Cohere Medicare Advantage Policy - Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

Clinical Policy for Medical Necessity Review

Version: 3
Revision Date: June 26, 2025

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Policy Information:

Specialty Area: Cardiovascular Disease
Policy Name: Cohere Medicare Advantage Policy - Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1,2]

- National Coverage Determination (NCD): Percutaneous transluminal angioplasty (PTA) (20.7)
- National Coverage Analysis (NCA): Percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting (CAG-00085R8)

Description

Carotid artery stenting (CAS) or transcarotid artery revascularization (TCAR) are less invasive procedures than carotid endarterectomy (CEA) and may be superior to CEA in patients in some clinical scenarios. These procedures must be supported by comprehensive imaging and neurological assessments and involve detailed shared decision-making to ensure optimal patient outcomes.

In October 2023, the Centers for Medicare & Medicaid Services (CMS) relaxed the need for CAS/TCAR only in high-risk patients for CEA. CMS published the Final Decision Memorandum (CAG-00085R8) that affects National Coverage Determination (NCD) 20.7 for Percutaneous Transluminal Angioplasty (PTA) (see sections B4 and D). The memorandum revises coverage for PTA of the carotid arteries concurrent with stenting by[1,2]:

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 the facility approval requirement;
4. Adding formal shared decision-making with the individual prior to furnishing CAS; and

5. Allowing Medicare Administrative Contractors (MACs) discretion for all other coverage of PTA of the carotid artery concurrent with stenting, not otherwise addressed in NCD 20.7.

Medical Necessity Criteria

Indications

Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) is considered appropriate if **ALL** of the following is **TRUE**[3,4]:

- **ANY** of the following:
  - The patient is enrolled in an FDA-approved investigational device exemption (IDE) clinical trial[1]; **OR**
  - The patient presents within 6 months of the onset of neurologic symptoms with **ALL** of the following:
    - Carotid artery stenosis between 50-99% by invasive or noninvasive imaging[5]; **AND**
    - An FDA-approved carotid stent and/or embolic protection device is being used; **OR**
  - The patient is asymptomatic with carotid artery stenosis between 70-99% by invasive or noninvasive imaging[6]; **AND**
- **ALL** of the following:
  - Neurological assessment by a neurologist or NIH Stroke Scale (NIHSS) certified health professional before and after CAS; **AND**
  - First-line evaluation of carotid artery stenosis; **AND**
  - When a duplex ultrasound (DUS) is performed (for this or other relevant indication) and identifies carotid stenosis potentially amenable to treatment interventions addressed by this policy, the degree/percentage occlusion of stenosis must be characterized by advanced imaging modality (computed tomography angiography [CTA] or magnetic resonance angiography [MRA]) as a required step in treatment planning[7-10]; **AND**
  - CTA or MRA, 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; **AND**
  - If applicable, intra-arterial digital subtraction (catheter) angiography may be used only when there is a significant discrepancy between

non-invasive imaging results or in lieu of CTA or MRA if these are contraindicated.

Non-Indications

Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) is not considered appropriate if **ANY** of the following is **TRUE**:

- A non-FDA-approved stent or embolic protection device is requested; **OR**
- Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection (CPT 37216); **OR**
- Carotid artery stenosis is less than 50% (stroke or TIA within the last 6 months)[11]; **OR**
- Carotid artery stenosis less than 70% (no stroke or TIA within past 6 months)[11]; **OR**
- Chronic carotid artery stenosis of 100%; **OR**
- Severe disability caused by cerebral infarction that precludes preservation of useful function, if applicable.[12]

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection. **Non-covered.**

37217	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) may include:

- Adverse effects from delayed or denied treatment, such as increased symptoms and complications, especially in patients with significant carotid artery stenosis. Halliday et al. (2021) reported a lower rate of stroke recurrence in patients treated with CAS compared to those with carotid endarterectomy (CEA).[13] According to CMS, inappropriate denials could result in stroke or transient ischemic attacks (TIA) due to unresolved carotid artery stenosis.[2] Adverse effects also include infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. Malas et al. (2019) demonstrated the safety and efficacy of TCAR, showing low complication rates and excellent durability at one year.[14] Increased healthcare costs and complications have also been attributed to the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for CAS and/or TCAR may include:

- Improved patient selection results in better long-term outcomes. Kleindorfer et al. (2021) highlighted the benefits of CAS and TCAR in reducing stroke incidence in high-risk patients.[3] Providing accurate diagnostics and effective treatment planning can reduce the risk of complications and improve overall patient health. Messas et al. (2020) emphasized the importance of accurate diagnostics and treatment planning to prevent stroke and improve patient outcomes.[11] Proper use of

CAS and TCAR criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Halliday et al. (2021) reported that CAS had a similar efficacy to CEA with fewer procedural complications.[13] Ensuring that CAS and TCAR are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. Malas et al. (2019) reported high patient satisfaction and low complication rates with TCAR.[14]

- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Hamouda et al. (2025) conducted a multi-institutional study on the utilization of a DEP during transcarotid artery revascularization (TCAR) with flow reversal versus transfemoral carotid artery stenting with DEP (TFCAS-DEP). Of the 99,030 patients enrolled in the study, 67% underwent TCAR followed by TFCAS-DEP (31%), TCAS-DEP (0.9%), and TFCAS-PBO (0.8%). Survival rates were higher, and postoperative neurological outcomes were lower with TCAR versus transfemoral carotid artery stenting (TFCAS) with DEP. Future research should compare TCAR with transcarotid artery stenting with DEP (TCAS-DEP).[15]

Stonko et al. (2022) conducted a retrospective cohort study to measure the utilization of carotid revascularization procedures and the risks associated with each. Carotid endarterectomy (CEA), TFCAS, and TCAR were included in the study, which included 108,676 patients with carotid artery stenosis. Data from January 1, 2015, through December 31, 2019, were obtained from the Vascular Quality Initiative database. The most performed procedure was CEA (81,508 or 75%), followed by TFCAS (15,578 or 14.3%), and TCAR (11,590 or 10.7%). The authors noted that between 2015 and 2019, utilization of CEA decreased from 84.9% in 2015 to 64.8% in 2019. Performance of TFCAS slightly decreased between 2015 and 2019 (14.4% to 13.3%) while TCAR increased from 0.8% to 13.3%. The study demonstrated that TCAR was favored for patients at high-risk of stroke, cardiovascular events, or cranial nerve injury. In 2015, the FDA approved the first TCAR device, which also contributed to higher utilization.[16]

Nazari et al. (2021) reported on the efficacy of DEPs during carotid artery stenting (CAS) placement with respect to major adverse cardiovascular events (MACE) (e.g., death, stroke, myocardial infarction/arrhythmia) within 30 days. The American College of Surgeons National Surgical Quality Improvement Program database identified 1200 adult patients undergoing CAS between 2011 and 2018. Of the total, 23.8% did not have a DEP. Preoperative antiplatelets were used less frequently among patients without DEPs. Patients also experienced an increased need for urgent carotid artery stent placement, along with a higher incidence of major adverse cardiovascular events and strokes. The absence of DEPs during CAS placement increases the risk of perioperative stroke by four times. Despite

this, nearly 25% of patients in a national quality improvement program had the procedure without such protection. Enhanced efforts to promote the use of DEPs are necessary.[17]

Halliday et al. (2021) performed an international multicenter randomized controlled trial (RCT). The Asymptomatic Carotid Surgery Trial (ACST-2) study CAS with CEA in asymptomatic patients with severe carotid artery stenosis. Both procedures aim to reduce the risk of stroke in these patients. The trial involved 3625 patients from 130 centers, randomly assigned to either CAS or CEA. Over a mean follow-up of 5 years, both procedures showed similar rates of disabling stroke or death within 30 days of the intervention (1% each). Non-disabling procedural stroke was slightly higher with CAS compared to CEA. The 5-year rates of non-procedural stroke, including fatal or disabling strokes, were similar between the two groups. The study suggested that CAS and CEA are similarly effective in reducing the risk of long-term fatal or disabling stroke in asymptomatic patients with severe carotid artery stenosis.[13]

Malas et al. (2019) conducted a prospective, single-arm trial titled "Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER)". The study reports on the one-year outcomes of a novel trans carotid neuroprotection system (NPS) called ENROUTE. The trial evaluated the safety of TCAR and its effectiveness over a year. It was a prospective, single-arm clinical trial conducted across 14 centers, enrolling patients with high-risk factors for CEA. Results showed that TCAR with the ENROUTE system was safe and effective, with a low incidence of ipsilateral stroke at one year (0.6%) and a mortality rate of 4.2%, none of which were neurologic in origin. Most patients were asymptomatic (79.9%) and had various anatomic and medical high-risk factors. TCAR demonstrated favorable outcomes perioperatively and at 1-year follow-up, suggesting it is a safe and durable option for high-risk patients compared to traditional CEA. The study attributes the promising results to the novel cerebral protection offered by the ENROUTE system and the advantages of the trans-carotid approach in avoiding aortic arch manipulation and minimizing embolization. (ClinicalTrials.gov NCT01685567).[14]

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Clinical Guideline Revision History/Information

Original Date: May 31, 2024		
Review History		
Version 2	06/11/2024	422.101 disclaimer added.
Version 3	06/26/2025	Annual review. Added indication for CAS/TCAR performed concurrent with carotid stent placement per CMS (NCD 20.7 & CAG-00085R8, 2023). Revised imaging requirement to include "first-line evaluation of carotid artery stenosis" AND "when a duplex ultrasound (DUS) is performed (for this or other relevant indication) and identifies carotid stenosis potentially amenable to treatment interventions addressed by this policy, the degree/percentage occlusion of stenosis must be characterized by advanced imaging modality (computed tomography angiography [CTA] or magnetic resonance angiography [MRA]) as a required step in treatment planning" AND "CTA or MRA, 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." Literature review - Medical Evidence section updated (Stonko et al., 2022).

		Archived the policy “Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR) without Distal Embolic Protection”; the following were merged with this policy: ● Added non-indication: “a non-FDA-approved stent or embolic protection device is requested” to account for CPT 37216 (non-covered). ● Added non-indication to account for CPT 37216 (non-covered): “Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection.”