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

Clinical Policy for Medical Necessity Review

Version: 2
Cohere Health UMC Approval Date: July 31, 2025
Last Annual Review: July 31, 2025
Revision: Not Applicable
Next Annual Review: July 31, 2026

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.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice.

Other Notices:

Policy Information:

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

Table of Contents

Medical Necessity Criteria

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

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
  - The medical necessity of each individual request
  - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
  - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

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.

Medical Necessity Criteria

Indications

Carotid artery stenting (CAS) and/or transcarotid artery revascularization (TCAR) is considered appropriate if **ALL** of the following are **TRUE**[1,2]:

- The patient has **ANY** of the following:
  - Within the past 6 months, the patient had **ALL** of the following:
    - **ANY** of the following:
      - Onset of neurologic symptoms as documented by a neurologist; **OR**
      - Documented radiographic evidence of a neurologic event; **AND**
    - The patient has **ALL** of the following:
      - Carotid artery stenosis between 50-99% by invasive or noninvasive imaging[3]; **AND**
      - An FDA-approved carotid stent and/or embolic protection device is being used; **OR**
  - The patient is asymptomatic with **ALL** of the following:
    - Carotid artery stenosis between 70-99% by invasive or noninvasive imaging[4]; **AND**
    - The patient has **ANY** of the following:
      - Ipsilateral stroke or TIA occurred more than 6 months ago; **OR**
      - The patient never had a neurological event; **AND**
    - Stenosis greater than or equal to 70% by invasive or noninvasive imaging; **AND**
- Imaging evaluation of carotid artery stenosis, including **ANY** of the following:
  - **ALL** of the following:
    - Duplex ultrasound demonstrates significant disease (greater than or equal to 50% for symptomatic patients, greater than or equal to 70% for asymptomatic patients); **AND**

        - Degree of stenosis is confirmed by advanced imaging (computed tomography angiography [CTA] or magnetic resonance angiography [MRA])[5-8]; **OR**
    - CTA, MRA, or intra-arterial digital subtraction (catheter) angiography demonstrates significant disease (greater than or equal to 50% for symptomatic patients, greater than or equal to 70% for asymptomatic patients).

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**
- Carotid artery stenosis is less than 50% (stroke or TIA within the last 6 months)[9]; **OR**
- Carotid artery stenosis less than 70% (no stroke or TIA within past 6 months)[9]; **OR**
- Chronic carotid artery stenosis of 100%; **OR**
- Severe disability caused by cerebral infarction that precludes preservation of useful function, if applicable[10]; **OR**
- Carotid artery stenosis determined by Duplex alone.

Level of Care Criteria

Inpatient

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.

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

Hamouda et al. (2025) conducted a multi-institutional study on the utilization of distal embolic protection (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).[11]

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.[12]

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.[13]

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.[14]

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).[15]

References

1. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 guideline for the prevention of stroke in patients with stroke and transient ischemic attack: A guideline from the American Heart Association/American Stroke Association. *Stroke*. 2021 Jul;52(7):e364-e467. doi:10.1161/STR.0000000000000375. Erratum in: *Stroke*. 2021 Jul;52(7):e483-e484. doi:10.1161/STR.0000000000000383
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
3. AbuRahma AF, Avgerinos ED, Chang RW, et al. Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease. *J Vasc Surg*. 2022 Jan;75(1S):4S-22S. doi:10.1016/j.jvs.2021.04.073
4. Del Brutto VJ, Gornik HL, Rundek T. Why are we still debating criteria for carotid artery stenosis? *Ann Transl Med*. 2020 Oct;8(19):1270. doi:10.21037/atm-20-1188a
5. Tekieli L, Kablak-Ziembicka A, Dabrowski W, et al. Imaging modality-dependent carotid stenosis severity variations against intravascular ultrasound as a reference: Carotid Artery intravasculaR Ultrasound Study (CARUS). *Int J Cardiovasc Imaging*. 2023 Oct;39(10):1909-1920. doi:10.1007/s10554-023-02875-1
6. Mohebali J, Patel VI, Romero JM, et al. Acoustic shadowing impairs accurate characterization of stenosis in carotid ultrasound examinations. *J Vasc Surg*. 2015;62(5):1236–1244. doi:10.1016/J.JVS.2015.06.137
7. Morales MM, Anacleto A, Filho CM, et al. Peak systolic velocity for calcified plaques fails to estimate carotid stenosis degree. *Ann Vasc Surg*. 2019;59:1–4. doi:10.1016/j.avsg.2018.12.086
8. Wardlaw JM, Lewis S. Carotid stenosis measurement on colour Doppler ultrasound: Agreement of ECST, NASCET and CCA methods applied to ultrasound with intra-arterial angiographic stenosis measurement. *Eur J Radiol*. 2005;56(2):205–211. doi:10.1016/j.ejrad.2005.04.021
9. Messas E, Goudot G, Halliday A, et al. Management of carotid stenosis for primary and secondary prevention of stroke: State-of-the-art 2020: A

critical review. *Eur Heart J Suppl*. 2020 Dec 6;22(Suppl M):M35-M42. doi:10.1093/eurheartj/suaa162

10. Brott TG, Halperin JL, Abbara S, et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. *J Am Coll Cardiol*. 2011 Feb 22;57(8):e16-94. doi:10.1016/j.jacc.2010.11.006
11. Hamouda M, Kang Sim DE, Vootukuru NR, et al. Impact of embolic protection methods versus access types on outcomes of carotid artery stenting. *J Vasc Surg*. 2025 Feb 28:S0741-5214(25)00351-9. doi:10.1016/j.jvs.2025.02.026
12. Stonko DP, Goldsborough E 3rd, Kibrik P, et al. Use of transcarotid artery revascularization, transfemoral carotid artery stenting, and carotid endarterectomy in the US from 2015 to 2019. *JAMA Netw Open*. 2022 Sep 1;5(9):e2231944. doi:10.1001/jamanetworkopen.2022.31944
13. 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
14. Halliday A, Bulbulia R, Bonati LH, et al. Second asymptomatic carotid surgery trial (ACST-2): A randomized comparison of carotid artery stenting versus carotid endarterectomy. *Lancet*. 2021 Sep 18;398(10305):1065-1073. doi:10.1016/S0140-6736(21)01910-3
15. 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

Policy Revision History/Information

Original Date: April 19, 2024		
Review History		
Version 2	07/31/2025	Annual review. Rearranged bullets for improved usability and organization. Clarified the indications for onset of neurologic symptoms for improved usability and organization. Included an indication for "FDA-approved carotid stent and/or embolic protection device". Clarified the indications for an asymptomatic patient. • Revised one indication to read "with carotid artery stenosis (CAS) between 70-99% by invasive or noninvasive imaging". • Removed the indication for "institution and surgeon complication rates (stroke or death) is less than 3% at 30 day". • Removed indication for "presence of anatomic or medical conditions that increase the risk for carotid endarterectomy surgery, including…carotid restenosis, radiation-induced stenosis, or surgically inaccessible lesion." Also removed indication for "life expectancy of at least 5 years."

		Added indications for "imaging evaluation" to include ANY of the following: ● Duplex ultrasound demonstrates significant disease (greater than or equal to 50% for symptomatic patients, greater than or equal to 70% for asymptomatic patients) and the degree of stenosis is confirmed by advanced imaging CTA or MRA; **OR** ● CTA, MRA, or intra-arterial digital subtraction (catheter) angiography demonstrates significant disease (greater than or equal to 50% for symptomatic patients, greater than or equal to 70% for asymptomatic patients). Clarified the non-indications for improved usability and organization. Added non-indications for: ● A non-FDA-approved stent or embolic protection device is requested; ● Carotid artery stenosis is less than 50% (stroke or TIA within the last 6 months); ● Carotid artery stenosis less than 70% (no stroke or TIA within past 6 months); ● Chronic carotid artery stenosis of 100%; ● Severe disability caused by cerebral infarction that precludes preservation of useful function, if applicable. Added CPT 37216. Literature review - Medical Evidence section updated (Hamouda et al., 2025; Stonko et al., 2022; Nazari et al., 2021).