

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12364	Date: November 16, 2023
	Change Request 13429

SUBJECT: NCD 220.6.20 - Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to announce that effective October 13, 2023, CMS removed NCD 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.

EFFECTIVE DATE: October 13, 2023

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: December 19, 2023 - A/B MACs; April 1, 2024 - CWF, MCS, FISS

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	13/60/12/Coverage for PET Scans for Dementia and Neurodegenerative Diseases

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

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EFFECTIVE DATE: October 13, 2023

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IMPLEMENTATION DATE: December 19, 2023 - A/B MACs; April 1, 2024 - CWF, MCS, FISS

I. GENERAL INFORMATION

A. Background: Effective for claims with dates of service on or after, September 27, 2013, CMS covered the use of Positron Emission Tomography (PET) beta amyloid imaging to improve health outcomes for Medicare beneficiaries with dementia or neurodegenerative disease in certain scenarios under National Coverage Determination (NCD) 220.6.20. Since then, Medicare allowed coverage for one PET beta amyloid imaging scan per lifetime through coverage with evidence development (CED) to: (1) develop better treatments or prevention strategies for Alzheimer’s Disease (AD), or, as a strategy to identify subpopulations at risk for developing AD, or (2) resolve clinically difficult differential diagnoses (e.g., frontotemporal dementia (FTD) versus AD) where the use of PET beta amyloid imaging appears to improve health outcomes, when the patient is enrolled in an approved clinical study under CED. CMS reconsidered NCD 220.6.20 and made a final determination on October 13, 2023, to remove the NCD in its entirety.

B. Policy: Effective for claims with dates of service on and after October 13, 2023, CMS removed NCD 220.6.20 from Publication 100-03, the NCD Manual, ending CED and the once-in-a-lifetime requirement for 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. See NCD Manual chapter 1, section 220.6.20, Claims Processing Manual, chapter 13, section 60.12, and the attached spreadsheet.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13429 - 04.1	Effective for claims with dates of service on and after October 13, 2023, as a result of the reconsideration of NCD 220.6.20 Beta Amyloid PET in Dementia/Neurodegenerative Disease, contractors shall be aware that this NCD has been removed. (See Pub. 100-03 NCD 220.6.20 and CPM Chapter 32 Section 60.12)	X	X							
13429 - 04.2	Effective for claims with dates of service on and after October	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	13, 2023, contractors shall determine coverage.									
13429 - 04.3	Effective for claims with dates of service on and after October 13, 2023, contractors shall retroactively deactivate any local edits pertaining to PET Beta Amyloid; i.e., the requirements of CED and once-in-a-lifetime PET scans, within 30 days of issuance of this CR.	X	X							
13429 - 04.4	Contractors shall deactivate all shared system edits for NCD 220.6.20 by April 1, 2024 for CWF Error 5279, MCS audits 010K, 011K, and RC 59233. NCD 220.6.20 should no longer apply to claims regardless of the date of service billed on the claim.		X			X	X		X	
13429 - 04.5	Effective for claims with dates of service on and after October 13, 2023, contractors shall adjust any PET beta amyloid claims brought to their attention.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13429 - 04.6	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get	X	X			

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

60.12 - Coverage for PET Scans for Dementia and Neurodegenerative Diseases

(Rev. 12364; Issued: 11-16-23; Effective: 10-13-23; Implementation:12-19-23)

Effective for dates of service on or after September 15, 2004, Medicare will cover *Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET)* scans for a differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (*AD*) OR; its use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Refer to Pub. 100-03, *National Coverage Determination (NCD)* Manual, section 220.6.13, for complete coverage conditions.

A. *NCD 220.6.13 - A/B Medicare Administrative Contractors (MACs)* (A and B) Billing Requirements for PET Scan Claims for FDG-PET for the Differential Diagnosis of Fronto-temporal Dementia and Alzheimer's Disease:

Current Procedural Terminology (CPT) Code for PET Scans for Dementia and Neurodegenerative Diseases

Contractors shall advise providers to use the appropriate CPT code from section 60.3.1 for dementia and neurodegenerative diseases for services performed on or after January 28, 2005.

Diagnosis Codes for PET Scans for Dementia and Neurodegenerative Diseases

The contractor shall ensure one of the following appropriate diagnosis codes is present on claims for PET Scans for AD:

- ICD-10-CM is applicable, ICD-10 codes are: F03.90, F03.90 plus F05, G30.9, G31.01, G31.9, R41.2 or R41.3

Medicare contractors shall deny claims when submitted with an appropriate CPT code from section 60.3.1 and with a diagnosis code other than the range of codes listed above.

Medicare contractors shall instruct providers to issue an Advanced Beneficiary Notice to beneficiaries advising them of potential financial liability prior to delivering the service if one of the appropriate diagnosis codes will not be present on the claim.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. *This Claim Adjustment Reason Code (CARC)/Remittance Advice Remark Code (RARC)* combination is compliant with CAQH CORE Business Scenario Three.

- Group Code: PR (*patient responsibility*) (if claim is received with a GA modifier) otherwise CO (*contractual obligation*)
- CARC: 11
- RARC: N/A
- Medicare Summary Notice (MSN)*: 16.48

Provider Documentation Required with the PET Scan Claim

Medicare contractors shall inform providers to ensure the conditions mentioned in the NCD Manual, section 220.6.13, have been met. The information must also be maintained in the beneficiary's medical record:

- Date of onset of symptoms,
- Diagnosis of clinical syndrome (normal aging, mild cognitive impairment or MCI: mild, moderate, or severe dementia),
- Mini mental status exam (MMSE) or similar test score,
- Presumptive cause (possible, probably, uncertain AD),
- Any neuropsychological testing performed,

- Results of any structural imaging (MRI, CT) performed,
- Relevant laboratory tests (B12, thyroid hormone), and,
- Number and name of prescribed medications.

B. *NCD 220.6.20* - Billing Requirements for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease.

Effective October 13, 2023, as a result of the reconsideration of NCD 220.6.20, and under section 1862(a)(1)(A) of the Social Security Act, this NCD has been removed. Coverage determinations are now made by the MACs. See NCD 220.6.20 of the NCD Manual.

Effective for claims with dates of service on and after September 27, 2013, *thru October 12, 2023*, Medicare will only allow coverage with evidence development (CED) for PET beta amyloid (also referred to as amyloid-beta (A β)) imaging (*Healthcare Common Procedure Coding System (HCPCS) A9586*) or (HCPCS Q9982) or (HCPCS Q9983) (one PET A β scan per patient).

Effective for dates of service on or after September 27, 2013, *thru October 12, 2023*, contractors shall return as unprocessable/return to provider claims for PET A β imaging, through CED during a clinical trial, not containing the following:

- Condition code 30, and value code D4 (FI only)
- Modifier Q0 as appropriate
- *ICD-10 dx code Z00.6* (in either the primary/secondary position)
- A PET HCPCS code (78811 or 78814)
- At least one *diagnosis* code from the table below,

And one of these additional diagnoses is required in addition to Z00.6

F03.90	Unspecified dementia without behavioral disturbance
F03.91	Unspecified dementia with behavioral disturbance
F01.50	Vascular dementia without behavioral disturbance
F01.51	Vascular dementia with behavioral disturbance
F02.80	Dementia in other diseases classified elsewhere without behavioral disturbance
F02.81	Dementia in other diseases classified elsewhere with behavioral disturbance
G31.01	Pick's disease
G31.09	Other frontotemporal dementia
G31.85	Corticobasal degeneration
G31.83	Dementia with Lewy bodies
G31.84	Mild cognitive impairment, so stated
R41.1	Anterograde amnesia
R41.2	Retrograde amnesia
R41.3	Other amnesia (amnesia NOS, memory loss NOS)

and

- A β HCPCS code A9586 or Q9982 or Q9983.

MSN, RARC and CARC Codes

Contractors shall return as unprocessable claims for PET A β imaging using the following messages:

-CARC 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.

Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

-RARC N519 - Invalid combination of HCPCS modifiers.

Contractors shall line-item deny claims for PET Aβ, HCPCS code A9586 or Q9982 or Q9983, where a previous PET Aβ, HCPCS code A9586 or Q9982 or Q9983 is paid in history using the following messages:

-CARC 149: “Lifetime benefit maximum has been reached for this service/benefit category.”

-RARC N587: “Policy benefits have been exhausted”.

-MSN 20.12: “This service was denied because Medicare only covers this service once a lifetime.”

Spanish Version: “Este servicio fue negado porque Medicare sólo cubre este servicio una vez en la vida.”

-Group Code: PR, if a claim is received with a GA modifier

-Group Code: CO, if a claim is received with a GZ modifier