# Cohere Medicare Advantage Policy - Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR) without Distal Embolic Protection

***Clinical Guidelines for Medical Necessity Review***

**Version:** 2
**Effective Date:** June 11, 2024


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## Guideline Information:

**Specialty Area:** Cardiovascular Disease
**Guideline Name:** Cohere Medicare Advantage Policy - Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR) without Distal Embolic Protection

**Date of last literature review**: 6/11/2024
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**Type:** [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)


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# Medical Necessity Criteria

***Service: Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR) without Distal Embolic Protection***

## Benefit Category

Not applicable.

## Recommended Clinical Approach

This service is clinically unproven and not medically necessary.

## Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of CAS and TCAR procedures without distal embolic protection. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in CAS and TCAR procedures without distal embolic protection can lead to increased symptoms and complications, especially in patients with significant carotid artery stenosis. Nazari et al. reported that carotid stenting without embolic protection increases major adverse events, emphasizing the need for careful patient selection and appropriate use of protection devices.[1]
- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. Malas et al. demonstrated the safety and efficacy of TCAR with dynamic flow reversal, showing low complication rates and excellent durability at one year.[2]


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- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. The CMS NCD for PTA highlights the importance of appropriate patient selection and procedural techniques to minimize complications.[3]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to CAS and TCAR procedures for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. Proper use of embolic protection devices during CAS and TCAR is crucial for reducing the risk of stroke and other adverse events.[1]
- Enhanced diagnostic accuracy: This is crucial for complex vascular conditions such as carotid artery stenosis. Accurate diagnostics and treatment planning help to prevent stroke and improve patient outcomes. Malas et al. highlighted the benefits of using dynamic flow reversal during TCAR to reduce the risk of embolic events.[2]
- Reduction in complications and adverse effects: Proper use of CAS and TCAR criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Nazari et al. reported higher rates of major adverse events in patients undergoing carotid stenting without embolic protection, underscoring the importance of appropriate procedural techniques.[1]
- Enhanced overall patient satisfaction: 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. reported high patient satisfaction and low complication rates with TCAR.[2]

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.


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In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

## Medical Necessity Criteria

### Indications

- ➔ **Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) without distal embolic protection** is considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

### Non-Indications

- ➔ **Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) without distal embolic protection** is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

## Level of Care Criteria

Inpatient or Outpatient

## Procedure Codes (CPT/HCPCS)

| CPT/HCPCS Code | Code Description |
|---|---|
| 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 |


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# Medical Evidence

Nazari et al. (2021) report on the efficacy of embolic protection devices during carotid artery stent (CAS) placement with respect to major adverse cardiovascular events (MACE) (e.g., death, stroke, or 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 embolic protection devices. Preoperative antiplatelets were used less frequently among patients without embolic protection devices. 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 embolic protection devices 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 embolic protection devices are necessary.[1]

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 aimed to evaluate the safety of trans carotid 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 carotid endarterectomy (CEA). Distal embolic protection devices were also evaluated. Results showed that TCAR with the ENROUTE system was safe and effective with favorable outcomes, however, distal protection lacked efficacy in the medical literature. (ClinicalTrials.gov NCT01685567).[2]

There is one related National Coverage Determination (NCD) from the Centers for Medicare and Medicaid Services (CMS):

- *Percutaneous Transluminal Angioplasty (PTA) (20.7)* (2023): CAS/TCAR are covered when used with an FDA-approved or cleared embolic protection device, except for the possible use in FDA-approved Category B investigational device exemption (IDE) clinical trial.[3]


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# References


1. Nazari P, Golnari P, Hurley MC, et al. Carotid stenting without embolic protection increases major adverse events: Analysis of the National Surgical Quality Improvement Program. *AJNR Am J Neuroradiol*. 2021 Jul;42(7):1264-1269. doi: 10.3174/ajnr.A7108. PMID: 34255736; PMCID: PMC8324283.
2. Malas MB, Lorenzo JIL, Nejim B, et al. Analysis of the ROADSTER pivotal and extended-access cohorts shows excellent 1-year durability of transcarotid stenting with dynamic flow reversal. *J Vasc Surg*. 2019 Jun;69(6):1786-1796. doi: 10.1016/j.jvs.2018.08.179. PMID: 30611582.
3. Centers for Medicare and Medicaid Services (CMS). National coverage determination: Percutaneous transluminal angioplasty (PTA) (20.7). Effective Date October 11, 2023. Accessed May 26, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx.




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# Clinical Guideline Revision History/Information

| Original Date: May 28, 2024 | | |
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| **Review History** | | |
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