**TCAR Prior Authorization Letter**

This is a sample template for requesting prior authorization for the TCAR procedure.

**Instructions for completing the letter:**

* Tailor the template to the patient’s condition and clinical history, as well as any specific high risk (physiological or anatomic characteristics) or standard risk payer requirements. Ensure that all information provided is accurate and the medical necessity of the procedure is clearly documented in the patient’s medical record.
* Customize the fields highlighted in yellow.
* Optional enclosures include FDA approval/clearance letters for the ENROUTE® Transcarotid Stent System and Transcarotid Neuroprotection System, and CMS approval letters for standard-risk and high-risk patients.
* Print the letter on your business letterhead.
* Contact the patient’s insurance for prior authorization timeline, submission process and requirements.
* Make copies of everything submitted to the payer. Regularly follow up to ensure timely response to the request. Document your phone calls and interactions with the payer, including date, time and name of contact person. Obtain reference numbers for your calls.

Silk Road Medical provides this template for physicians and providers to complete; it is not meant to be used as a form letter. Silk Road Medical cannot guarantee success in obtaining coverage or payment. It is always the provider’s responsibility to determine the appropriateness of any treatment and accurately describe patient characteristics and services furnished. Providers should contact their third-party payers for specific information on their coding, coverage, and payment policies. This document is in no way intended to promote the off‐label use of any medical device. AP142.D

[Date]

[Attn: Utilization Management/Prior Authorization Dept.]

[Payer Name]

[Street Address]

[City, State, Zip Code]

[Phone Number]

[Patient Name]

[ID #]

[Group #]

[Social Security or Patient Identification]

[Date of Birth]

[RE: Prior authorization/Predetermination of coverage for TransCarotid Artery Revascularization procedure]

Dear [Payer Contact]:

I am requesting [prior authorization/ predetermination of coverage] for my patient, [Patient Name], to undergo a TransCarotid Artery Revascularization (TCAR) procedure using the ENROUTE® Transcarotid Stent System (TSS) in conjunction with the ENROUTE® Transcarotid Neuroprotection System (NPS) to treat carotid artery stenosis.

**Therapy Background**

TCAR is a minimally invasive procedure that has been available in the U.S. since 2015 to treat carotid artery disease. It combines surgical principles of neuroprotection with endovascular techniques to treat severe stenosis in the carotid artery that may cause stroke.1-3 The ENROUTE Transcarotid NPS and TSS used in the TCAR procedure have both received FDA approval/clearance.4,5 The ENROUTE Transcarotid NPS is intended for patients diagnosed with carotid artery stenosis and who have appropriate anatomy for TCAR. It is the first and only device that allows the physician to directly access the common carotid artery in the neck and initiate high-rate temporary blood flow reversal to protect the brain from atherosclerotic debris that could be dislodged during stent placement that may result in procedural stroke. The ENROUTE TSS is the only stent indicated for use in conjunction with the ENROUTE Transcarotid NPS and is indicated for the treatment of patients at standard risk and high risk for adverse events from carotid endarterectomy and who require carotid revascularization.

**Clinical Justification**

I have determined that TCAR is the best course of therapy for my patient. [Explain the clinical rationale leading to the decision to recommend TCAR. Personalize the letter for the specific patient addressing the following points in the body of the letter or in an attached report. TCAR coverage varies by payer. Medicare and Medicare Advantage cover TCAR for both standard and high surgical risk patients if medical necessity criteria are met. Most non-Medicare payers, such as private insurers, Medicaid, and the Veteran's Administration, only cover TCAR for high surgical risk patients. Contact the payer before the procedure to verify coverage]

* Document current findings/status, including detailed diagnostic description and ICD-10 diagnosis codes.
* Describe the patient’s specific medical history, including the following:
  + Applicable high-risk criteria (physiological or anatomic characteristics). Significant comorbidities and/or anatomic risk factors include but are not limited to:
    - Age > 80 years old
    - Congestive heart failure (CHF) class III/IV
    - Left ventricular ejection fraction (LVEF) < 30%
    - Unstable angina
    - Contralateral carotid occlusion
    - Recent myocardial infarction (MI)
    - Previous CEA with recurrent stenosis
    - Prior radiation treatment to the neck
  + Diagnostic work-up studies and results.
  + Anatomical location of the stenosis and degree of stenosis as indicated by CTA/duplex ultrasound, etc.
  + Symptomatic vs asymptomatic status. Symptoms usually include focal cerebral ischemia (transient ischemic attack or monocular blindness) in the previous 120 days, symptom duration less than 24 hours, or nondisabling stroke. If patient is symptomatic, describe the symptoms (when they started), duration, any prior diagnosis (when), conservative management that may have failed, drug therapies (drug prescribed, dosage, when).
* Document shared decision-making interaction with your patient and explain why TCAR is the best treatment option for them, compared to CEA and other carotid stenting procedures. Explain the outcomes and limitations of previous treatments (e.g., medically managed interventions). Discuss the clinical benefits and goals of TCAR for your patient (e.g., impact on quality of life and activities of daily living).
* State how patient meets FDA indications for use.
* Describe other factors supporting your request (e.g., clinical studies, payers that have covered TCAR).

**Treatment Options**

Carotid artery disease accounts for 20% of all ischemic strokes.6-8 Revascularization for carotid artery disease has been shown to reduce stroke and death rates in multiple randomized trials.8-10 Current strategies for carotid revascularization include surgical revascularization using carotid endarterectomy (CEA) or endovascular revascularization using carotid artery stenting (CAS), such as transfemoral (TF-CAS), transradial (TR-CAS), or transcarotid (TCAR).

CEA carries a higher risk of adverse events in patients presenting with certain anatomic and/or physiologic risk factors.11,12 Schermerhorn, et al.13 reported outcomes from the Society for Vascular Surgery (SVS) Vascular Registry in high surgical risk patients as defined by the Centers for Medicare and Medicaid Services (CMS) criteria that were published in the National Coverage Determination for Percutaneous Transluminal Angioplasty (20.7).14 In this “real world” analysis, in symptomatic high-risk patients, the 30-day stroke and death rate for CEA was 6.4%.13 In asymptomatic high-risk patients, the 30-day stroke and death rate for CEA was 3.7%.13 These stroke and death rates, stratified by symptom status, exceed the risk/benefit thresholds of 6% (symptomatic) and 3% (asymptomatic) set by the American Heart Association.13,15

CAS is endorsed by all relevant medical societies as an appropriate treatment option for carotid artery disease.8 Although TF-CAS is less invasive than CEA, TF-CAS is associated with twice the stroke risk in the periprocedural (30-day) setting when compared to CEA (4.1% vs. 2.3%, respectively).16

TCAR is a hybrid approach to carotid revascularization that combines the protection of surgery with the benefits of a minimally invasive procedure. Multiple clinical trials have demonstrated the safety and efficacy of TCAR for the treatment of patients with carotid stenosis. These studies demonstrated high rates of procedural success and low rates of perioperative stroke or death as well as low rates of perioperative cardiac and stroke complications.2,3,17-19 With over 45,000 procedures performed to date, TCAR has been validated as a safe, less invasive standard in stroke prevention treatment options. Refer to the Appendix for a listing of TCAR clinical studies and publications.

The ROADSTER study2 was a prospective, single-arm, multi-center clinical trial of the TCAR procedure using the ENROUTE Transcarotid NPS in high surgical risk patients with carotid artery stenosis. The overall stroke rate of 1.4% was the lowest reported to date for any prospective multi-center trial of carotid stenting. The cranial nerve injury rate was 0.7% at 30 days and 0% at 6 months. The myocardial infarction rate was 0.7%. The overall 30-day major adverse event rate (stroke, death, and myocardial infarction) was 3.5%. ROADSTER demonstrated that the ENROUTE Transcarotid NPS, used in conjunction with commercially approved stents, is safe and effective at preventing stroke during carotid artery stenting.

The ROADSTER study2 was followed by the larger, post-market ROADSTER 2 study,3 which evaluated the safety and efficacy of TCAR with the ENROUTE TSS when used in conjunction with the ENROUTE Transcarotid NPS. This study showed excellent outcomes with a stroke rate of 0.6% in the per protocol population, which may be the lowest reported rate after any carotid intervention. The death rate was 0.2%. The stroke/death rate was 0.8%. The adverse event rate for stroke/death/myocardial infarction was 1.7%. ROADSTER 2 demonstrated that TCAR is a safe and effective procedure in a broad user base with varying TCAR experience levels and that excellent outcomes, such as low stroke and death rates, are achievable if you follow the protocol and society guidelines (patient/lesion selection, drug regimen, procedure technique).

The SVS Vascular Quality Initiative (VQI) is a collaborative effort to improve the quality, safety, effectiveness, and cost of vascular healthcare. The initiative sponsors several registries, one of which is the TCAR Surveillance Project (TSP) designed to monitor the safety and effectiveness of stents placed in the carotid artery while reversing blood flow within the carotid artery using a transcarotid approach to reduce stroke risk. An analysis of the TSP registry showed TCAR had significant reductions in the risk of postoperative myocardial infarction (TCAR, 0.5% vs. CEA, 0.9%, P<0.005) and cranial nerve injury (0.4% vs. 2.7%, P<0.001) compared to CEA.18 In another study using data from the VQI TSP, TCAR was associated with a significantly lower risk of stroke or death compared to TF-CAS (TCAR, 1.6% vs. TF-CAS, 3.1%, P<0.001).19 Results from these studies support the decisions by the 2021 SVS guidelines that TCAR is recommended over CEA or TF-CAS in certain patient populations.20

[The following paragraph describes Medicare coverage for TCAR. Include the information if the denial is from a Medicare or Medicare Advantage plan. If the information does not apply, delete the paragraph and corresponding references (21 and 22) from the References section.]

**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,14 which was last updated on October 11, 2023.21 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)22
* B4. Concurrent with Carotid Stent Placement

I have enclosed the patient’s medical records for your review. Please grant coverage for the TCAR procedure based on the patient’s medical condition. The primary CPT codes are 37215 and 76937. TCAR has been scheduled at [name of facility] on [date].

Thank you for your prompt attention to this request. Please contact me at [phone] if you have any questions.

Sincerely,

[Physician Name]

[NPI/Tax ID Number]

[Title/Specialty]

[Institution]

[Phone]

[Email]

[You may decide to use the following letters as part of the submission for TCAR prior authorization.]

Enclosures:

* FDA approval letter for ENROUTE Transcarotid Stent System
* FDA clearance letter for ENROUTE Transcarotid Neuroprotection System
* CMS approval letter for standard risk
* CMS approval letter for high risk

**References**

1. Pinter L, Ribo M, Loh C, et al. Safety and feasibility of a novel transcervical access neuroprotection system for carotid artery stenting in the PROOF Study. J Vasc Surg. 2011;54(5):1317-1323. doi:10.1016/j.jvs.2011.04.040
2. Kwolek CJ, Jaff MR, Leal JI, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. J Vasc Surg. 2015;62(5):1227-1234. doi:10.1016/j.jvs.2015.04.460
3. Kashyap VS, Schneider PA, Foteh M, et al. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020;51(9):2620-2629. doi:10.1161/STROKEAHA.120.030550
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5. Premarket Approval (PMA) (ENROUTE Transcarotid Stent System). Fda.gov. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140026
6. Lloyd-Jones D, Adams RJ, Brown TM, et al. Executive summary: heart disease and stroke statistics--2010 update: a report from the American Heart Association [published correction appears in Circulation. 2010 Mar 30;121(12):e259]. Circulation. 2010;121(7):948-954. doi:10.1161/CIRCULATIONAHA.109.192666
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8. Brott TG, Halperin JL, Abbara S, et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/ SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease: executive summary. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery [published correction appears in Circulation. 2011 Jul 26;124(4):e145. Dosage error in article text]. Circulation. 2011;124(4):489-532. doi:10.1161/CIR.0b013e31820d8d78
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11. Ouriel K, Hertzer NR, Beven EG, et al. Preprocedural risk stratification: identifying an appropriate population for carotid stenting. J Vasc Surg. 2001;33(4):728-732. doi:10.1067/mva.2001.111981
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18. Malas MB, Dakour-Aridi H, Kashyap VS, et al. TransCarotid Revascularization With Dynamic Flow Reversal Versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. Ann Surg. 2022;276(2):398-403. doi:10.1097/SLA.0000000000004496
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21. 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
22. Carotid Artery Stenting (CAS) Investigational Studies | CMS. Cms.gov. https://www.cms.gov/medicare/coverage/approved-facilities-trials-registries/carotid-artery-stenting-studies

**Appendix: TCAR Clinical Studies and Publications** (not an exhaustive list)

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| --- | --- | --- | --- | --- | --- | --- |
|  | **PROOF[[1]](#footnote-2)** | **ROADSTER[[2]](#footnote-3)** | **TCAR vs TF-CAS[[3]](#footnote-4)** | **ROADSTER 2[[4]](#footnote-5)** | **TCAR for HSR[[5]](#footnote-6)** | **TCAR for SSR[[6]](#footnote-7)** |
| **Study Type** | First In Man &  DW-MRI Sub-Study | US Pivotal IDE  (prospective, single arm, multi-center) | VQI TCAR Surveillance Project | US Post-Market Registry | VQI TCAR Surveillance Project | VQI TCAR Surveillance Project |
| **Author (Year)** | Pinter (2011) | Kwolek (2015) | Schermerhorn (2019) | Kashyap (2020) | Malas (2022) | Liang (2023) |
| **Patients** | 75 | 219 | 3,286 pairs of matched patients | 632 | 6,384 pairs of matched patients | TCAR: 2,962  CEA: 8,886 |
| **Profile** | All-comers | HSR Sym & Asx | HSR Sym & Asx | HSR Sym & Asx | HSR Sym & Asx | SSR Sym & Asx |
| **TCAR Outcomes** | * 0.0% major S/D/MI * 1.3% minor contralateral stroke * 17.9% new ipsilateral DWI lesions | * 1.4% all stroke (ITT) * 0.7% all stroke (PP) * 0.0% major stroke * 0.7% MI * 0.0% CNI at 6 months | * 1.6% (vs 3.1%)  in-hospital stroke * 1.3% (vs. 2.4%) stroke * 0.4% (vs. 1.0%) death * 5.1% (vs. 9.6%) ipsilateral S/D at  1 year | * 1.7% S/D/MI (PP) * 0.6% stroke (PP) * 0.2% death (PP) * 1.3% CNI (PP) | * 1.6% S/D * 1.4% in-hospital stroke * 0.4% death * 0.5% MI * 0.4% CNI | * 3.0% S/D/MI\* at 30 days and 1-year ipsilateral stroke * 1.6% 1-year ipsilateral stroke * 2.6% death at 1 year   \*MI was restricted to  in-hospital events only |
| **Conclusions** | DW-MRI findings suggest controlled reverse flow provides cerebral embolic protection similar to that seen with CEA. | The overall stroke rate of 1.4% is the lowest reported to date for any prospective multi-center trial of carotid stenting. | TCAR had a significantly lower risk of stroke or death compared to TF-CAS with improved procedural efficiencies. | The stroke rate of 0.6% after TCAR in the PP population may be the lowest reported rate after any carotid intervention. | TCAR had a significant reduction in the risk of post-op MI and CNI compared to CEA, with no differences in the S/D rates. | TCAR has a similar risk of 30-day S/D/MI and 1-year ipsilateral stroke compared to CEA. |

Definitions: Asx – Asymptomatic, CEA – Carotid endarterectomy, CNI – Cranial nerve injury, DW-MRI – Diffusion-weighted magnetic resonance imaging, DWI – Diffusion weighted imaging, HSR – High surgical risk, ITT – Intention to treat, MI – Myocardial infarction, PP – Per protocol, S/D – Stroke/Death, S/D/MI – Stroke/Death/Myocardial infarction, SSR – Standard surgical risk, Sym – Symptomatic, VQI – Vascular Quality Initiative

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3. Schermerhorn ML, Liang P, Eldrup-Jorgensen J, et al. Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery Stenting With Stroke or Death Among Patients With Carotid Artery Stenosis. JAMA. 2019;322(23):2313-2322. [↑](#footnote-ref-4)
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