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

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medicare Advantage Policy - Carotid Artery Stenting (CAS) and/or Transcarotid Artery Revascularization (TCAR)

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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)

Benefit Category

Physicians' Services, Inpatient Hospital Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1]

Recommended Clinical Approach

CAS or TCAR is an appropriate treatment option for patients with symptomatic extracranial carotid artery occlusive disease between 50%-99%. 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) and may be superior to CEA in patients with previous neck surgery or radiation injury. CAS is an acceptable alternative for treating asymptomatic patients with severe stenosis of the extracranial carotid circulation of 70%-99%. These procedures must be supported by comprehensive imaging and neurological assessments and involve detailed shared decision-making to ensure optimal patient outcomes.

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. 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 can lead to increased symptoms and

complications, especially in patients with significant carotid artery stenosis. Halliday et al. reported a lower rate of stroke recurrence in patients treated with CAS compared to those with carotid endarterectomy (CEA).[6] According to the CMS NCA for PTA of the carotid artery concurrent with stenting, inappropriate denials could result in stroke or transient ischemic attacks (TIA) due to unresolved carotid artery stenosis.[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, showing low complication rates and excellent durability at one year.[7]
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Brott et al. outlined the importance of appropriate management of extracranial carotid and vertebral artery disease to prevent complications and improve patient outcomes.[5]

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. Kleindorfer et al. highlighted the benefits of CAS and TCAR in reducing stroke incidence in high-risk patients.[3]
- Enhanced diagnostic accuracy: This is crucial for complex vascular conditions such as carotid artery stenosis. Messas et al. emphasized the importance of accurate diagnostics and treatment planning to prevent stroke and improve patient outcomes.[4]
- 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. Halliday et al. reported that CAS had a similar efficacy to CEA with fewer procedural complications.[6]
- 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.[7]

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.

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)** is considered appropriate if **ANY** of the following is **TRUE**[2-3]:
  - ◆ The patient is enrolled in an FDA-approved IDE clinical trial; **OR**
  - ◆ For patients with a TIA or ischemic stroke within 6 months, and **ALL** of the following are **TRUE**:
    - ICA stenosis is between 50%-99% by invasive or noninvasive imaging[4]; **AND**
    - An FDA-approved or cleared carotid stent and embolic protection device is being used; **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 is between 70%-99% by invasive or noninvasive imaging; **AND**
    - An FDA-approved or cleared carotid stent and embolic protection device is being used.

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%[4]; **OR**
    - Chronic carotid stenosis of 100%; **OR**
    - Severe disability caused by cerebral infarction that precludes preservation of useful function[5]; **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**
    - ◆ Severe disability caused by cerebral infarction that precludes preservation of useful function (if applicable).

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
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

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.[6]

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 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).[7]

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 by[8]:

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.

References

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2. Kernan WN, Ovbiagele B, Black HR, et al. Guidelines for the prevention of stroke in patients with stroke and transient ischemic attack: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2014 Jul;45(7):2160-236. doi: 10.1161/STR.0000000000000024. PMID: 24788967.
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7. 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.

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Clinical Guideline Revision History/Information

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