

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.

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| 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. | <ul style="list-style-type: none">• 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 have 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
 - **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 and almost always go home the next day³ to return to full and productive lives with less pain and smaller scars.^{6,7}

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.”*

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

⁷ TCAR Patient Stories | Carotid Disease Treatment Successes. Silk Road Medical | Global website. <https://silkroadmed.com/healthcare-professionals/patient-stories/>

Discuss the clinical benefits and goals of TCAR for your patient.³⁻⁷

- 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
- 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 transcatheter stenting and have previous experience with the transcatheter 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).
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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® Transcatheter Stent System in a diverse user group with varying levels of TCAR experience.⁸

- Prospective, multi-center trial that included 692 patients at 43 sites
- Objective: Evaluate **real world use** of the ENROUTE Transcatheter 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 comparison of TCAR vs CEA outcomes using Vascular Quality Initiative (VQI) TCAR Surveillance Project (TSP) data.³

- 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).

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⁸ Kashyap VS, Schneider PA, Foteh M, et al. Early Outcomes in the ROADSTER 2 Study of Transcatheter Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020;51(9):2620-2629. doi:10.1161/STROKEAHA.120.030550

TCAR vs CEA in VQI – High Surgical Risk
continued

- 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.

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 TF-CAS in VQI
Real-world comparison of TCAR vs TF-CAS outcomes using VQI TSP data.⁹

- 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.¹⁰

- 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.¹¹

- Multi-center, retrospective review of VQI TSP data
- Objective: Comparing the association between age and outcomes after TCAR, TF-CAS, and CEA

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⁹ 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

¹⁰ 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

¹¹ 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

Impact of Age on Outcomes

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- Results: TCAR had equivalent stroke and death rates to CEA and significantly lower CNI rates across all age groups. In patients ≥ 80 years of age, TCAR had a 72% lower risk of stroke, 65% lower risk of stroke/death, and 76% lower risk of stroke/death/MI than TF-CAS.
 - Conclusions: **TCAR is a safe procedure regardless of age**, with advantages over TF-CAS in elderly patients who are at high surgical risk. TCAR had statistically equivalent outcomes to CEA regardless of age, with significantly lower CNI rates.
 - Key Takeaway: TCAR is a safe procedure for patients of all ages.
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Reimbursement Support

For reimbursement assistance, please contact Silk Road Medical's Reimbursement team:

- Email: reimbursement@silkroadmed.com
- Phone: (855) 410-8227, Option #5
- Website: <https://tcar.at/reimbursement>



Scan or click the QR code to access our website and reimbursement resources or visit us at: <https://tcar.at/reimbursement>.

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