

# ENROUTE™

Transcarotid Neuroprotection System

## 2025/2026 Reimbursement Guide



# Table of Contents

<b>ENROUTE™ Transcarotid Neuroprotection System .....</b>	<b>3</b>
Overview .....	3
FDA Approval .....	3
ENROUTE™ TCAR Procedure .....	3
Ultrasound Guidance .....	3
<b>Coverage .....</b>	<b>4</b>
Medicare .....	4
Non-Medicare .....	4
Reimbursement Denials .....	4
<b>ICD-10-CM Diagnosis Codes .....</b>	<b>5</b>
<b>Hospital Inpatient Reimbursement .....</b>	<b>6</b>
ICD-10-PCS Procedure Codes .....	6
Carotid Stenting .....	6
Reverse Flow Embolic Neuroprotection .....	6
MS-DRG Codes & Payments (effective October 1, 2025 – September 30, 2026).....	7
HCPCS II Device Codes.....	7
<b>Physician Reimbursement .....</b>	<b>8</b>
CPT® Codes & Payments (effective January 1, 2025 – December 31, 2025).....	8
<b>Clinical Trial Numbers .....</b>	<b>8</b>
<b>Billing Requirements .....</b>	<b>9</b>
Hospital Claims .....	9
Physician Claims .....	9
<b>Revenue Codes .....</b>	<b>10</b>

# ENROUTE™ Transcarotid Neuroprotection System

## Overview

TransCarotid Artery Revascularization (TCAR) is a less invasive, clinically proven treatment option for carotid artery disease.

Boston Scientific's TCAR procedure utilizes the ENROUTE™ Transcarotid Neuroprotection System to temporarily reverse blood flow away from the brain, collecting any potential debris in the device filter, before returning the blood to a vessel in the leg.

With reverse flow neuroprotection established, the ENROUTE™ Transcarotid Stent is then implanted in the lesion for long-term plaque stabilization and stroke prevention.

## FDA Approval

The ENROUTE™ Transcarotid Neuroprotection System received FDA 510(k) clearance on February 9, 2015.

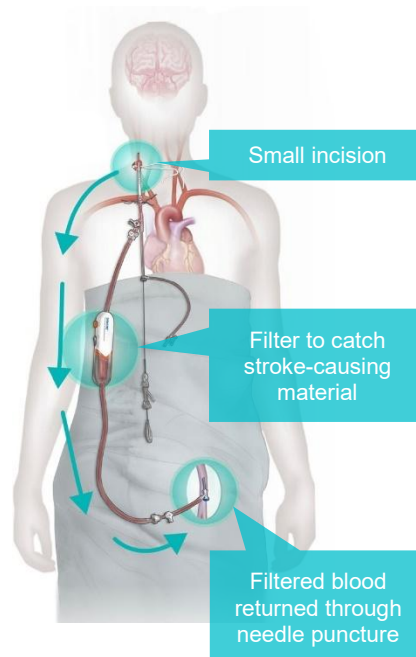
The ENROUTE™ Transcarotid Stent System received FDA premarket approval (PMA) for high-risk patients on May 18, 2015, and for standard-risk patients on April 28, 2022.

## ENROUTE™ TCAR Procedure

The ENROUTE™ TCAR procedure begins with a small incision above the collarbone to access the carotid artery. A temporary sheath is placed directly in the carotid artery away from the plaque. The sheath connects to the ENROUTE™ Transcarotid Neuroprotection System outside the body.

The neuroprotection system connects to another small sheath and is placed directly into the femoral vein through a needle puncture. The pressure difference causes the blood to flow in reverse from the carotid artery, through the filter in the system, and into the femoral vein, away from the brain. This creates a circuit outside the body.

The ENROUTE™ Transcarotid Stent is then inserted through the arterial sheath to open the blocked artery. Because of blood flow reversal, any debris dislodged from the lesion during stent placement is captured, preventing it from traveling to the brain.



## Ultrasound Guidance

The ENROUTE™ TCAR procedure uses ultrasound to access the femoral vein for the ENROUTE™ Transcarotid Neuroprotection System, which protects the brain from stroke during the procedure. The neuroprotection system remains in place for the entire procedure and is removed afterward.

# Coverage

## Medicare

Medicare covers TCAR under the National Coverage Determination (NCD) 20.7 for Percutaneous Transluminal Angioplasty (PTA).<sup>1</sup> This NCD covers carotid stenting procedures for traditional Medicare and Medicare Advantage beneficiaries under the following indications:

- **Section B3:** Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies (e.g., SVS VQI TransCarotid Revascularization Surveillance Project (VQI TSP))
- **Section B4:** Concurrent with Carotid Stent Placement

Traditional Medicare does not require prior authorization for procedures.

Medicare Advantage plans are managed by private insurers and must cover TCAR according to NCD 20.7. They cannot have more restrictive coverage criteria than the NCD, but they may require prior authorization or precertification. Contact the patient's Medicare Advantage plan for claims processing requirements.

## Non-Medicare

Non-Medicare payers, such as private insurers, Medicaid, and the Veteran's Administration, have different coverage plans and policies. Contact the payer before the TCAR procedure to verify coverage and billing requirements for carotid artery stenting.

Prior authorization or precertification is often required for elective procedures like TCAR. Reviewing payer guidelines is essential to avoid denials, payment losses, and penalties. The provider can contact Boston Scientific's TCAR Reimbursement Team at [srm-reimburse@bsci.com](mailto:srm-reimburse@bsci.com) to determine coverage availability before scheduling a patient's procedure.

## Reimbursement Denials

Payers may deny prior authorizations, precertifications, or claims. Providers can appeal these denials and request reconsideration. For assistance with appeals, email the TCAR Reimbursement Team at [srm-reimburse@bsci.com](mailto:srm-reimburse@bsci.com) with the payer's denial letter. Please ensure all sensitive patient information is redacted before sending the letter.

---

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

## ICD-10-CM Diagnosis Codes

Physicians and hospitals use diagnosis codes to document the indication for TCAR procedures, including any additional diagnoses of other clinical conditions applicable to the patient's healthcare visit. Common diagnosis codes associated with TCAR procedures include:

ICD-10-CM Code	Code Description
Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction	
I65.21	Occlusion and stenosis of right carotid artery
I65.22	Occlusion and stenosis of left carotid artery
I65.23	Occlusion and stenosis of bilateral carotid arteries
I65.29	Occlusion and stenosis of unspecified carotid artery
I65.8	Occlusion and stenosis of other precerebral arteries
I65.9	Occlusion and stenosis of unspecified precerebral artery
Cerebral infarction due to embolism of carotid artery	
I63.131	Cerebral infarction due to embolism of right carotid artery
I63.132	Cerebral infarction due to embolism of left carotid artery
I63.133	Cerebral infarction due to embolism of bilateral carotid arteries
I63.139	Cerebral infarction due to embolism of unspecified carotid artery
Cerebral infarction due to thrombosis of carotid artery	
I63.031	Cerebral infarction due to thrombosis of right carotid artery
I63.032	Cerebral infarction due to thrombosis of left carotid artery
I63.033	Cerebral infarction due to thrombosis of bilateral carotid arteries
I63.039	Cerebral infarction due to thrombosis of unspecified carotid artery
Cerebral infarction due to unspecified occlusion or stenosis of carotid arteries	
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries
I63.239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid artery

# Hospital Inpatient Reimbursement

## ICD-10-PCS Procedure Codes

Hospitals use ICD-10-PCS codes to report inpatient procedures. The ENROUTE™ TCAR procedure has two distinct ICD-10-PCS codes: one for carotid stenting and another for reverse flow embolic neuroprotection. Use both ICD-10-PCS code sets to accurately reflect the procedure performed.

### Carotid Stenting

ICD-10-PCS Codes			
Section	<b>0</b> Medical and Surgical		
Body System	<b>3</b> Upper Arteries		
Operation	<b>7</b> Dilation		
Body Part	Approach	Device	Qualifier
<b>H</b> Common Carotid Artery, Right	<b>3</b> Percutaneous	<b>D</b> Intraluminal Device	<b>Z</b> No Qualifier
<b>J</b> Common Carotid Artery, Left		<b>E</b> Intraluminal Device (2)	
<b>K</b> Internal Carotid Artery, Right		<b>F</b> Intraluminal Device (3)	
<b>L</b> Internal Carotid Artery, Left		<b>G</b> Intraluminal Device (4+)	

### Reverse Flow Embolic Neuroprotection

ICD-10-PCS Codes			
Section	<b>5</b> Extracorporeal or Systemic Assistance and Performance		
Body System	<b>A</b> Physiological Systems		
Operation	<b>0</b> Assistance: Taking over a portion of a physiological function by extracorporeal means		
Body System	Duration	Function	Qualifier
<b>5</b> Circulatory	<b>A</b> Intraoperative	<b>6</b> Cerebral Embolic Filtration	<b>Q</b> Extracorporeal Flow Reversal Circuit



## FY2026 MS-DRG Codes & Payments (effective October 1, 2025 – September 30, 2026)

Medicare reimburses TCAR as an inpatient procedure<sup>2</sup> using the Medicare Severity Diagnosis-Related Group (MS-DRG) system. Each inpatient stay is assigned a single MS-DRG based on the patient's diagnoses (ICD-10-CM) and procedures (ICD-10-PCS). The highest-ranked procedure code typically determines the assigned MS-DRG. Common MS-DRGs assigned for TCAR are included below.

Non-Medicare reimbursement for TCAR procedures may vary. Payment methods may include MS-DRG, case rates, percentage of billed charges, or device carve outs.

MS-DRG Code	Code Description	Medicare National Average <sup>3</sup>	National Discharge Volume (%) <sup>4</sup>
<b>034</b>	Carotid Artery Stent Procedures with MCC	\$28,166	2,115 (12.8%)
<b>035</b>	Carotid Artery Stent Procedures with CC	\$17,395	6,071 (36.9%)
<b>036</b>	Carotid Artery Stent Procedures without CC/MCC	\$14,137	8,275 (50.3%)
Weighted National Average <sup>5</sup>		\$17,141	16,461 (100%)

MS-DRG 034 represents Major Complications or Comorbidities (MCC), MS-DRG 035 represents Complications or Comorbidities (CC), and MS-DRG 036 represents neither CC nor MCC (CC/MCC).

## HCPCS II Device Codes

HCPCS II codes may be utilized by some hospitals for internal tracking across different care settings, even when not used for billing. The HCPCS codes for the ENROUTE™ TCAR procedure include:

Device	HCPCS C-Code	Device
ENROUTE™ Transcarotid Neuroprotection System	<b>C1884</b>	Embolization protective system
ENROUTE™ Transcarotid Stent System	<b>C1876</b>	Stent, non-coated/non-covered, with delivery system
ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter	<b>C1725</b>	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)
ENHANCE™ Transcarotid Peripheral Access Kit	<b>C1894</b>	Introducer/Sheath, non-laser
ENROUTE™ 0.014" Guidewire	<b>C1769</b>	Guidewire

<sup>2</sup> Medicare will continue to pay CPT code 37215 as a hospital inpatient only procedure in 2025. Addendum E.-- HCPCS Codes That Would Be Paid Only as Inpatient Procedures for calendar year 2025. <https://www.cms.gov/license/ama?file=/files/zip/2025-nfrm-opps-addenda.zip>

<sup>3</sup> Medicare payment amounts are estimates for the provider shown, effective October 1, 2025 - September 30, 2026. Payments do not include the 2% sequestration reduction and are subject to change without notice. See FY 2026 Medicare Inpatient Prospective Payment System (IPPS) at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page>.

<sup>4</sup> After Outliers Removed (AOR) v43 CMS. Cms.gov. <https://www.cms.gov/files/zip/fy2026-ipps-fr-aor-bor.zip>

<sup>5</sup> Weighted National Average reflects the estimated average fiscal year 2026 payment for all Carotid Artery Stent Procedures, weighted by the proportion of fiscal year 2024 cases within each relevant MS-DRG.

# Physician Reimbursement

## CY2025 CPT® Codes<sup>6</sup> & Payments (effective January 1, 2025 – December 31, 2025)

Physicians use Current Procedural Terminology (CPT) codes to describe the TCAR procedures performed. Proper documentation is crucial for selecting the correct CPT codes. The CPT codes below describe the procedures associated with the ENROUTE™ TCAR procedure.

Medicare physician payments for TCAR procedures are determined using the Resource-Based Relative Value Scale (RBRVS) methodology. Each CPT code is assigned a relative value unit (RVU), which contributes to the final payment amount.

CPT Code	Code Description	Facility RVU		Medicare National Average <sup>7</sup>
		Work	Total	
<b>37215</b>	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	17.75	29.01	\$938
<b>76937-26</b>	Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent real time ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)	0.30	0.40	\$13

## Clinical Trial Numbers

The ENROUTE™ TCAR procedure is covered under the National Coverage Determination (NCD) 20.7.<sup>1</sup> For coverage under Section B3 (Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies), participation in an approved clinical study is required. The following studies are associated with Section B3 coverage, where study participation and accurate National Clinical Trial (NCT) number billing are mandatory<sup>8</sup>:

Study Title	Sponsor	National Clinical Trial (NCT) Number
SVS VQI TransCarotid Revascularization Surveillance Project (VQI TSP)	Society for Vascular Surgery	<b>NCT02850588</b>
The ROADSTER 3 Study	Silk Road Medical	<b>NCT05365490</b>

<sup>6</sup> CPT copyright 2025 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

<sup>7</sup> Medicare payments to physicians are based on the CY 2025 Medicare Physician Fee Schedule and effective January 1, 2025 - December 31, 2025. The conversion factor for CY 2025 is \$32.3465. Payments do not include the 2% sequestration reduction and are subject to change without notice. Actual physician payment will vary based on geographic location and may differ based on policies and fee schedules outlined in health plan and/or payer contracts. <https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1807-f>

<sup>8</sup> Carotid Artery Stenting (CAS) Investigational Studies | CMS. Cms.gov. <https://www.cms.gov/medicare/coverage/approved-facilities-trials-registries/carotid-artery-stenting-studies>



## Billing Requirements

Medicare has specific claims submission instructions for the ENROUTE™ TCAR procedure, varying depending on the covered indication under NCD 20.7.<sup>9</sup>

- **Section B3:** Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies (e.g., SVS VQI TransCarotid Revascularization Surveillance Project (VQI TSP))
- **Section B4:** Concurrent with Carotid Stent Placement

See the tables below for claim submission instructions for hospitals and physicians. Section B3 provides instructions for providers participating in the VQI TSP, as an example of an approved clinical study.

Non-Medicare payers may have different billing requirements. Contact the payer directly to verify specific billing and claims submission requirements for carotid artery stent procedures.

## Hospital Claims

Medicare Billing Requirements	Section B3	Section B4
Secondary Diagnosis Code	<b>Z00.6</b> Encounter for examination for normal comparison and control in clinical research program <sup>10</sup>	NA
Bill Type <sup>2</sup>	<b>11X</b> Inpatient	<b>11X</b> Inpatient
Condition Code	<b>30</b> Qualifying clinical trial	NA
National Clinical Trial (NCT)	<b>NCT02850588</b> is required for cases enrolled in the VQI TSP <sup>11</sup>	NA

## Physician Claims

Medicare Billing Requirements	Section B3	Section B4
Secondary Diagnosis Code	<b>Z00.6</b> Encounter for examination for normal comparison and control in clinical research program <sup>10</sup>	NA
Modifier	<b>Q0</b> Investigational service provided in a clinical research study that is in an approved clinical research study <sup>12</sup>	NA
Place of Service <sup>2</sup>	<b>21</b> Inpatient Hospital	<b>21</b> Inpatient Hospital
National Clinical Trial (NCT)	<b>NCT02850588</b> is required for cases enrolled in the VQI TSP <sup>13</sup>	NA

<sup>9</sup> Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections. Cms.gov. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

<sup>10</sup> ICD-10-CM diagnosis code Z00.6 is billed with NCT02850588.

<sup>11</sup> For institutional claims, 02850588 should be placed in the value amount of value code D4 on Form UB-40 (Form Locators 39-41) or in Loop 2300 REF02 (REF01=P4) in the electronic 837I.

<sup>12</sup> Modifier Q0 is appended to CPT code 37215 for professional claims submitted to Medicare or Medicare Advantage.

<sup>13</sup> For professional claims, 02850588 should be preceded by "CT" and placed in Field 19 of Form CMS-1500 or it should be entered without the "CT" prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4).

## Revenue Codes

Medicare generally does not specify which revenue codes hospitals must use, instead instructing hospitals to choose codes that correspond to how charges are classified in their cost reports. The recommended revenue codes below are the same as those for other FDA-approved carotid stents and embolic protection devices.

Device	Revenue Code	Code Description
ENROUTE™ Transcarotid Neuroprotection System	<b>0279</b>	Medical/Surgical Supplies & Devices – Other Supplies/Devices
ENROUTE™ Transcarotid Stent System	<b>0278</b>	Medical/Surgical Supplies & Devices – Other Implants

### **ENROUTE Transcarotid Stent System**

**INTENDED 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.

**Boston  
Scientific**

Advancing science for life™

### **Peripheral Interventions**

300 Boston Scientific Way  
Marlborough, MA 01752-1234

[bostonscientific.com/reimbursement](https://www.bostonscientific.com/reimbursement)

### **Medical Professionals**

[srm-reimburse@bsci.com](mailto:srm-reimburse@bsci.com)

© 2025 Boston Scientific Corporation  
or its affiliates. All rights reserved.

PI-2172701-AD | NOV 2025