CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12571	**Date: April 11, 2024**
	Change Request 13512

SUBJECT: National Coverage Determination (NCD) 20.7 Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make contractors aware of policy updates for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting sections B4 and D of NCD 20.7.

EFFECTIVE DATE: October 11, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 13, 2024 - MACs; October 7, 2024 - FISS for BR 13512-04.2 for Pub.100-04

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	32/Table of Contents
R	32/68//68.4/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE
R	32/160/160.2/Post-Approval Study Coverage
R	32/160/160.3/Carotid Artery Stenting (CAS) With Embolic Protection Coverage
D	32/160/160.4/510k Post-Approval Extension Studies using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures

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

Pub. 100-04	Transmittal: 12571	Date: April 11, 2024	Change Request: 13512

SUBJECT: National Coverage Determination (NCD) 20.7 Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

EFFECTIVE DATE: October 11, 2023
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I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to to make contractors aware of policy updates for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting sections B4 and D of NCD 20.7.

The Centers for Medicare & Medicaid Services (CMS) previously covered PTA of the carotid artery concurrent with stenting under national coverage determination (NCD) 20.7 for certain beneficiaries when furnished in CMS-approved facilities with programs that met standards to determine competency including physician training standards, facility support requirements, and data collection to evaluate outcomes during a required reevaluation. The previous version of NCD 20.7 covered PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection for:

- Patients at high risk for CEA with symptomatic carotid artery stenosis ≥ 70%;
- Patients at high risk for CEA with symptomatic carotid artery stenosis between 50 and 70% in accordance with the Category B investigational device exemption (IDE) clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (NCD 310.1), or in accordance with the NCD on CAS post-approval studies (NCD 20.7, B3);
- Patients at high risk for CEA with asymptomatic carotid artery stenosis ≥ 80% in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (NCD 310.1), or in accordance with the NCD on CAS post-approval studies (NCD 20.7, B3).

In 2023, CMS reconsidered this NCD and issued a final decision memorandum on October 11, 2023.

B. Policy: On October 11, 2023, CMS issued an NCD updating coverage under section B4 of NCD 20.7. The updated NCD covers PTA of the carotid artery concurrent with stenting with the placement of an FDA-approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries with symptomatic carotid artery stenosis ≥50% and asymptomatic carotid artery stenosis ≥70%. The NCD also sets forth requirements regarding neurological assessments, imaging, shared decision-making, and retains institutional and physician standards. It removes the requirement that facilities that perform CAS procedures must be approved by CMS. Additionally, CMS revised section D of NCD 20.7 to allow MACs to make reasonable and necessary determinations under section 1862(a)(1)(A) for any other beneficiary seeking coverage for PTA of the carotid artery concurrent with stenting.

Note: As a result of the revised eligibility criteria for this NCD, CMS is replacing the current text of 20.7 sections B4 and D of the NCD Manual, Publication (Pub.) 100-03, Chapter 1, Part 1, and Chapter 32, Section 160 of the Claims Processing (MCP) Manual, Pub. 100-04.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13512 - 04.1	Effective for claims with dates of service on and after October 11, 2023, contractors shall cover PTA of the carotid artery concurrent with stenting with the placement of an FDA-approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries under the following updated conditions: A. Patients with symptomatic carotid artery stenosis ≥50%; and, B. Patients with asymptomatic carotid artery stenosis ≥70%.	X	X							
13512 - 04.2	Contractors shall end-date the logic associated with ICD-10 Diagnosis Code Z00.6 and any editing related to clinical trial or approved facility requirements effective for dates of service on or after October 11, 2023.	X	X			X				
13512 - 04.3	Contractors should cover claims for PTA of the carotid artery concurrent with stenting not otherwise addressed in NCD 20.7 at local discretion.	X	X							
13512 - 04.4	Contractors shall not search and adjust for previously submitted claims unless bought to their attention.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13512 - 04.5	Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.	X	X			

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

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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(Rev.12571; Issued:04-11-24)

68.4 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE

(Rev. 12571; Issued: 04-11-24) Effective: 10-11-23; Implementation: -05-13-24)

As noted above in section 68.2, of this chapter, providers shall first notify their contractor of the IDE device trial before submitting claims for Category B IDE devices and the routine costs of clinical trials involving Category B IDE devices. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill Category B IDE claims.

When billing for Category B IDEs, providers shall bill for the device and all related procedures. The Category B IDE device and the routine costs associated with its use are eligible for payment under Medicare. (Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.)

Institutional Inpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

Institutional Outpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable.
- Appropriate HCPCS modifier:
    - Q0 or Q1 as appropriate for claims with dates of service on or after January 1, 2014; or
    - Q0 (numeral 0 versus the letter O) modifier for claims with dates of service on or after January 1, 2008; or
    - QA modifier for claims with dates of service prior to January 1, 2008.
- Category B IDE number
- Charges for the device billed as covered charges

NOTE: For claims prior to January 1, 2014, if the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing 'no cost items' under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Effective January 1, 2014, if the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with condition code "53" and Value Code "FD". For more information on billing 'no cost items' under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Practitioner Billing

Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Providers report the 8-digit number on the following claims locators:

- 837 professional claim format (do not use 'CT' on the electronic claim) or,
- CMS-1500 paper form-place in Field 19 (preceded by 'CT').

In addition to the clinical trial number, claims shall include (in either the primary/secondary positions):

- If ICD-9-CM is applicable, ICD-9 diagnosis code V70.7
- If ICD-10-CM is applicable, ICD-10 diagnosis code Z00.6
- HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code-Contractual Obligation (CO)

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter O) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category B IDE number on institutional and practitioner claims:

Data	**CMS-1450**	**CMS-1500**	**837 institutional claim format and 837 professional claim format**
IDE #	Revenue Code Description field	Item 23	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services."

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT."

Claims that are submitted without the 'Q0' modifier will be returned with the following messages:

CARC 16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N822 – Missing procedure modifier(s).

160.1 – Category B Investigational Device Exemption (IDE) Study Coverage

(Rev. 12571; Issued: 04-11-24) Effective: 10-11-23; Implementation: -05-13-24)

Effective July 1, 2001, Medicare covers percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stent placement when furnished in accordance with the Food and Drug Administration (FDA) protocols governing Category B Investigational Device Exemption (IDE) studies.

The billing for this procedure is based upon how the service is delivered. There are several CPT codes that may be billed depending upon how the procedure is performed. Contractor medical directors should consider what provider education information is needed to assist providers on the billing for this service.

Contractors must review their local coverage determinations to ensure that payment is provided for claims for PTA in an FDA-approved clinical study.

As a requirement for Category B IDE coverage, providers must bill a six-digit IDE Number that begins with a "G" (i.e., G123456). To identify the line as an IDE line, institutional providers must bill this IDE Number on a 0624 Revenue Code line while practitioners must bill this IDE Number along with a Q0 modifier.

160.2 – Post-Approval Study Coverage

(Rev. 12571; Issued: 04-11-24) Effective: 10-11-23; Implementation: -05-13-24)

Effective October 12, 2004, *under section B3 of NCD 20.7*, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or –cleared embolic protection device (effective December 9, 2009) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. *Also included in the currently covered population of patients participating in FDA-approved post-approval studies are patients participating in post-approval extension studies and patients participating in studies following FDA 510k approval of these devices.*

Billing post-approval studies is similar to normal Category B IDE billing procedures, except that under post-approval coverage, providers must bill the Pre-Market Approval (PMA) number assigned to the stent system by the FDA. PMA numbers are like typical IDE Numbers in that they have six-digits, but they begin with a "P" (i.e., P123456) instead of a "G."

160.3 – Carotid Artery Stenting (CAS) With Embolic Protection Coverage

(Rev. 12571; Issued: 04-11-24) Effective: 10-11-23; Implementation: -05-13-24)

On October 11, 2023, CMS issued a reconsideration of NCD 20.7. The updated NCD covers PTA of the carotid artery concurrent with stenting with the placement of an FDA-approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries with symptomatic carotid artery stenosis ≥50% and asymptomatic carotid artery stenosis ≥70%. The NCD also sets forth requirements regarding neurological assessments, imaging, shared decision-making, and retains institutional and physician standards but removes the requirement that facilities that perform CAS procedures must be approved by CMS. Additionally, CMS revised section D of NCD 20.7 to allow MACs to make reasonable and necessary determinations under section 1862(a)(1)(A) for any other beneficiary seeking coverage for PTA of the carotid artery concurrent with stenting.

A. Billing

Effective for claims with dates of services on or after October 11, 2023, contractors shall cover PTA of the carotid artery concurrent with stenting with the placement of an FDA-approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries under the following conditions:
A. Patients with symptomatic carotid artery stenosis- ≥50%; and,
B. Patients with asymptomatic carotid artery stenosis ≥70%.
Also effective for claims with dates of service on or after October 11, 2023, beneficiaries no longer have to be enrolled in a clinical trial for this service. Contractors may also pay for claims for PTA of the carotid artery concurrent with stenting not otherwise addressed in The National Coverage Determinations Manual, Chapter 1, part 1, section 20.7 at local discretion.

Effective March 17, 2005, *through October 10, 2023,* Medicare covered PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection under specific patient indications found in Pub. 100-03, Medicare National Coverage Determinations Manual, part 1, section 20.7. Coverage was limited to procedures performed using FDA-approved CAS systems and FDA-approved or –cleared (effective December 9, 2009) embolic protection devices (EPDs). If deployment of the EPD was not technically possible, and not performed, then the procedure was not covered.

In addition to the specific patient indications, CMS determined that CAS with embolic protection was reasonable and necessary only if performed in facilities that had been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. CMS created a list of minimum standards modeled in part on professional society statements on competency. All facilities were required to at least meet CMS's standards in order to receive coverage for CAS for high-risk patients. Facilities were required to recertify every 2 years in order to maintain coverage of CAS procedures.