SILKROAD MEDICAL®

TransCarotid Artery Revascularization

Hospital Reimbursement Guide

Fiscal Year 2024 (October 1, 2023 – September 30, 2024)

AP00992.A

Introduction

This Hospital Reimbursement Guide helps hospitals 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.

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.

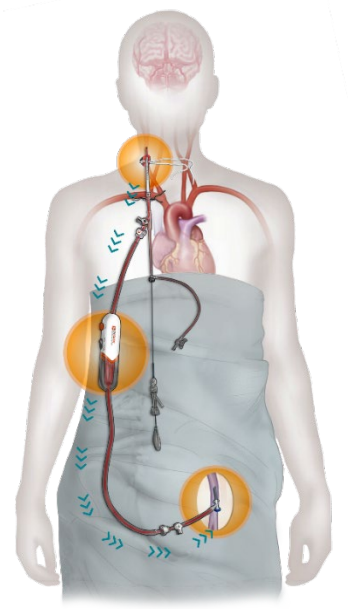
Devices

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

Documentation

Clinical documentation in hospitals is the creation of a digital record that details a patient's medical treatment, diagnostic tests, and clinical trials. It must be timely, accurate, and complete for the specific services provided.

Daily documentation and review while the patient is in the hospital are essential for conveying the full patient narrative and allowing coders to assign the appropriate codes. Inpatient coding and billing professionals rely on clinical documentation to assign codes and process claims for services administered by the hospital and sent to payers for reimbursement. DRG (Diagnosis Related Group) classification depends on the physician's documentation.

Reimbursement Denials

Payers may deny prior authorizations, precertifications, or claims. Hospitals 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

Hospitals use diagnosis codes to document the reason for TCAR procedures, including any additional diagnoses of other clinical conditions relevant 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

ICD-10-PCS Procedure Codes

Hospitals use ICD-10-PCS codes to report inpatient procedures. TCAR has two distinct ICD-10-PCS codes to identify carotid stenting and reverse flow embolic neuroprotection components.

Procedure	ICD-10-PCS Code	Code Description
Carotid Stenting	**037(H/J/K/L)3(D/E/F/G)Z**	Percutaneous dilation of vessel using an intraluminal device
Reverse Flow Embolic Neuroprotection	**X2A(H/J)336**	Cerebral embolic filtration, extracorporeal flow reversal

Fourth Character: H - Common carotid artery, right, J - Common carotid artery, left, K - Internal carotid artery, right, L - Internal carotid artery, left

Sixth Character: D - Intraluminal Device, E - Intraluminal Device (2), F - Intraluminal Device (3), G - Intraluminal Device (4+)

HCPCS II Device Codes

HCPCS II codes are used to report the device itself and are submitted on hospital outpatient bills only. However, some hospitals want HCPCS II codes for internal tracking purposes for all cases, including inpatient cases.

Device	HCPCS C-Code	Code Description
ENROUTE® Transcarotid Neuroprotection System	**C1884**	Embolization protective system

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Device	HCPCS C-Code	Code Description
ENROUTE® Transcarotid Stent System	**C1876**	Stent, non-coated/non-covered, with delivery system
ENROUTE Enflate® Transcarotid RX Balloon Catheter	**C1725**	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)
ENHANCE® Transcarotid Access Kit	**C1894**	Introducer/Sheath, non-laser
ENROUTE® 0.014" Guidewire	**C1769**	Guidewire

MS-DRG Codes & Payments

Medicare reimburses TCAR as an inpatient procedure[8] according to a Medicare Severity Diagnosis-Related Group (MS-DRG). Each inpatient stay is assigned to a DRG based on the patient's ICD-10-CM diagnosis and ICD-10-PCS procedure codes. Only one DRG is assigned per inpatient stay, regardless of the number of procedures performed. The highest-ranked procedure code determines the DRG assignment when multiple procedures are coded. The DRGs below are commonly assigned for TCAR procedures.

Non-Medicare payers may reimburse TCAR in different care settings. They may use the MS-DRG methodology, a variation of it, or another payment methodology, such as case rates, percent of billed charges, or device carve outs.

MS-DRG Code	Code Description	Medicare National Average[9]	National Discharge Volume (%)
034	Carotid Artery Stent Procedures W MCC	$27,316	1,612 (12.8%)
035	Carotid Artery Stent Procedures W CC	$16,100	4,539 (36.2%)
036	Carotid Artery Stent Procedures WO CC/MCC	$12,660	6,406 (51.0%)
	Weighted National Average[10]	$15,785	12,557 (100%)

DRG 034, 035, and 036 differ by the presence or absence of secondary diagnosis codes designated as major complications or comorbidities (MCC) and other (non-major) complications or comorbidities (CC). A DRG designated as W CC/MCC means that at least one of the secondary diagnosis codes is a CC or MCC. Otherwise, the DRG WO CC/MCC is assigned.

Billing Requirements

Medicare has specific claims submission instructions for TCAR procedures, depending on the covered indication that the hospital 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[11]	**Z00.6** Encounter for examination for normal comparison and control in clinical research program	NA
Bill Type[8]	**11X** Inpatient	**11X** Inpatient
Condition Code	**30** Qualifying clinical trial	NA
National Clinical Trial (NCT)[12]	**NCT 02850588** is required for cases enrolled in the VQI TSP	NA

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	**0279**	Medical/Surgical Supplies & Devices – Other Supplies/Devices
ENROUTE® Transcarotid Stent System	**0278**	Medical/Surgical Supplies & Devices – Other Implants

[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/pmn.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/ncacal-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 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.

[9] Medicare payments to hospital inpatient are based on the FY 2024 Medicare Inpatient Prospective Payment System (IPPS), effective October 1, 2023 - September 30, 2024. Payments do not include the 2% sequestration reduction and are subject to change without notice. Actual hospital payments will vary. https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page

[10] Weighted National Average is an estimated payment and determined by multiplying the DRG payment by the utilization of cases assigned to the DRG group in fiscal year 2022.

[11] ICD-10-CM diagnosis code Z00.6 is billed with NCT 02850588.

[12] 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.