Neuraceq), flortaucipir F18 injection (Tauvid), flutemetamol F18 (Vizamyl)] reasonable and medically necessary for members with a clinical diagnosis of mild cognitive impairment due to Alzheimer disease or mild Alzheimer Dementia who are being considered for enrollment in a clinical trial of Food and Drug Administration (FDA) approved monoclonal antibodies [(e.g., aducanumab (Aduhelm) or lecanemab-irmab (Leqembi)] ○ Effective Oct. 13, 2023, Centers for Medicare & Medicaid (CMS) removed NCD for *Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease (220.6.20)* from *Publication 100-03*, of the *NCD Manual*, ending coverage with evidence development (CED) for positron emission tomography (PET) beta amyloid imaging and permitting Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors under section *1862(a)(1)(A) of the Social Security Act* **Supporting Information** • Added *Clinical Evidence* and *References* sections • Updated list of available LCDs/LCAs to reflect the most current information • Archived previous policy version MCS076.06

Instructions for Use

This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member's Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member's EOC/SB, the member's EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. UnitedHealthcare utilizes the additional criteria noted above to supplement Medicare coverage guidelines in order to determine medical necessity consistently. The additional coverage criteria was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.