



ENROUTE™ Medicare National Determination (NCD 20.7) Coverage Pathway

TCAR is covered under NCD 20.7 according to these indications¹:

- **B3** – Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies (e.g., VQI TCAR Surveillance Project or VQI-TSP)
- **B4** – Concurrent with Carotid Stent Placement

Indications	B3. VQI-TSP* (No change) (NCT02850588)	B4. Carotid Stent Placement (Revised 10/11/2023)
Clinical Criteria		
Surgical Risk Factor	<ul style="list-style-type: none"> • Standard Risk & High Risk 	
Symptom Status & Degree of Stenosis	<ul style="list-style-type: none"> • Symptomatic & ≥50% stenosis** • Asymptomatic & ≥70% stenosis** 	
Additional Criteria		
Facility Requirements	<ul style="list-style-type: none"> • Facility standards and approval 	<ul style="list-style-type: none"> • Facility and physician standards for carotid stent program
Registry or Data Collection	<ul style="list-style-type: none"> • Registry participation (VQI-TSP) 	<ul style="list-style-type: none"> • Not required for coverage
Neurological Assessments	<ul style="list-style-type: none"> • Not specified 	<ul style="list-style-type: none"> • Pre & post-op neurological assessments by a neurologist or NIHSS certified HCP
Imaging Guidelines	<ul style="list-style-type: none"> • Not specified 	<ul style="list-style-type: none"> • Duplex US and CTAMRA or • Duplex US and DSA when non-invasive imaging is inconclusive or CTAMRA are contraindicated
Shared Decision-Making	<ul style="list-style-type: none"> • Not specified 	<ul style="list-style-type: none"> • Shared decision-making with patients about CEA, CAS (including TCAR), and OMT before treatment

Reimbursement Support

For reimbursement assistance, please contact Boston Scientific PI HEMA team:

- Email: VT.Reimbursement@bsci.com
- Website: [Peripheral Vascular - Reimbursement - Boston Scientific](#)

References

* Medicare coverage for VQI TSP is based on the study protocol (clinicaltrials.gov (NCT02850588)). **Stenosis requirements vary depending on the diagnostic imaging type (angiogram or ultrasound), surgical risk factor, and symptomatic status.

Definitions: CAS – Carotid Artery Stenting, CEA – Carotid Endarterectomy, CTA – Computed Tomography Angiography, DSA – Digital Subtraction Angiography, HCP – Healthcare Professional, MRA – Magnetic Resonance Angiography, NIHSS – National Institutes of Health Stroke Scale, OMT – Optimal Medical Therapy, US – Ultrasound

Disclaimer: This is a high-level summary of the final decision memo. Please refer to the ENROUTE® Transcarotid Stent and Neuroprotection Systems Instructions For Use (IFU) for detailed indications, contraindications, warnings, and precautions. Visit the CMS webpage for the final decision memo: <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncid=311>.

1 NCD - Percutaneous Transluminal Angioplasty (PTA) (20.7). Cms.gov. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=201>

ENROUTE Transcarotid Stent System

USE/INDICATIONS FOR USE The ENROUTE® Transcarotid Stent System used in conjunction with the ENROUTE Transcarotid Neuroprotection System (NPS) is indicated for the treatment of patients at high risk and standard risk for adverse events from carotid endarterectomy, who require carotid revascularization and meet the criteria outlined below: High Risk | Standard Risk With neurological symptoms: $\geq 50\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram | $\geq 70\%$ stenosis of the common or internal carotid artery by ultrasound or $\geq 50\%$ stenosis of the common or internal carotid artery by angiogram Without neurological symptoms: $\geq 80\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram | $\geq 70\%$ stenosis of the common or internal carotid artery by ultrasound or $\geq 60\%$ stenosis of the common or internal carotid artery by angiogram Reference vessel diameter: Must be within 4.0 mm – 9.0 mm at the target lesion Carotid bifurcation location: Minimum 5 cm above the clavicle to allow for placement of the ENROUTE Transcarotid NPS

ENROUTE Transcarotid Neuroprotection System

INTENDED USE/INDICATIONS FOR USE The ENROUTE Transcarotid Neuroprotection System (ENROUTE Transcarotid NPS) is intended to provide transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have appropriate anatomy described below: • Adequate femoral venous access • Common carotid artery reference diameter of at least 6 mm • Carotid bifurcation is a minimum of 5 cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography.

IMPORTANT INFORMATION

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

Boston Scientific does not promote the use of its products outside their FDA-approved label. Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. All trademarks are the property of their respective owners.

The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options. This coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote the use of any Boston Scientific products for which they are not cleared or approved. The Health Care Provider (HCP) is solely responsible for selecting the site of service and treatment modalities appropriate for the patient based on medically appropriate needs of that patient and the independent medical judgment of the HCP.

CPT Copyright 2025 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. All trademarks are the property of their respective owners.



Vascular Therapies

300 Boston Scientific Way
Maple Grove, MN 55369-4309

<https://www.bostonscientific.com/reimbursement>

Medical Professionals

VT.Reimbursement@bsci.com

© 2026 Boston Scientific Corporation
or its affiliates. All rights reserved.

PI-2473906-AA | 2026