



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

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

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

Literature review current through: 4/19/2024

Document last updated: 4/19/2024

Type: Adult (18+ yo) | Pediatric (0-17yo)

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Medical Necessity Criteria

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

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Repeat Carotid Artery Stenting (CAS) or repeat Transcarotid Artery Revascularization (TCAR) represents an unusual clinical scenario that could necessitate a peer-to-peer review for approval.
- **Recommended Clinical Approach:** CAS or TCAR is an appropriate treatment option for patients with symptomatic extracranial carotid artery occlusive disease between 50%-99%.¹ For stroke patients with symptomatic extracranial carotid artery occlusive disease, treatment can lower the risk of subsequent stroke. CAS and/or TCAR are less invasive procedures than Carotid Endarterectomy (CEA). CAS and/or TCAR may be superior to CEA in patients with previous neck surgery or radiation injury.¹ CAS is an acceptable alternative for treating asymptomatic patients with severe stenosis of the extracranial carotid circulation of 70%-99%.
- **Exclusions:** Visible thrombus within the lesion detected on preoperative or intraoperative imaging (e.g., ultrasound, angiography), inability to gain vascular access, or active infection.^{2,9}

Medical Necessity Criteria

Indications

→ **Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)** is considered appropriate if **ANY** of the following is **TRUE**⁴⁻⁵:

- ◆ For patients with a TIA or ischemic stroke within 6 months with **ALL** of the following:
 - The diameter of the lumen of the internal carotid artery (ICA) is reduced by **ANY** of the following²:
 - Greater than or equal to 50% by noninvasive imaging; **OR**
 - Greater than 50% by catheter-based imaging; **AND**
 - Institution and surgeon complication (e.g., stroke, mortality) rates less than 6% at 30 days; **OR**

- ◆ The patient is asymptomatic with **ALL** of the following:
 - **ANY** of the following:
 - Ipsilateral stroke or TIA occurred more than 6 months ago; **OR**
 - The patient never had a neurological event; **AND**
 - ICA stenosis greater than or equal to 70% by invasive or noninvasive imaging; **AND**
 - Institution and surgeon complication rates (stroke or death) is less than 3% at 30 days; **AND**
 - Life expectancy of at least 5 years; **OR**
- ◆ The patient has asymptomatic, severe stenosis with **ALL** of the following:
 - **ANY** of the following:
 - Ipsilateral stroke or TIA occurred more than 6 months ago; **OR**
 - The patient never had a neurological event; **AND**
 - Stenosis is greater than or equal to 70%; **AND**
 - Presence of anatomic or medical conditions that increase the risk for carotid endarterectomy surgery, including **ANY** of the following⁶:
 - Carotid restenosis; **OR**
 - Radiation-induced stenosis; **OR**
 - Surgically inaccessible lesion; **AND**
 - Life expectancy of at least 5 years.

Non-Indications

→ **Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient had a stroke or TIA within the last 6 months with **ANY** of the following:
 - Carotid stenosis less than 50%²; **OR**
 - Chronic carotid stenosis of 100%; **OR**
 - Institution and surgeon complication rates greater than or equal to 6%; **OR**
 - Severe disability caused by cerebral infarction that precludes preservation of useful function¹; **OR**
- ◆ The patient had a stroke or TIA more than 6 months ago, or the patient never had a neurologic event with **ANY** of the following:
 - ◆ Carotid stenosis less than 70%; **OR**
 - ◆ Chronic carotid stenosis of 100%; **OR**

- ◆ Institution and surgeon complication rates greater than or equal to 3%; **OR**
- ◆ Life expectancy less than 5 years; **OR**
- ◆ Severe disability caused by cerebral infarction that precludes preservation of useful function (if applicable).

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
37215	Open transcatheter placement of intravascular stent in cervical carotid artery with distal embolic protection
37216	Percutaneous transcatheter placement of intravascular stent in cervical carotid artery
37217	Transcatheter placement of intravascular stent in innominate artery by retrograde treatment with open exposure of ipsilateral cervical carotid artery
37218	Transcatheter insertion of stent of intrathoracic common carotid artery by open antegrade approach with angioplasty, and radiological supervision and interpretation

Medical Evidence

Halliday et al. (2021) performed an international multicenter randomized control trial (RCT). The ACST-2 study compared carotid artery stenting (CAS) with carotid endarterectomy (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% for 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 suggests that both 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.⁷

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 transcatheter neuroprotection system (NPS) called ENROUTE. The trial aimed to evaluate the safety of transcatheter artery revascularization (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 transcatheter approach in avoiding aortic arch manipulation and minimizing embolization. (ClinicalTrials.gov NCT01685567).⁸

In October 2023, CMS relaxed the need for CAS/TCAR only in high risk patients for CEA. In summary, this final decision memorandum, which affects National Coverage Determination (NCD) 20.7 sections B4 and D, revises Medicare coverage for PTA of the carotid arteries concurrent with stenting by¹⁰:

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.

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