**TCAR Prior Authorization Denial Appeal Letter**

This is a sample template for appealing a denial of coverage for the TCAR procedure.

**Instructions for completing the letter:**

* Review the denial letter to understand the specific reason for denial and the options and timelines for appeal.
* Tailor the appeal letter 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- and high-risk patients.
* Print the letter on your business letterhead.
* Make copies of everything submitted to the payer. Regularly follow up to ensure timely resolution of the appeal. 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. AP00938.B

[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: PA/Reference Number – Prior authorization denial for TransCarotid Artery Revascularization procedure]

Dear [Payer Contact]:

I am writing to appeal the denial of coverage for the TransCarotid Artery Revascularization (TCAR) procedure for [Patient Name]. The plan cited [list reason given by the plan] as the reason for denial. I am requesting that a physician with similar medical specialty review the denial and enclosed clinical documentation.

**Clinical Justification**

TCAR is the best treatment option for [Patient Name]. [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. If applicable, add: You will find details of my patient’s clinical history and need for this therapy outlined in my request for [prior authorization/predetermination of coverage] to you dated [date]. 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).

**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 Neuroprotection System (NPS) and ENROUTE® Transcarotid Stent System (TSS) are devices used in the TCAR procedure and 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. 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.

TCAR has been shown to be a safe and effective treatment for carotid artery stenosis in multiple clinical trials. The studies showed high rates of procedural success and low rates of stroke, death, and cardiac and stroke complications.2,3,6-8 With over 45,000 procedures performed, TCAR is a safe, less invasive option for stroke prevention. Refer to the Appendix for a listing of TCAR clinical studies and publications.

[The following paragraph describes Medicare coverage for TCAR. Include the information if the denial is from a Medicare or Medicare Advantage plan. Otherwise, delete the paragraph and corresponding references (9-11) 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,9 which was last updated on October 11, 2023.10 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)11
* B4. Concurrent with Carotid Stent Placement

In conclusion, I have determined that TCAR is medically necessary for my patient. I respectfully request reconsideration for coverage and reimbursement of all charges associated with this procedure, including physician professional fees, facility costs, device/supplies charges, and fees for follow-up care.

Thank you for your prompt review of this information and for reconsidering your coverage decision. 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
4. 510(k) Premarket Notifications (ENROUTE Transcarotid Neuroprotection System). Fda.gov. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230402, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K153485, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K143072
5. Premarket Approval (PMA) (ENROUTE Transcarotid Stent System). Fda.gov. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140026
6. Liang P, Cronenwett JL, Secemsky EA, et al. Risk of Stroke, Death, and Myocardial Infarction Following Transcarotid Artery Revascularization vs Carotid Endarterectomy in Patients With Standard Surgical Risk. JAMA Neurol. 2023;80(5):437-444. doi:10.1001/jamaneurol.2023.0285
7. 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
8. 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. doi:10.1001/jama.2019.18441
9. NCD - Percutaneous Transluminal Angioplasty (PTA) (20.7). Cms.gov. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=201
10. 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
11. 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: 2,962CEA: 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

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. [↑](#footnote-ref-2)
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. [↑](#footnote-ref-3)
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)
4. 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. [↑](#footnote-ref-5)
5. 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 [↑](#footnote-ref-6)
6. Liang P, Cronenwett JL, Secemsky EA, et al. Risk of Stroke, Death, and Myocardial Infarction Following Transcarotid Artery Revascularization vs Carotid Endarterectomy in Patients With Standard Surgical Risk. JAMA Neurol. 2023;80(5):437-444. doi:10.1001/jamaneurol.2023.0285 [↑](#footnote-ref-7)