ENROUTE®
Transcarotid Artery Revascularization

Boston Scientific
Advancing science for life™

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.

Reimbursement Support

For reimbursement assistance, please contact the **Boston Scientific PI Reimbursement team:**

- Email: **SRM-Reimburse@bsci.com**
- Website: **Peripheral Vascular - Reimbursement - Boston Scientific**

Boston Scientific provides this template for physicians and providers to complete; it is not meant to be used as a form letter.

ENROUTE Transcarotid Stent System

INTENDED USE/INDICATIONS FOR USE The ENROUTE® Transcarotid Stent System used in conjunction with the ENROUTE Transcarotid Neuroprotection System (NPS) is indicated for the treatment of patients at high risk 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

ENROUTE Transcarotid Neuroprotection System

INTENDED USE/INDICATIONS FOR USE The ENROUTE Transcarotid Neuroprotection System (ENROUTE Transcarotid NPS) is intended to provide transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have appropriate anatomy described below: • Adequate femoral venous access • Common carotid artery reference diameter of at least 6 mm • Carotid bifurcation is a minimum of 5 cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography.

IMPORTANT INFORMATION

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

Boston Scientific does not promote the use of its products outside their FDA-approved label. Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. All trademarks are the property of their respective owners.

[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 and review the coverage criteria before the procedure..]

- 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.[2,3,6-9] TCAR has been adopted into real-world practice, with over 100,000 procedures performed and representing almost one-fourth of carotid interventions at facilities that offer it.[10] 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,[11] which was last updated on October 11, 2023.[12] 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)[13]
- 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. Caron E, Van Galen I, Darling JD, et al. Comparative outcomes of transfemoral carotid artery stenting versus carotid endarterectomy versus transcarotid artery revascularization in standard- and high-risk patients since the CMS decision in October 2023 using the VQI. J Vasc Surg. Published online August 22, 2025. doi:10.1016/j.jvs.2025.08.021
8. Ramsay IA, Burks JD, Lu VM, et al. Perioperative Outcomes in Transcarotid Artery Revascularization Versus Carotid Endarterectomy or Stenting Nationwide. Oper Neurosurg. 2023;25(5):453-460. doi:10.1227/ons.0000000000000865
9. Zhu J, Rao A, Berger K, et al. Determinants of Mortality and Mid-Term Outcomes After Transcarotid Artery Revascularization and Transfemoral Carotid Artery Stenting. J Endovasc Ther. Published online March 6, 2024. doi:10.1177/15266028241235791
10. Columbo JA, Stone DH, Martinez-Camblor P, Goodney PP, O'Malley AJ. Adoption and Diffusion of Transcarotid Artery Revascularization in Contemporary Practice. Circ: Cardiovasc Interv. 2023;16(9):e012805. doi:10.1161/circinterventions.122.012805
11. NCD - Percutaneous Transluminal Angioplasty (PTA) (20.7). Cms.gov. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=201
12. 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
13. 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)

	PROOF[1]	ROADSTER[2]	TCAR vs TF-CAS[3]	TCAR for Asx[4]	TCAR vs CEA[5]	TCAR for SSR[6]
Study Type	First In Man & DW-MRI Sub-Study	US Pivotal IDE (prospective, single arm, multi-center)	VQI TCAR Surveillance Project	VQI TCAR Surveillance Project (Oct '23-Mar '25)	National Inpatient Database	VQI TCAR Surveillance Project
Author (Year)	Pinter (2011)	Kwolek (2015)	Zhu (2024)	Caron (2025)	Ramsay (2023)	Liang (2023)
Patients	75	219	22,322 pairs of matched patients	2,1814 TCAR & 9,123 TF-CAS	2,390 TCAR & 280,935 CEA	TCAR: 2,962 CEA: 8,886
Profile	All-comers	HSR Sym & Asx	Sym & Asx	SSR & HSR, Sym & Asx	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
			• Sym pts:
			  • TCAR: Signif lower death at 6 mths, 1 yr, 3 yrs
			  • TCAR: Signif lower S/D at 3 yrs
			• Asx pts:
			  • TCAR: Signif lower death at 6 mths, 1 yr, 3 yrs
			  • TCAR: Signif lower S at 3 yrs
				• Sym:
				  • 1.9% (vs 2.9%) S/D
				• Asx:
				  • 1.2% (vs 1.6%) S/D
					• 0.42% (vs 0.74%) in-hosp S
					• 1.46% in-hosp MI
					• 0.47 odds ratio for S vs CEA
					• 0.66 odds ratio for MI vs CEA
					• 0.73 odds ratio for D/S/MI vs CEA
						• 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.	Short and long-term outcomes are better after TCAR than TF-CAS in propensity-matched cases	Compared with TF-CAS, in-hospital stroke or death was lower with TCAR for both Sym and Asx patients	After adjusting for covariates, including symptomatic carotid disease status, TCAR has lower odds of in-hospital stroke, MI, or D/S/MI combined	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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[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.

[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.

[3] Zhu J, Rao A, Berger K, et al. Determinants of Mortality and Mid-Term Outcomes After Transcarotid Artery Revascularization and Transfemoral Carotid Artery Stenting. J Endovasc Ther. Published online March 6, 2024.

[4] Caron E, Van Galen I, Darling JD, et al. Comparative outcomes of transfemoral carotid artery stenting versus carotid endartecrectomy versus transcarotid artery revascularization in standard- and high-risk patients since the CMS decision in October 2023 using the VQI. J Vasc Surg. 2025 Aug 22 (Online ahead of print);

[5] Ramsay IA, Burks JD, Lu VM, et al. Perioperative outcomes in transcarotid artery revascularization versus carotid endarterectomy or stenting nationwide. 2023;25(5):453-60.

[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