

# National Coverage Determination 20.7: Percutaneous Transluminal Angioplasty

Related CR Release Date: April 11, 2024 MLN Matters Number: MM13512

Effective Date: October 11, 2023 Related Change Request (CR) Number: CR 13512

Implementation Date: May 13, 2024 Related CR Transmittal Numbers:

R12571CP; R12571NCD

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

## **Affected Providers**

- Providers
- Hospitals
- Other providers billing Medicare Administrative Contractors (MACs) for PTA and stenting services they provide to Medicare patients

## **Action Needed**

Learn about changes in coverage for PTA of the carotid artery concurrent with stenting effective October 11, 2023:

- Patients don't have to enroll in a clinical trial
- Facilities don't need CMS approval to perform this service
- You must engage in formal shared decision-making with the patient
- MACs can decide if this service is covered if it's not addressed in this NCD

Your MAC will adjust claims processed in error that you bring to their attention.

# **Background**

CMS previously covered PTA of the carotid artery concurrent with stenting under NCD 20.7 for certain patients when provided in CMS-approved facilities with programs that met standards to decide competency including physician training standards, facility support requirements, and data collection to evaluate outcomes during a required reevaluation.

# **NCD Manual Updates**

Effective October 11, 2023, we 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





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protection device, for Medicare patients under the following conditions:

- Patients with symptomatic carotid artery stenosis ≥50%
- Patients with asymptomatic carotid artery stenosis ≥70%

## **Neurological Assessments and Imaging Requirement**

For the above conditions:

- A neurologist or NIH stroke scale (NIHSS) certified health professional must perform a neurological assessment before and after carotid artery stenting (CAS)
- First-line evaluation of carotid artery stenosis must use duplex ultrasound
- 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
- Only use intra-arterial digital subtraction (catheter) angiography when there's significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated.

#### **Shared Decision-Making Requirement**

Before providing CAS, you must engage in a formal shared decision-making interaction with the patient. 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 patient's clinical situation
- Integration of clinical guidelines, such as patient comorbidities and concomitant treatments
- Discussion and incorporation of patient's personal preferences and priorities in choosing a treatment plan

## Facility's Requirement

We removed the requirement that facilities performing CAS procedures must have our approval. However, facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. These standards must at least include and make sure of 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 must be empowered to identify the minimum case volume for a physician to maintain privileges, as well as the (risk-adjusted)





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threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. We encourage oversight committees to apply published standards from specialty societies and widely used, published professional society guidelines to decide 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.

We allow MACs to make reasonable and necessary determinations under Section 1862(a)(1)(A) of the <u>Social Security Act</u> for any other patient seeking coverage for PTA of the carotid artery concurrent with stenting.

#### **More Information**

We issued CR 13512 to your MAC in 2 transmittals as the official instruction for this change. Transmittal 12571NCD updates the NCD Manual and transmittal 12571CP updates the Medicare Claims Processing Manual.

For more information, find your MAC's website.

# **Document History**

Date of Change	Description
April 16, 2024	Initial article released.

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