

ROADSTER 3 Study Reimbursement Guide

The ROADSTER 3 Study is an FDA-approved post approval study.¹ This reimbursement guide is intended to support clinical sites with reimbursement efforts for the Study.

For additional information or assistance, please contact our **Health Economics & Reimbursement** team at reimbursement@silkroadmed.com.

Guidelines for Medicare & Non-Medicare Payers

Medicare (e.g., Original Medicare and Medicare Advantage)

- ROADSTER 3 is covered under Medicare's National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7), including the new population at standard surgical risk.^{2,3}
- Facilities and providers must include the National Clinical Trial (NCT) identifier, **NCT05365490**, on Medicare claims along with the appropriate codes and modifiers.⁴
- Sites do not need to seek coverage approval from Medicare Administrative Contractors because the Study is covered under an NCD.³
- Medicare Advantage Organizations may request notification before participation but cannot require prior authorization.

Non-Medicare (e.g., Commercial, Medicaid, Veteran's Administration)

- Non-Medicare payers are not required to provide coverage for clinical studies. Sites must seek a coverage decision from non-Medicare payers for the device and implant related charges.
- Contact non-Medicare payers to verify specific billing and claims submission requirements. Reviewing payer guidelines regarding clinical study coverage and reimbursement is critical to avoiding payment losses and penalties related to non-compliant billing.
- The process for seeking coverage and payment for clinical studies from non-Medicare payers can be challenging. Please contact us for additional information if you submit coverage requests to non-Medicare payers.

Medicare Billing Requirements

Billing instructions associated with CMS-approved studies are important to ensure appropriate billing for the device and all routine costs associated with the

ROADSTER 3 Study. Medicare billing and coding requirements for physician claims and hospital inpatient claims are provided in this section.

Physician Billing & Claims

Primary ICD-10-CM Diagnosis Codes*	I65.8 Occlusion and stenosis of other precerebral arteries I65.9 Occlusion and stenosis of unspecified precerebral artery I65.2X Occlusion and stenosis of carotid artery I63.13X Cerebral infarction due to embolism of carotid artery I63.03X Cerebral infarction due to thrombosis of carotid artery I63.23X Cerebral infarction due to unspecified occlusion or stenosis of carotid arteries
Secondary ICD-10-CM Diagnosis Codes	Z00.6 Examination of participant or control in a clinical research program Applicable Major Complications & Co-morbidities (MCC) Applicable Complications & Co-morbidities (CC)
Place of Service	21 Inpatient Hospital
CPT Procedure Codes for Index Procedure	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 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
CPT Modifier	Q0 Investigational service provided in a clinical research study that is in an approved clinical research study

* The "X" is used as a fifth- or sixth-character placeholder to allow for greater specificity of the disease or condition.

Hospital Billing & Claims

Primary ICD-10-CM Diagnosis Codes*	I65.8 Occlusion and stenosis of other precerebral arteries I65.9 Occlusion and stenosis of unspecified precerebral artery I65.2X Occlusion and stenosis of carotid artery I63.13X Cerebral infarction due to embolism of carotid artery I63.03X Cerebral infarction due to thrombosis of carotid artery I63.23X Cerebral infarction due to unspecified occlusion or stenosis of carotid arteries
Secondary ICD-10-CM Diagnosis Codes	Z00.6 Examination of participant or control in a clinical research program Applicable Major Complications & Co-morbidities (MCC) Applicable Complications & Co-morbidities (CC)
Bill Type	11X Inpatient
Condition Code	30 Qualifying clinical trial
ICD-10-PCS Procedure Codes**	037(H/J/K/L)3(D/E/F/G)Z Percutaneous dilation of vessel using an intraluminal device X2A(H/J)336 Reverse flow embolic neuroprotection 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+)

* The "X" is used as a fifth- or sixth-character placeholder to allow for greater specificity of the disease or condition.

** Use both ICD-10-PCS codes to identify the TCAR procedure.

Additional Information

The following materials are included with this guide and can be used to supplement your pre-approval request for coverage and payment for ROADSTER 3.

- FDA approval for expanded indications for the ENROUTE® Transcarotid Stent System to include patients at standard risk for adverse events from carotid endarterectomy.⁵

- CMS coverage approval for standard surgical risk patients participating in FDA-approved post approval studies.⁶

References

- Premarket Approval (PMA). Fda.gov. April 28, 2022. https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140026S016A.pdf
- NCD - Percutaneous Transluminal Angioplasty (PTA) (20.7). Cms.gov. Published 2021. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=201>
- Carotid Artery Stenting (CAS) Investigational Studies. Cms.gov. Published 2014. <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/Carotid-Artery-Stenting-CAS-Investigational-Studies>
- Post-approval Study of Transcarotid Artery Revascularization in Standard Risk Patients With Significant Carotid Artery Disease. Clinicaltrials.gov. Published 2022. <https://clinicaltrials.gov/ct2/show/NCT05365490>
- ENROUTE® Transcarotid Stent System Instructions For Use. Silkroadmed.com. Published April 2022. <https://silkroadmed.com/wp-content/uploads/2022/05/PL11752.09-ENROUTE-Transcarotid-Stent-System-IFU.pdf>
- TCAR Surveillance Project Expanded Indication Coverage Letter from CMS. The Vascular Quality Initiative. Published June 16, 2022. <https://www.vqi.org/wp-content/uploads/VQI-TCAR-Surveillance-Project-expanded-indication-coverage-letter-053122.pdf>

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April 28, 2022

Silk Road Medical, Inc
Richard Ruedy
Executive Vice President
1213 Innsbruck Drive
Sunnyvale, California 94089

Re: P140026/S016

Trade/Device Name: ENROUTE® Transcarotid Stent System

Product Code: NIM

Filed: March 17, 2021

Amended: May 6, 2021; July 9, 2021; November 1, 2021

Dear Mr. Ruedy:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the ENROUTE® Transcarotid Stent System (TSS) for expanding the indications to include patients at standard risk for adverse events from carotid endarterectomy. This device used in conjunction with the ENROUTE Transcarotid Neuroprotection System (NPS) is indicated for the treatment of patients at high 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	≥ 50% stenosis of the common or internal carotid artery by ultrasound or angiogram	≥ 70% stenosis of the common or internal carotid artery by ultrasound or ≥ 50% stenosis of the common or internal carotid artery by angiogram
Without neurological symptoms	≥ 80% stenosis of the common or internal carotid artery by ultrasound or angiogram	≥ 70% stenosis of the common or internal carotid artery by ultrasound or ≥ 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	

We are pleased to inform you that the PMA supplement is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 3 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. The ROADSTER 3 Study is an open label, single arm, multi-center post-approval study to evaluate real world usage of the ENROUTE® TSS and the ENROUTE Transcarotid NPS for the treatment of patients at standard risk for adverse events from carotid endarterectomy who require carotid revascularization and who are eligible for treatment with these devices. A maximum of 400 patients will be enrolled in up to 60 sites in the United States and up to 5 sites in the European Union according to the protocol (SRM-2022-01) provided via email dated March 2, 2022. Patients will be followed at 30 days (± 7 days), 6 months/180 days (± 30 days), and 1 year/365 days (± 45 days).

The primary endpoint is the hierarchical composite of Major Adverse Events (MAEs) defined as any death, stroke, or myocardial infarction (MI) within 30 days of the index procedure and ipsilateral stroke within 31 days to 365 days of the index procedure.

Key secondary endpoints are:

- Incidence of cranial nerve injury within 30 days of the index procedure
- Stroke within 30 days of the index procedure
- Death within 30 days of the index procedure
- MI within 30 days of the index procedure

- Stroke/Death/MI within 30 days of the index procedure
- Ipsilateral stroke at 1 year

Additional secondary endpoints are:

- Persistent cranial nerve injury at 6 months and 1 year
- Rate of cardiac death within 30 days of the index procedure
- Rate of neurological death within 30 days of the index procedure
- Rate of hierarchical ipsilateral stroke, death, and MI within 30 days of the index procedure
- Cardiac death at 1 year of patients who experienced an MI within 30 days of the index procedure
- Access site complications (arterial/venous)
- Hematoma/bleeding complications (arterial/venous access site)
- Rate of stent thrombosis or occlusion within 30 days of the index procedure
- Rate of dissection within 30 days of the index procedure (during index procedure or a reintervention procedure)

From the time of study protocol approval, you must meet the following timelines for ROADSTER 3:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months
- Submission of Final study report: 6 months from study completion (i.e., last subject, last follow-up date)

In addition, you must submit separate periodic reports on the progress of ROASTER 3 as follows:

- PAS Progress Reports every six (6) months until subject enrollment has been completed, and annually thereafter.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports (i.e., every 3 months), in addition to your periodic (6-months) PAS Progress Reports, until FDA notifies you otherwise.

For all other condition of approval studies, you must submit separate PAS Progress Reports for each study, every six (6) months for the first two (years) and annually thereafter, unless otherwise specified by FDA.

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including the initiation, enrollment, and completion requirement outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study

involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (<https://www.fda.gov/media/71327/download>).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system>.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" <https://www.fda.gov/media/81431/download>.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> and on combination product post-marketing safety reporting is available at (see

[https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products"\).](https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products)

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at

<https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals>. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Sadaf Toor at 301-796-6381 or Sadaf.Toor@fda.hhs.gov.

Sincerely,

 Brian D. Pullin -S

Brian Pullin
Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality
Coverage and Analysis Group

Jens Eldrup-Jorgensen, MD
SVS PSO Medical Director

05/31/2022

Dear Dr. Eldrup-Jorgensen:

Thank you for sharing the protocol revisions adding standard surgical risk patients to the SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR) with the Centers for Medicare & Medicaid Services (CMS). CMS has determined that patients participating in the VQI-TCAR Surveillance Project, including the new population at standard surgical risk, continue to be included in the currently covered population of patients participating in FDA-approved post approval studies (Pub. 100-03, 20.7, B3).

As noted in the 09/01/2016 letter originally confirming coverage, because this trial is covered under a national coverage determination, the process does not require study sites to get approval from the Medicare Administrative Contractors. For billing purposes, facilities and providers will submit claims for the TCAR surveillance project using National Clinical Trial (NCT) identifier, NCT02850588.

To facilitate the Medicare payment process, you should provide your study sites with appropriate billing instructions. These include entering the NCT identifier from the ClinicalTrials.gov website on Medicare claims along with the other codes and modifiers provided in the NCD claims processing instructions.

Sincerely,

X A handwritten signature in blue ink that reads "Joseph Chin".

Joseph Chin, MD, MS
Dep Dir, Coverage and Analysis Group
Signed by PIV