



TransCarotid Artery Revascularization

Physician Reimbursement Guide

Calendar Year 2023 (January 1, 2023 – December 31, 2023)



Introduction

This Physician Reimbursement Guide helps physicians and their staff understand payer coverage, coding, and payment for Silk Road Medical's TransCarotid Artery Revascularization (TCAR) procedure when used according to its labeling.

For reimbursement assistance, please contact Silk Road Medical's Reimbursement team:

- Email: reimbursement@silkroadmed.com
- Phone: (855) 410-8227 option #5
- Website: <https://tcar.at/reimbursement>

Scan or click the QR code to access our TCAR reimbursement resources or visit us at:
<https://tcar.at/reimbursement-resources>.



Silk Road Medical has compiled this information for your convenience. Silk Road Medical cannot guarantee success in obtaining coverage or payment. Silk Road Medical cannot guarantee the accuracy or appropriateness of any patient or procedure characterizations provided using this template. It is always the provider's responsibility to determine the appropriateness of any treatment and accurately describe patient characteristics and services furnished. Providers should consult with their payers regarding appropriate documentation, medical necessity, and coding information consistent with individual payer requirements and policies. This document is in no way intended to promote the off-label use of any medical device.

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Devices & Procedure Description

Overview

TransCarotid Artery Revascularization (TCAR) is a clinically proven and minimally invasive hybrid approach that combines elements of carotid artery stenting (CAS) and carotid endarterectomy (CEA) to treat carotid artery disease.

TCAR differs from other carotid artery stenting procedures by using direct carotid artery access and reverse blood flow neuroprotection to reduce the risk of stroke.

Devices

The ENROUTE® Transcarotid Stent is inserted directly into the carotid artery through a surgical incision to stabilize the plaque and minimize the risk of stroke.

The ENROUTE® Transcarotid Neuroprotection System temporarily reverses blood flow to remove emboli during the procedure to prevent a stroke. It consists of an arterial sheath and dilator, a venous sheath and dilator, flow controller with filter, and a support guidewire.

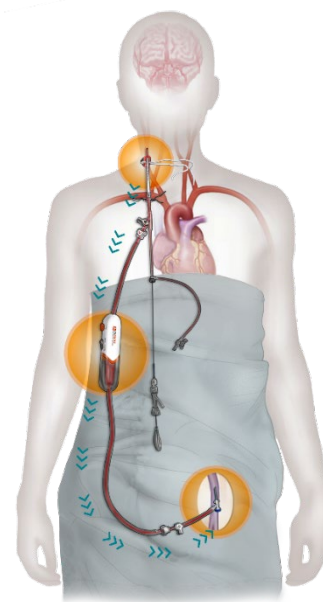
TCAR Procedure

The 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.

Click [here](#) to watch an animation of the TCAR procedure.



Ultrasound Guidance

TCAR 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

FDA Approval

The ENROUTE® Transcarotid Stent System received FDA premarket approval (PMA) for high-risk patients on May 18, 2015,¹ and was expanded to include standard-risk patients on April 28, 2022.² The ENROUTE® Transcarotid Neuroprotection System received FDA 510(k) clearance on February 9, 2015.³

Medicare Coverage

Medicare covers TCAR under the National Coverage Determination (NCD) 20.7 for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting,⁴ which was last updated on October 11, 2023.⁵ This NCD covers carotid stenting procedures for traditional Medicare and Medicare Advantage beneficiaries under the following indications:

- B3. Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies (e.g., Vascular Quality Initiative TCAR Surveillance Project or VQI TSP)⁶
- 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 the NCD.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 Coverage

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 physician can contact Silk Road Medical's Reimbursement Team at reimbursement@silkroadmed.com to determine coverage availability before scheduling a patient's procedure.

Documentation

Document the medical necessity of TCAR in the patient's medical record. Include the following in the documentation:

- Current findings and status, including a detailed diagnostic description and ICD-10 diagnosis codes.
- Specific medical history, including high-risk criteria, comorbidities, anatomic risk factors, diagnostic work-up studies and results, anatomical location and degree of stenosis, and symptomatic vs asymptomatic status.
- Explain why TCAR is the best treatment option for your patient and why you recommend it over CEA and other carotid stenting procedures.
- State how the patient meets the FDA indications for use.
- Describe other factors supporting your request, such as clinical studies or payer coverage.

Reimbursement Denials

Payers may deny prior authorizations, precertifications, or claims. Physicians can appeal these denials and request reconsideration. For assistance with appeals, contact Silk Road Medical's Reimbursement Team at reimbursement@silkroadmed.com and provide the payer's denial letter outlining the reason(s) for denial.

Coding & Payment

ICD-10-CM Diagnosis Codes

Physicians 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. The following codes are commonly associated with TCAR procedures:

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

CPT® Codes & Payment

Physicians use CPT codes to describe the TCAR procedures performed. Documentation determines the appropriate codes. The CPT codes below describe the procedures associated with the TCAR procedure.

Under Medicare's Resource-Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT code is assigned a relative value unit (RVU). RVUs are part of the formula to determine the payment amount and are converted to a flat payment amount.

CPT Code	Code Description	Facility RVU		Medicare National Average ⁸
		Work	Total	
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	17.75	29.01	\$983
76937-26	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	0.42	\$14

Billing Requirements

Medicare has specific claims submission instructions for TCAR procedures, depending on the covered indication that the physician is pursuing (such as the VQI TSP or Concurrent with Carotid Stent Placement). The table below summarizes the claims submission instructions for traditional Medicare and Medicare Advantage claims.^{6,7}

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

Medicare Billing Requirements	VQI TSP	Concurrent w/ Carotid Stent Placement
Secondary Diagnosis Code ⁹	Z00.6 Encounter for examination for normal comparison and control in clinical research program	NA
Modifier ¹⁰	Q0 Investigational service provided in a clinical research study that is in an approved clinical research study	NA
Place of Service ¹¹	21 Inpatient Hospital	21 Inpatient Hospital
National Clinical Trial (NCT) ¹²	NCT 02850588 is required for cases enrolled in the VQI TSP	NA

¹ Premarket Approval (PMA). Fda.gov. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140026>

² Premarket Approval (PMA). Fda.gov. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140026S016>

³ 510(k) Premarket Notification. Fda.gov. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K143072>

⁴ NCD - Percutaneous Transluminal Angioplasty (PTA) (20.7). Cms.gov. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=201>

⁵ NCA - Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R8) - Decision Memo. Cms.gov. <https://www.cms.gov/medicare-coverage-database/view/ncaal-decision-memo.aspx?proposed=N&ncaid=311>

⁶ Carotid Artery Stenting (CAS) Investigational Studies | CMS. Cms.gov. Published 2020. Accessed October 10, 2023. <https://www.cms.gov/medicare/coverage/approved-facilities-trials-registries/carotid-artery-stenting-studies>

⁷ Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections. Cms.gov. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

⁸ Medicare payments to physicians are based on the CY 2023 Medicare Physician Fee Schedule and effective January 1, 2023 - December 31, 2023. The conversion factor is \$33.8872. 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/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notice/cms-1770-f>

⁹ ICD-10-CM diagnosis code Z00.6 is billed with NCT 02850588.

¹⁰ Modifier Q0 is appended to CPT code 37215 for the primary procedure.

¹¹ Medicare will continue to pay CPT code 37215 as a hospital inpatient only procedure in 2024. Addendum E.- Proposed HCPCS Codes That Would Be Paid Only as Inpatient Procedures for CY 2024. <https://www.cms.gov/license/ama?file=/files/zip/2024-nprm-opps-addenda.zip>

¹² 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).