



TCAR Peer to Peer Guide

This document can be used to support peer-to-peer discussions with payers about the TCAR procedure.

Rules of the Road

- Payers offer peer-to-peer reviews (P2P) to allow physicians to discuss denied prior authorizations.
- P2P calls are between the payer's Medical Director and the requesting physician or designated person from the office.
- Payers may require the call to be within 24-48 hours following a denied prior authorization.
- P2P calls are typically 5-15 minutes and must be arranged by the requesting physician's office.
- The Medical Director is typically not a Vascular Surgeon or familiar with the TCAR procedure.
- P2P should take place prior to submitting a written appeal.
- P2P may not be an option for all payers. Request a P2P to determine if the payer will allow the review.
- A determination is usually made at the conclusion of the P2P conversation.

Checklist: Things to Do Before Contacting a Payer

1. Understand the prior authorization denial reason. This will provide information that can be addressed during the P2P conversation.
2. Review the specific coverage policy for that patient's plan.
3. Have clinical information about the patient readily available to you, including:
 - Applicable high-risk criteria (physiological or anatomic characteristics).
 - Diagnostic work-up studies and results.
 - Anatomical location of the stenosis and degree of stenosis.
 - Symptomatic status. If the 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).
 - Note some payers may exclude asymptomatic patients from coverage.
4. Make sure that your documentation meets the guidelines and requirements listed in the payer's specific coverage policy.
5. Familiarize yourself with the "talking points" section of this document and the clinical articles (see article summaries in this document).
6. Think through the other options that are available to this patient and why TCAR is the best treatment option.

Key Talking Points

Below is a list of recommendations when speaking with the Medical Director.

State your request and why you disagree with the denial.

- If the denial is because of a payer's non-coverage policy, then request a one-time patient exception for coverage based on medical necessity.

Describe the TCAR procedure.

- TransCarotid Artery Revascularization (TCAR) is a clinically proven and minimally invasive procedure that has received FDA approval/clearance^{1,2} for the treatment of carotid artery disease in patients at high risk and standard risk for adverse events from carotid endarterectomy.
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¹ 510(k) Premarket Notification. Fda.gov. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K143072>

² Premarket Approval (PMA). Fda.gov. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140026>

Describe the TCAR procedure.

continued

- The entire TCAR procedure is performed through a smaller incision in the neck and in less than half the time of a carotid endarterectomy³ – limiting the stress on the heart and significantly cutting the risk of the patient having a stroke or heart attack during the procedure. During the TCAR procedure, a tube inserted into the carotid artery is connected to a system temporarily directing blood flow away from the brain to protect against dangerous debris from reaching the brain and causing a stroke during the procedure. The blood is filtered before returning it to a vein in the groin, and a stent is implanted to the carotid artery to stabilize plaque and prevent strokes.
- TCAR has been studied extensively, and the clinical data has been excellent. Based on published clinical trials, the procedure offers several advantages:
 - **Better Outcomes:** TCAR results in a low periprocedural stroke rate of 1.4% in high surgical risk patients⁴ and 1.5% in standard surgical risk patients.⁵ TCAR's low stroke rate in high-risk patients is the lowest reported to date for any prospective, multi-center trial of carotid stenting.⁴ In high-risk patients, TCAR offers lower risk of perioperative stroke/death⁶ and MI⁷ than CEA
 - **Less Invasive:** The TCAR approach has significantly lower cranial nerve injury and myocardial infarction rates compared to CEA.³
 - **Patient-Friendly:** Local anesthesia is more common with TCAR, and hospital stays are typically overnight for observation.³ TCAR patients recover quickly, have less pain (and use fewer narcotics)⁸ and almost always go home the next day³ to return to full and productive lives with less pain and smaller scars.^{9,10}
- Favorable clinical outcomes have also been demonstrated within asymptomatic and standard-risk patients:
 - Among standard risk patients, similar 30-day mortality/stroke and 1-, 2-, and 3-year mortality were similar between TCAR and CEA¹¹; in those same patients, TCAR was associated with a lower risk of MI.¹¹
 - In other studies, adjusted analyses have typically found no difference in stroke/death rates between TCAR and CEA among standard-risk patients.^{6,7}
 - Among asymptomatic patients, adjusted analyses have demonstrated that risk of stroke/death perioperatively and at 1 year are similar between TCAR and CEA,¹² as are 3-year stroke risks.¹³

³ 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

⁴ 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

⁵ 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

⁶ Caron E, Galen IV, Darling J, et al. Comparative Outcomes of tFCAS vs CEA vs TCAR in Standard and High-Risk Patients Since the CMS decision in October 2023 using the VQI. *J Vasc Surg.* Published online 2025. doi:10.1016/j.jvs.2025.08.021

⁷ Sakowitz S, Vadlakonda A, Bakhtiyar SS, et al. Transcarotid Artery Revascularization Versus Carotid Endarterectomy With and Without High-Risk Criteria. *Ann Surg.* Published online 2025. doi:10.1097/SLA.0000000000006825

⁸ Dorey T, Parmiter S, Sanders J, Turcotte J, Jeyabalan G. Comparing Post-operative Pain and Other Outcomes in Carotid Endarterectomy Versus Transcarotid Artery Revascularization. *Vasc Endovasc Surg.* 2024;58(7):706-713. doi:10.1177/15385744241257153

⁹ Silk Road Medical. Patient Satisfaction Survey: TCAR vs. CEA. 2023; Sunnyvale, CA.

¹⁰ TCAR Patient Stories | Carotid Disease Treatment Successes. Silk Road Medical | Global website. <https://silkroadmed.com/healthcare-professionals/patient-stories/>

¹¹ Willie-Permor D, Straus S, Elsayed N, Malas M. Mid-term Outcomes Of Transcarotid Artery Revascularization vs Carotid Endarterectomy Among Standard Risk Patients. *J Vasc Surg.* 2024;79(6):e193-e194. doi:10.1016/j.jvs.2024.03.248

¹² Columbo JA, Martínez-Cambor P, Stone DH, Goodney PP, O'Malley AJ. Procedural Safety Comparison Between Transcarotid Artery Revascularization, Carotid Endarterectomy, and Carotid Stenting: Perioperative and 1-Year Rates of Stroke or Death. *Journal of the American Heart Association.* 2022;11(19). doi:10.1161/jaha.121.024964

¹³ Columbo JA, Martínez-Cambor P, Stone DH, Goodney PP, Creager MA, MacKenzie TA, et al. Three-year risk of stroke after transcarotid artery revascularization versus carotid endarterectomy among Medicare beneficiaries. *J Vasc Surg.* Published online 2025. doi:10.1016/j.jvs.2025.06.052

Explain the medical necessity for your patient.

- Provide a brief overview of the patient’s relevant medical history.
 - Diagnosis, date of diagnosis, and diagnostic testing that has been done.
 - Current clinical description of the patient, symptoms, severity of the stenosis, impact on quality of life the patient is experiencing.
 - Any significant risk factors, comorbidities, or other relevant patient history (e.g., previous stroke, CEA, hospitalizations)
- Discuss outcomes and limitations of previous treatments (e.g., CEA, TF-CAS, medical management). *“Traditional CEA is not appropriate for my patient. [Describe any high-risk criteria and anatomic contraindications.] While it is recognized as a safe, effective surgery, it’s still a major surgery that typically takes a couple of hours and usually requires general anesthesia.”*
- Describe the reason for the procedure and why TCAR is recommended for this patient (e.g., high risk for CEA, recent MI; previous CEA with recurrent stenosis, prior radiation treatment to the neck, etc.). *“TCAR is less invasive than open surgery (CEA), and there is less chance of heart attack and nerve injury. Because of its low stroke risk and faster patient recovery, I believe TCAR is the best treatment option for my patient.”*

Discuss the clinical benefits and goals of TCAR for your patient.³⁻¹⁰

continued

- Less invasive
- Reverse flow neuroprotection to reduce risk of stroke.
- Less risk of MI
- Less risk of CNI
- Less risk of bleeding
- Less time in OR
- Less time in hospital for more than 1 day
- Shorter incision length
- Speedier recovery, less pain
- Ability to perform procedure with local anesthesia vs. general.
- Describe your goal for the patient. *“In my experience, patients who undergo TCAR recover quickly (typically spending just one night in the hospital) and almost always go home the next day to return to full and productive lives with less pain, smaller scars and a reduced risk of future strokes.”*

Share your experience with TCAR in your patient population.

- State that you have received the appropriate training for transcarotid stenting and have previous experience with the transcarotid approach.
- TCAR procedure volume for patients in your practice.
- Provide information on your TCAR patient outcomes.

Describe other factors supporting your request.

- Payers that have covered TCAR for your patients (e.g., Medicare and Medicare Advantage).

Summaries of Key Articles

The following is a summary of relevant data and clinical benefits for TCAR.

ROADSTER 2

Post approval outcomes of TCAR with the ENROUTE® Transcarotid Stent System in a diverse user group with varying levels of TCAR experience.¹⁴

- Prospective, multi-center trial that included 692 patients at 43 sites.
- Objective: Evaluate **real world use** of the ENROUTE Transcarotid Stent and Neuroprotection System in a broad user group
- Results: 30-day outcomes in high surgical risk patients (n=692 intention-to-treat, n=632 per protocol):
 - Intention-to-treat: stroke 1.9%, death 0.4%, MI 0.9%, stroke/death rate 2.3%, stroke/death/MI rate 3.2%
 - Per protocol: stroke 0.6%, death 0.2%, MI 0.9%, stroke/death 0.8%, stroke/death/MI 1.7%
- Conclusion: **TCAR is a safe and effective procedure in a broad user base with varying TCAR experience levels.** Excellent outcomes are achievable by following the protocol and society guidelines.
- Key Takeaway: **TCAR stroke rate is 0.6%** in the per-protocol population.

TCAR vs CEA in VQI – High Surgical Risk

Real-world comparisons of TCAR vs CEA outcomes using Vascular Quality Initiative (VQI) TCAR Surveillance Project (TSP) data.^{3,6}

- Study by Malas, et al. (2022)
 - Retrospective, propensity-score matched analysis using VQI TSP data.
 - Objective: Compare outcomes after TCAR vs. CEA in high-risk patients
 - Results: TCAR and CEA had similar rates of in-hospital stroke/death (1.6% vs. 1.6%, P=0.945), stroke (1.4% vs. 1.4%, P=0.881), and death (0.4% vs.0.3%, P=0.662). However, TCAR was associated with lower rates of in-hospital MI (0.5% vs 0.9%, P=0.005) and CNI (0.4% vs 2.7%, P<0.001), and a shorter LOS (≤ 1 day) vs CEA (P<0.001).
 - Conclusion: **TCAR significantly reduced the risk of in-hospital MI and CNI compared to CEA, with no differences in the rates of stroke/death.**
 - Key Takeaway: TCAR and CEA had similar rates of in-hospital stroke/ death in high-risk patients.
- Study by Caron, et al. (2025)
 - Retrospective study using inverse probability of treatment weighting (IPTW)
 - Objective: Compare outcomes among transfemoral carotid artery stenting (tfCAS), TCAR, and CEA in standard-risk and high-risk patients.
 - Results: In high-risk patients, TCAR was associated with lower odds of perioperative stroke/death overall compared with CEA (1.5% vs. 2.1%, adjusted odds ratio and 95% confidence interval = 0.75 (0.59, 0.94), p=0.01)
 - Conclusion: **In high-risk patients, TCAR performed better with lower odds of stroke/death than CEA (and tfCAS).**
 - Key Takeaway: TCAR had lower rates of perioperative stroke/death than CEA in high-risk patients

TCAR vs CEA in Nationwide Readmissions Database – Low and High Surgical Risk

Real-world comparison of TCAR vs CEA outcomes⁷

- Retrospective analysis using 2021-2022 Nationwide Readmissions Database, using a probability-weighted regression analysis
- Objective: To evaluate 90-day outcomes associated with TCAR vs. CEA for carotid artery stenosis.
- Results: The adjusted risk of composite morbidity (in-hospital stroke, MI, or death) at 90 days was 4.1% for both procedures. In low-risk patients, TCAR and CEA produced a similar hazard for 90-day composite morbidity. In high-risk

¹⁴ 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

patients, TCAR was associated with a reduced hazard of myocardial infarction (HR = 0.76, CI = 0.58-0.98)

- Conclusion: TCAR and CEA had comparable morbidity over 90 days overall, but TCAR conveyed a lower risk of MI among high-risk patients.
- Key Takeaway: In high-risk patients, TCAR had lower rates of MI than CEA in the first 90 days; in low-risk patients, there was no difference in 90-day composite morbidity between TCAR and CEA.

TCAR vs CEA in VQI – Standard Surgical Risk

Real-world comparison of TCAR vs CEA outcomes in standard surgical risk patients using the VQI TSP.⁵

- Retrospective, propensity-score matched analysis of VQI TSP data.
- Objective: Compare outcomes after TCAR and CEA in standard risk patients
- Results: No statistically significant difference in the risk of 30-day stroke, death, or MI*, and 1-year ipsilateral stroke between TCAR and CEA (3.0% vs 2.6%, P=0.34).
Conclusion: **TCAR and CEA have equivalent risks of 30-day stroke, death, MI*, and 1-year ipsilateral stroke rate in standard risk patients** undergoing carotid revascularization.
- Key Takeaway: TCAR and CEA have similar risks for standard risk patients. This led to FDA approval of TCAR for standard risk patients.
- *MI restricted to in-hospital events only.

TCAR vs CEA in Standard-Risk and Asymptomatic Patients

Multiple studies that include analyses of these populations.^{6,7,11-13}

- Willie-Permor (2025)
 - Retrospective analysis of Vascular Implant Surveillance and Outcomes Network (VISION)
 - 65,009 standard risk patients
 - 30-day mortality rate was 0.41% (TCAR) vs. 0.47% (CEA, p=0.63)
 - 30-day mortality/stroke rate was 1.96% (TCAR) vs. 1.86% (CEA, p=0.68)
 - After adjustment, there were no difference in mortality risks after TCAR or CEA (1-year HR = 1.18, p=0.20; 2-year HR = 1.22, p=0.08; 3-year HR = 1.15, p=0.20)
 - TCAR was associated with lower risk of MI (OR = 0.46, p=0.002) vs. CEA
- Caron, et al. (2025)
 - Retrospective analysis of VQI data (described previously)
 - Among standard risk patients, the analysis utilizing inverse probability weighting found no significant differences in perioperative stroke/death for TCAR vs CEA
- Sakowitz, et al. (2025)
 - Retrospective analysis of Nationwide Readmission Database (described previously)
 - Among “low-risk” patients, TCAR conferred a similar hazard of 90-day composite morbidity (stroke, MI, or death) between TCAR and CEA (HR 0.85, CI 0.72-1.01).
- Columbo, et al. (2022)
 - Retrospective analysis of VQI data from 2016-2021
 - Perioperative stroke/death for asymptomatic patients was 1.2% for TCAR and 1.1% for CEA and the unadjusted odds ratio was not significant, nor was the odds ratio from an instrumental variable analysis of perioperative stroke/death for these two treatments.
 - Additionally, at 1-year, the estimate risk of stroke/death among asymptomatic patients was not significantly different between TCAR and CEA (HR for CEA vs TCAR = 1.04 CI = 0.77-2.80).
- Columbo, et al. (2025)

- Retrospective analysis of Vascular Implant Surveillance and Outcomes Network (VISION) of patients undergoing TCAR or CEA in 2016-2019, and followed for up to 3 years.
- Among asymptomatic patients, the 3-year risk of stroke was similar between TCAR (5.1% CI = 3.0-7.1%) and CEA (4.9% CI = 4.4-5.4%, p=0.93)
- Compared to CEA, the adjusted hazard ratio for 3-year stroke after TCAR was not significant (HR = 1.10 CI = 0.82-1.49)

TCAR vs TF-CAS in VQI

Real-world comparison of TCAR vs TF-CAS outcomes using VQI TSP data.¹⁵

- Propensity-score matched analysis of VQI TSP and Carotid Stent Registry
- Objective: Compare outcomes associated with TCAR vs. TF-CAS
- Results: TCAR had a significantly lower risk of in-hospital stroke or death (1.6% vs 3.1%, P<0.001), stroke (1.3% vs 2.4%, P=0.001), death (0.4% vs 1.0%), P=0.008).
- Conclusion: **TCAR had a significantly lower risk of stroke or death** than TF-CAS, with improved procedural efficiencies (radiation/contrast).
- Key Takeaways: Not all carotid stenting procedures are the same. TCAR addresses the pitfalls of TF-CAS. VQI data consistently shows best-in-class outcomes for TCAR.

TCAR Learning Curve

Learning curve of TCAR surgeons based on data from VQI TSP.¹⁶

- Objective: Examine the TCAR learning curve using VQI TSP data
- Results: 3,456 TCAR procedures were performed by 417 surgeons from 178 centers. Major outcomes were statistically equivalent regardless of experience level, suggesting a short learning curve and no increased risk of inferior outcomes for patients treated by early adopters of TCAR.
- Conclusion: TCAR has excellent stroke and mortality rates, even in the early stages of the learning curve.
- Key Takeaways: **TCAR is safe and effective for surgeons of all experience levels.**

Impact of Age on Outcomes

How age affects outcomes of TCAR, TFCAS, and CEA.¹⁷

- Multi-center, retrospective review of VQI TSP data
- Objective: Comparing the association between age and outcomes after TCAR, TF-CAS, and CEA
- Within TCAR there was no significant difference in in-hospital mortality, stroke, or MI between age groups (≤ 70 , 71 to 79, and ≥ 80 years)
- Among patients aged 80 years and older, those receiving TFCAS had significantly higher rates (compared with those receiving TCAR) of in-hospital mortality (2.5% vs. 0.7%), stroke (4.7% vs. 1.0%), stroke/TIA (5.4% vs. 1.7%), stroke/death (4.6% vs. 1.5%), and stroke/death/MI (5.3% vs. 2.5%), all p-values < 0.01
- In adjusted analyses among those aged 80 years and older, TCAR was associated with significantly lower odds of stroke, stroke/death, and stroke/death/MI versus TFCAS
- Adjusted odds ratios from models using an age-by-treatment interaction show that compared with TCAR, TFCAS is associated with twice the odds of in-hospital stroke at age 85 and double the odds of stroke/death at age 77.
- When comparing outcomes after CEA versus TCAR, there were no significant differences, except for the occurrence of cranial nerve injury, where CEA patients in all three age groups experienced significantly higher rates than TCAR

¹⁵ 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

¹⁶ Kashyap VS, King AH, Liang P, et al. Learning Curve for Surgeons Adopting Transcarotid Artery Revascularization Based on the Vascular Quality Initiative-Transcarotid Artery Revascularization Surveillance Project. *J Am Coll Surg*. 2020;230(1):113-120. doi:10.1016/j.jamcollsurg.2019.09.020

¹⁷ Dakour-Aridi H, Kashyap VS, Wang GJ, Eldrup-Jorgensen J, Schermerhorn ML, Malas MB. The impact of age on in-hospital outcomes after transcarotid artery revascularization, transfemoral carotid artery stenting, and carotid endarterectomy. *J Vasc Surg*. 2020;72(3):931-942.e2. doi:10.1016/j.jvs.2019.11.037

Versus Medical Management in Asymptomatic Patients (CREST-2)

Comparing outcomes of TFCAS and CEA to medical management.¹⁸

- Two parallel, 4-year clinical trials of TFCAS and CEA
- Objective: To determine if adding revascularization to intensive medical management (IMM) would provide greater benefit than IMM alone
- TFCAS was associated with a 3.2% absolute improvement in stroke/death versus IMM alone (6.0% versus 2.8%; while CEA was associated with a non-significant absolute improvement of 1.6%
- Though TCAR was not part of this trial, it uses the same stent technology (Precise stent) as TFCAS, providing indirect evidence for TCAR's potential efficacy.
- Key Takeaway: **CREST-2 shows the value of repair and long-term durability of carotid stenting.**

Reimbursement Support

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

- Email: SRM-Reimburse@bsci.com
- Website: [Peripheral Vascular - Reimbursement - Boston Scientific](#)

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

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¹⁸ Brott TG, Howard G, Lal BK, et al. Medical Management and Revascularization for Asymptomatic Carotid Stenosis. N Engl J Med. Published online 2025. Doi:10.1056/nejmoa2508800.