CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	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	1/Part1/20.7/Percutaneous Transluminal Angioplasty (PTA) (Various Effective Dates Below)

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. 100-03	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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IMPLEMENTATION DATE: May 13, 2024 - MACs; October 7, 2024 - FISS for BR 13512-04.2 for Pub.100-04

I. GENERAL INFORMATION

A. Background: 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.

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 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 MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13512 - 03.1	Effective for claims with dates of service on and after October 11, 2023, contractors shall cover claims for percutaneous transluminal angioplasty as described in section 20.7 specifically revised B4 and D of the NCD Manual.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13512 - 03.2	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: 1

Medicare National Coverage Determinations Manual
Chapter 1, Part 1 (Sections 10 – 80.12)
Coverage Determinations

Table of Contents
(Rev. 12571, Issued: 04-11-24)

20.7 – Percutaneous Transluminal Angioplasty (PTA) (Various Effective Dates Below)

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

A. General

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of percutaneous transluminal angioplasty (PTA) is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.

B. Nationally Covered Indications

The PTA is covered when used under the following conditions:

1. Treatment of Atherosclerotic Obstructive Lesions

-In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries. The upper extremities do not include head or neck vessels.

-Of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics:

- Angina refractory to optimal medical management;
- Objective evidence of myocardial ischemia; and
- Lesions amenable to angioplasty

-Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.

-Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

2. Concurrent with Carotid Stent Placement in Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials

Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service when provided in the context of such a clinical trial.

3. Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies

Effective October 12, 2004, 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. The Centers for Medicare & Medicaid Services (CMS) determines that coverage of PTA of the carotid artery is reasonable and necessary in these circumstances.

4. Concurrent with Carotid Stent Placement

Effective October 11, 2023, CMS 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 under the following conditions:

A. Patients with symptomatic carotid artery stenosis ≥50%; and,
B. Patients with asymptomatic carotid artery stenosis ≥70%.

For both A and B above:

1. *Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after CAS must be performed.*
2. *First-line evaluation of carotid artery stenosis must use duplex ultrasound.*
3. *Computed tomography angiography or magnetic resonance angiography, if not contraindicated, must be used to confirm the degree of stenosis and provide additional information about the aortic arch, and extra- and intra-cranial circulation.*
4. *Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated.*

Prior to furnishing CAS, the practitioner must engage in a formal shared decision-making interaction with the beneficiary. The shared decision-making interaction must include:

- *Discussion of all treatment options including carotid endarterectomy (CEA), CAS (which includes transcarotid artery revascularization (TCAR), and optimal medical therapy (OMT)).*
- *Explanation of risks and benefits for each option specific to the beneficiary's clinical situation.*
- *Integration of clinical guidelines (e.g., patient comorbidities and concomitant treatments).*
- *Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.*

Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. These standards must at least include and ensure the following:

- *Facilities have a clearly delineated program for granting carotid stent privileges and for monitoring patient outcomes for individual physicians and the program as a whole.*
- *The oversight committee for this program shall be empowered to identify the minimum case volume for a physician to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are encouraged to apply published standards from specialty societies and widely-used, published professional society guidelines to determine appropriate physician qualifications.*
- *Facilities have appropriately trained staff capable of fulfilling roles and responsibilities as delineated under the dedicated carotid stent program.*
- *Facilities have appropriate supporting personnel and equipment for imaging, emergency management, advanced physiologic monitoring, and other ancillary care.*
- *Facilities must ensure continuous quality improvement by assessing procedural outcomes and making necessary programmatic adjustments to assure patient safety.*

5. Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials

Effective November 6, 2006, Medicare covers PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis ≥50% in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.

C. Nationally Non-Covered Indications

All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain non-covered.

All other indications for PTA without stenting for which CMS has not specifically indicated coverage remain non-covered.

D. Other

In addition to the national coverage described above, Medicare Administrative Contractors (MACs) may make reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act for any other beneficiary seeking coverage for PTA of the carotid artery concurrent with stenting.

Coverage of PTA with stenting not specifically addressed or discussed in this NCD is at *the* discretion *of the MACs*.

(This NCD last reviewed October 2023)

NCD:	20.7		
NCD Title:	Percutaneous Transluminal Angioplasty (PTA)		
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1925CP.pdf		
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0		
	CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.		
		ICD-10 CM	**ICD-10 DX Description**
Indications for PTA of the Carotid Artery Concurrent with Stenting (must bill one of these primary codes to meet coverage under 20.7B2, 20.7B3, 20.7B4) **Coverage of PTA with stenting not specifically addressed or discussed in this NCD is at the discretion of the MACs.** **Effective 10/11/23: In addition to the national coverage described , Medicare Administrative Contractors (MACs) may make reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act for any other beneficiary seeking coverage for PTA of the carotid artery concurrent with stenting.**			
		I63.031	Cerebral infarction due to thrombosis of right carotid artery
		I63.032	Cerebral infarction due to thrombosis of left carotid artery
		I63.033	Cerebral infarction due to thrombosis of bilateral carotid arteries
		I63.131	Cerebral infarction due to embolism of right carotid artery
		I63.132	Cerebral infarction due to embolism of left carotid artery
		I63.133	Cerebral infarction due to embolism of bilateral carotid arteries
		I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
		I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
		I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries
		I65.21	Occlusion and stenosis of right carotid artery
		I65.22	Occlusion and stenosis of left carotid artery
		I65.23	Occlusion and stenosis of bilateral carotid arteries
Indications for PTA and Stenting of Intracranial Arteries (must bill I67.2 and one of these primary codes to meet coverage under 20.7B5)			
		I67.2	Cerebral atherosclerosis
		I66.01	Occlusion and stenosis of right middle cerebral artery
		I66.02	Occlusion and stenosis of left middle cerebral artery
		I66.03	Occlusion and stenosis of bilateral middle cerebral arteries
		I66.11	Occlusion and stenosis of right anterior cerebral artery
		I66.12	Occlusion and stenosis of left anterior cerebral artery
		I66.13	Occlusion and stenosis of bilateral anterior cerebral arteries
		I66.21	Occlusion and stenosis of right posterior cerebral artery
		I66.22	Occlusion and stenosis of left posterior cerebral artery
		I66.23	Occlusion and stenosis of bilateral posterior cerebral arteries
		I66.8	Occlusion and stenosis of other cerebral arteries
		I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
Claims must include codes from the lists as noted above. This does not preclude the inclusion of additional codes specific to each procedure. Z00.6 must be appended to claims for clinical trials covered under this policy as described below and specified in NCD 20.7.			
For Clinical Trial Billing (clinical trial participation required for all claims under 20.7B2, 20.7B3, 20.7B5. Effective 10/11/23, clinical trial participation is not required for 20.7B4.			
		Z00.6	Encounter for examination for normal comparison and control in clinical research program
For Denials			
		T85.9xxA	Unspecified complication of internal prosthetic device, implant and graft, initial encounter

NCD:	20.7
NCD Title:	Percutaneous Transluminal Angioplasty (PTA)
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1925CP.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0

CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.

		ICD-10 PCS	ICD-10 PCS Description
		037G34Z	Dilation of Intracranial Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
		037G35Z	Dilation of Intracranial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
		037G36Z	Dilation of Intracranial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
		037G37Z	Dilation of Intracranial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
		037G3DZ	Dilation of Intracranial Artery with Intraluminal Device, Percutaneous Approach
		037G3EZ	Dilation of Intracranial Artery with Two Intraluminal Devices, Percutaneous Approach
		037G3FZ	Dilation of Intracranial Artery with Three Intraluminal Devices, Percutaneous Approach
		037G3GZ	Dilation of Intracranial Artery with Four or More Intraluminal Devices, Percutaneous Approach
		037G44Z	Dilation of Intracranial Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
		037G45Z	Dilation of Intracranial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
		037G46Z	Dilation of Intracranial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
		037G47Z	Dilation of Intracranial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
		037G4DZ	Dilation of Intracranial Artery with Intraluminal Device, Percutaneous Endoscopic Approach
		037G4EZ	Dilation of Intracranial Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
		037G4FZ	Dilation of Intracranial Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
		037G4GZ	Dilation of Intracranial Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
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		037N35Z	Dilation of Left External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
		037N36Z	Dilation of Left External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
		037N37Z	Dilation of Left External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
		037N3DZ	Dilation of Left External Carotid Artery with Intraluminal Device, Percutaneous Approach
		037N3EZ	Dilation of Left External Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
		037N3FZ	Dilation of Left External Carotid Artery with Three Intraluminal Devices, Percutaneous Approach
		037N3GZ	Dilation of Left External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
		037N44Z	Dilation of Left External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
		037N45Z	Dilation of Left External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
		037N46Z	Dilation of Left External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach

		037N47Z	Dilation of Left External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
		037N4DZ	Dilation of Left External Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
		037N4EZ	Dilation of Left External Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
		037N4FZ	Dilation of Left External Carotid Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
		037N4GZ	Dilation of Left External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach

NCD:	20.7
NCD Title:	Percutaneous Transluminal Angioplasty (PTA) (CR3811, CR8197 CR8691, CR9252, CR9631, CR9751, CR11005, CR11392, CR13070, **CR13512**)
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1925CP.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0

Part A	Rule Description Part A	Proposed HCPCS/CPT Part A	Frequency Limitations	TOB (Part A)	Revenue Code Part A	Modifier Part A	Provider Specialty	Proposed MSN Message Part A	Proposed CARC Message Part A	Proposed RARC Message Part A
Part A	**A/MACs:** Effective 7/1/01, covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved- protocols governing Category B IDE clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be R&N when provided in the context of such a clinical trial.	See ICD Procedure Tab	N/A	N/A	N/A	Q0 Q1 FB	N/A	16.77	16	MA50
Part A	As a requirement for Category B IDE coverage, providers must bill a 6-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	N/A	N/A	N/A	0624	N/A	N/A	16.77	16	M50
Part A	**A/MACs:** Effective 10/12/04, 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 12/9/09) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. CMS determines that coverage of PTA of the carotid artery is R&N in these circumstances	See ICD Procedure Tab	N/A	N/A	N/A	Q0	N/A	16.77	16	MA50
Part A	**A/MACs:** Effective 3/17/05, Shall pay claims that contain the following for beneficiaries that meet the high risk criteria listed under the policy section of this instruction and in Pub 100-03, chapter 1, section 20.7B4. MCS edit 037L remains. **NOTE:** Procedures that are not performed in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (NCD310.1), or in accordance with the NCD on (CAS) post-approval studies (NCD20.7) must be performed in approved CAS facilities. A list of approved facilities is available/viewable at https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-Facilities.html End-dated 10/10/2023. Effective 10/11/2023, see new 20.7B4 coverage.	See ICD Procedure Tab								

NCD:	20.7									
NCD Title:	Percutaneous Transluminal Angioplasty (PTA) (CR3811, CR8197 CR8691, CR9252, CR9631, CR9751, CR11005, CR11392, CR13070, **CR13512**)									
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1925CP.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0									
	A/MACs: Effective 10/11/23, under 20.7B4, CMS 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 under the following conditions: A. Patients with symptomatic carotid artery stenosis ≥50%; and, B. Patients with asymptomatic carotid artery stenosis ≥70%. For both A and B above: 1. Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after carotid artery stenting (CAS) must be performed. 2. First-line evaluation of carotid artery stenosis must use duplex ultrasound. 3. Computed tomography angiography or magnetic resonance angiography, if not contraindicated, must be used to confirm the degree of stenosis and provide additional information about the aortic arch, and extra-and intra-cranial circulation. 4. Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated. Prior to furnishing CAS, the practitioner must engage in a formal shared decision-making interaction with the beneficiary. The shared decision-making interaction must include the elements specified in NCD 20.7. Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. These standards must include and ensure the elements specified in NCD 20.7. In addition to the national coverage described above, Medicare Administrative Contractors (MACs) may 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.	See ICD Procedure Tab	N/A	N/A	N/A	N/A	N/A	N/A	15.20	50 272	N386
Part A	Providers of covered intracranial PTA with stenting shall use Category B IDE billing requirements providers must bill the appropriate procedure and dx codes to receive payment. Under Part A, providers must bill intracranial PTA using ICD procedure codes along with dx I67.2. **NOTE:** Part A edit 59118/59119 should use procedure code as trigger and NOT dx I67.2.	See ICD Procedure Tab	N/A	N/A	N/A	Q0 Q1 FB	N/A	9.2 16.77	16	M64

NCD:	20.7									
NCD Title:	Percutaneous Transluminal Angioplasty (PTA) (CR3811, CR8197 CR8691, CR9252, CR9631, CR9751, CR11005, CR11392, CR13070, **CR13512**)									
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1925CP.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0									
Part A	**A/MACs:** Deny services for patients if the appropriate dx & procedure codes are not on the claim. The use of an FDA-approved or cleared embolic protection device is required. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare. End-dated 10/10/2023. Effective 10/11/2023, see new 20.7B4 coverage.	See ICD Procedure Tab	N/A	N/A	N/A	N/A	N/A	9.2	16	MA128
Part A	Providers of covered intracranial PTA with stenting shall use Category B IDE billing requirements providers must bill the appropriate procedure & dx codes to receive payment. Providers must bill ICD-10 procedure code along with dx I67.2. See line 10 Note.	See ICD Procedure Tab	N/A	N/A	N/A	Q0 Q1 FB	N/A	9.2 16.77	16	M64
Part A	**FISS:** Deny claims with 996.70/T85.9xxA, pay all claims for clincal trials, and covered intracranial PTA with stenting. **NOTE:** Policy is finite that any indication for PTA w/or w/o stenting to treat obstructive lesions of vertebral/cerebral arteries are NON-COVERED. Any indication for PTA w/o stenting not specifically indicated in NCD20.7 is NON-COVERED. Coverage of PTA w/stenting not specifically addressed in NCD 20.7 is left to contractor discretion. (End date High-risk requirement as of 10/11/2023 decision memo)	See ICD Procedure Tab	N/A	N/A	N/A	N/A	N/A	9.2 16.77	16	M64

Part B	**Rule Description Part B**	**Proposed HCPCS/CPT Part B**	**Frequency Limitations**	**POS (Part B)**	**n/a**	**Modifier Part B**	**Provider Specialty**	**Proposed MSN Message Part B**	**Proposed CARC Message Part B**	**Proposed RARC Message Part B**
Part B	**MCS & B/MACs:** Effective 7/1/01, covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved- protocols governing Category B IDE clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be R&N when provided in the context of such a clinical trial.	37215	N/A	N/A	N/A	Q0 Q1 FB	N/A	16.77	16	MA50
Part B	As a requirement for Category B IDE coverage, providers must bill a 6-digit IDE Number that begins with a “G” (i.e., G123456) practitioners must bill this IDE Number along with a -Q0 modifier.	N/A	N/A	N/A	N/A	Q0 Q1 FB	N/A	16.77	16	MA50 N822
Part B	**B/MACs:** Effective 10/12/04, covers PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent and an FDA-approved or -cleared embolic protection device (effective 12/9/09) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. CMS determines that coverage of PTA of the carotid artery is R&N in these circumstances.	37215	N/A	N/A	N/A	Q0 Q1 FB	N/A	16.77	16	MA50

NCD:	20.7									
NCD Title:	Percutaneous Transluminal Angioplasty (PTA) (CR3811, CR8197 CR8691, CR9252, CR9631, CR9751, CR11005, CR11392, CR13070, **CR13512**)									
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1925CP.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0									
Part B	**B/MACs:** Effective 3/17/05, Shall pay claims that contain the following for beneficiaries that meet the high risk criteria listed under the policy section of this instruction and in Pub 100-03, chapter 1, section 20.7B4. MCS edit 037L remains. **NOTE**: Procedures that are not performed in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (NCD310.1), or in accordance with the NCD on (CAS) post-approval studies (NCD20.7) must be performed in approved CAS facilities. A list of approved facilities is available/viewable at https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-Facilities.html. End-dated 10/10/2023. Effective 10/11/2023, see new 20.7B4 coverage.	N/A								
Part B	**B/MACs:** Effective 10/11/23, under 20.7B4, CMS 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 under the following conditions: A. Patients with symptomatic carotid artery stenosis- ≥50%; and, B. Patients with asymptomatic carotid artery stenosis ≥70%. For both A and B above: 1. Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after carotid artery stenting (CAS) must be performed. 2. First-line evaluation of carotid artery stenosis must use duplex ultrasound. 3. Computed tomography angiography or magnetic resonance angiography, if not contraindicated, must be used to confirm the degree of stenosis and provide additional information about the aortic arch, and extra-and intra-cranial circulation. 4. Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated. Prior to furnishing CAS, the practitioner must engage in a formal shared decision-making interaction with the beneficiary. The shared decision-making interaction must include the elements specified -in NCD 20.7. Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. These standards must include and ensure the elements specified in NCD 20.7. In addition to the national coverage described above, Medicare Administrative Contractors (MACs) may 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.	37215	N/A	N/A	N/A	N/A	N/A	15.20	50 272	N386
Part B	Providers of covered intracranial PTA with stenting shall use Category B IDE billing requirements, providers must bill the appropriate procedure & dx codes to receive payment. Under Part B, providers must bill procedure code 37799 along with dx I67.2.	37799	N/A	N/A	N/A	Q0 Q1 FB	N/A	9.2 16.77	16	M64
Part B	If the device has not been submitted to the FDA for approval; if it has a category A classification;or it has category B classification; or it is part of a post-market approval study, and has not been approved by the appropriate Medical Directors in writing, indicate this with use of ICD-10 code T85.9xxA. Place this ICD-10 code in position 1 on Box 21 of the 1500 form to receive the appropriate, non-covered denial. No other ICD-10 code should be listed in order to receive a non-covered denial.	37215	N/A	N/A	N/A	N/A	N/A	14.9	96	N569

NCD:	20.7									
NCD Title:	Percutaneous Transluminal Angioplasty (PTA) (CR3811, CR8197 CR8691, CR9252, CR9631, CR9751, CR11005, CR11392, CR13070, **CR13512**)									
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1925CP.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0									
Part B	**B/MACs:** Deny services for patients if the appropriate dx & procedure codes are not on the claim. The use of an FDA-approved or -cleared embolic protection device is required. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare. End-dated 10/10/2023. Effective 10/11/2023, see new 20.7B4 coverage.	37215	N/A	N/A	N/A	N/A	N/A	9.2	16	MA128
Part B	**MCS:** Deny claims with T85.9xxA. Pay all claims for clincal trials, covered intracranial PTA with stenting. MCS edit 058L. NOTE: Policy is finite that any indication for PTA w/or w/o stenting to treat obstructive lesions of vertebral/cerebral arteries are NON-COVERED. Any indication for PTA w/o stenting not specifically indicated in NCD20.7 is NON-COVERED. Coverage of PTA w/stenting not specifically addressed in NCD 20.7 is left to contractor discretion.	37215 37799	N/A	N/A	N/A	N/A	N/A	9.2 16.77	16	M64

Revision Date	Revision History
	CR8691: Revise to add high risk patient information.
	ADD RARC N386. "No other ICD-10 code" noted in spreadsheet. Add procedure 37799 to A/MAC billing. No MCS SSM-controlled edit is needed for procedure 37799 since this is a NOC code which could have other uses outside of this NCD policy. Per MM5667, CR5667, 6/15/13, claims submitted by physicians to MACs may also contain CPT 37215, 0075T, or 0076T. Claims submitted by institutional providers to MACs should contain the appropriate PCS codes 00.61 and 00.63.
	Add FISS & MCS denial of T85.9xxA, payment of high risk indications, clincal trials, covered intracranial PTA with stenting.
	Remove references to 37799 in Part A instructions. Change "To be billed with IP procedure codes or 37799 for Part B billing" to "To be billed with IP procedure Codes for A/MAC or 37799 for B/MAC billing" on ICD-10 dx tab Remove RARCN386 with CARC251 for CORE compliance.
	CR9252: Remove NOC codes I65.29, I63.039, I63.139, I63.239 per Palmetto. Change all instances of CARC 251 and RARC M64 to CARC 16 and RARC M64 to make the combination CORE compliant. Add ICD procedure codes 00.61 and 00.63. Note in line 10 that Part A edit 59118/59119 should use procedure code as trigger and NOT I67.2
	CR9631:Add requested ICD-10 codes I63.3, I63.4 and I66. Remove 51 ICD procedure codes including Extripation ones effective 10/1/15. See comment. Edits included in CR9631. Remove reference to effective date of 7/1/01 for cells B7 and B16 and replace with updated clinical trial information as listed in CR6839. Rules Description updated. ICD procedure mapping clarified and duplicative procedure codes removed. 0075T, 0076T removed effective 10/1/15
	CR9751: Add additional 210 2017 PCS codes starting on line 53 and ending on 262 on ICD Procedures tab effective 10/1/16.
	CR11005: Add ICD-10 dx I63.031, I63.032, I63.033, I63.131, I63.132, I63.133, I63.233 effective 10/1/15. End-date ICD-10 unspecified dx I66.9, I66.09, I66.19, I66.29 effective 4/1/19.
	CR11392: End-date ICD-10 procedure codes effective 9/30/19: 037G346, 037G356, 037G366, 037G376, 037G3D6, 037G3E6, 037G3F6, 037G3G6, 037G446, 037G456, 037G466, 037G476, 037G4D6, 037G4E6, 037G4F6, 037G4G6, 037H346, 037H356, 037H366, 037H376, 037H3D6, 037H3E6, 037H3F6, 037H3G6, 037H446, 037H456, 037H466, 037H476, 037H4D6, 037H4E6, 037H4F6, 037H4G6, 037J346, 037J356, 037J366, 037J376, 037J3D6, 037J3E6, 037J3F6, 037J3G6, 037J446, 037J456, 037J466, 037J476, 037J4D6, 037J4E6, 037J4F6, 037J4G6, 037K346, 037K356, 037K366, 037K376, 037K3D6, 037K3E6, 037K3F6, 037K3G6, 037K446, 037K456, 037K466, 037K476, 037K4D6, 037K4E6, 037K4F6, 037K4G6, 037L346, 037L356, 037L366, 037L376, 037L3D6, 037L3E6, 037L3F6, 037L3G6, 037L446, 037L456, 037L466, 037L476, 037L4D6, 037L4E6, 037L4F6, 037L4G6, 037M346, 037M356, 037M366, 037M376, 037M3D6, 037M3E6, 037M3F6, 037M3G6, 037M446, 037M456, 037M466, 037M476, 037M4D6, 037M4E6, 037M4F6, 037M4G6, 037N346, 037N356, 037N366, 037N376, 037N3D6, 037N3E6, 037N3F6, 037N3G6, 037N446, 037N456, 037N466, 037N476, 037N4D6, 037N4E6, 037N4F6, 037N4G6.
	CR13070: Short descriptor change to 37799 effective 1/1/2023.

NCD:	20.7
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IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1925CP.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0
	CR13512: Cell K19 RARC message changed from M50 to MA50,N822. Revised as per Final Decision Memo Effective 10/11/2023, modification of section PTA Concurrent with Carotid Stent Placement, and section D, Other, as summarized below. 1. Expanding coverage to individuals previously only eligible for coverage in clinical trials; 2. Expanding coverage to standard surgical risk individuals by removing the limitation of coverage to only high surgical risk individuals; 3. Removing facility approval requirement; 4. Adding formal shared decision-making with the individual prior to furnishing CAS; and 5. Allowing MAC discretion for all other coverage of PTA of the carotid artery concurrent with stenting not otherwise addressed in NCD 20.7