TCAR Frequently Asked Questions

Q: WHAT IS THE TCAR REGISTRY?

A: There is no specific standalone TCAR registry. Entry of TCAR procedures is included in the VQI Carotid Artery Stent (CAS) registry. The VQI CAS registry includes all carotid artery stent procedures regardless of the approach. The registry offers multiple approaches for carotid artery stenting including TCAR, Femoral, Brachial, Radial...

Q: WHAT IS THE NCT NUMBER FOR THE VQI - TCAR SURVEILLANCE PROJECT (TSP)?

A: NCT02850588

Q: WHAT ARE THE VQI PARTICIPATION REQUIREMENTS?

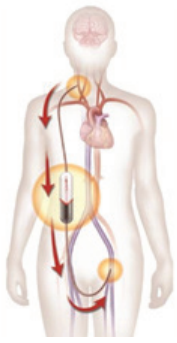
A: There are two contracts plus appropriate Business Associate Agreements (BAAs), one with the SVS PSO and one with Fivos, for the Fivos PATHWAYS database management services. All contracting is facilitated through Fivos, and both agreements are required in order to participate in the VQI registries. For the VQI CAS and CEA registries, a participating physician must enter all of their TCAR, CAS and CEA cases. The VQI requires participating sites to submit claims data verifying that all cases have been submitted to the VQI. Centers and physicians may choose to participate in the TCAR/CAS, CEA or both registries.

Q: HOW DOES THE TSP WORK?

A: Like the other surgical and endovascular procedures tracked by the Society for Vascular Surgery Vascular Quality Initiative (VQI), procedural and outcomes data from TCAR procedures will be input via a web-based electronic data capture system that is provided by Fivos. TCAR data will be entered into the Carotid Artery Stenting registry of the VQI. Carotid endarterectomy (CEA) procedures entered into the VQI CEA registry will be compared with TCAR procedure outcomes.

Q: WHAT IS A TRANSCAROTID APPROACH?

A: A Transcarotid approach includes both arterial and venous access. A small incision is made at the base of the neck for direct carotid visualization where a direct puncture of the carotid artery is made, and a sheath is placed. A venous sheath is placed in either the right or left femoral vein. During the TCAR procedure, the surgical team reverses blood flow in the area of the blockage. The approach utilizes a system that temporarily reverses blood flow away from the brain, collecting any potential debris in the device filter, before returning the blood to a vessel in the leg. With reverse flow neuroprotection established, a stent is then implanted in the lesion for long term plaque stabilization and stroke prevention.



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Q: HOW WILL I KNOW IF THE PROCEDURE IS BILLED USING THE CLINICAL TRIAL NUMBER?

A: Centers will need to work with their billing departments to make sure that all Medicare/Medicare Advantage TCAR procedures are billed including the clinical trial number NCT02850588.

Q: WHAT IS THE ADVANTAGE OF ENTERING TCAR PATIENTS INTO THE VQI CAS REGISTRY?

A: The decision states that facilities enrolled in a CMS-approved national CAS registry, which includes centers entering CAS data as part of The Society for Vascular Surgery® Vascular Quality Initiative® (SVS VQI) Transcarotid Revascularization Surveillance Project (TSP), "will automatically meet the data collection standards required for initial and continued facility certification."

- What does this mean? TSP participation alleviates select mandates within the ruling, such as the neurological assessment requirements and Shared Decision Making (SDM). Specifically, SDM will not be required for TSP participants (though it is recommended–and facilitated through VQI's CAS registry–as it remains best practice). Sites should continue to include the National Clinical Trial (NCT) identifier, NCT02850588, on Medicare claims to document their participation in the study.

See B3 VQI-TSP below.

Medicare NCD 20.7 – Final Decision Memo

TCAR continues to be covered under the National Coverage Determination (NCD 20.7) for Percutaneous Transluminal Angioplasty (PTA), according to these indications[1]:

- B3 – Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies (e.g., Vascular Quality Initiative TCAR Surveillance Project or VQI-TSP)
- B4 – Concurrent with Carotid Stent Placement

Indications	B3. VQI-TSP* (No change)	B4. Carotid Stent Placement (Updated 10/11/2023)	B4. Carotid Stent Placement (Original thru 10/10/2023)
Clinical Criteria			
Surgical Risk Factor	• Standard Risk & High Risk		• High Risk
Symptom Status & Degree of Stenosis	• Symptomatic & ≥50% stenosis** • Asymptomatic & ≥70% stenosis**		• Symptomatic & ≥70% stenosis
Additional Criteria			
Facility Requirements	• Facility standards and approval	• Facility and physician standards for carotid stent program	• CMS facility approval and certification
Registry or Data Collection	• Registry participation (VQI-TSP)	• Not required for coverage	• Data collection
Neurological Assessments	• Not specified	• Pre & post-op neurological assessments by a neurologist or NIHSS certified HCP	• Not specified
Imaging Guidelines	• Not specified	• Duplex US and CTA/MRA or • Duplex US and DSA when non-invasive imaging is inconclusive or CTA/MRA are contraindicated	• Not specified
Shared Decision Making	• Not specified	• Shared decision-making with patients about CEA, CAS (including TCAR), and OMT before treatment	• Not specified

*Medicare coverage for VQI TSP is based on the study protocol (clinicaltrials.gov (NCT02850588)). **Stenosis requirements vary depending on the diagnostic imaging type (angiogram or ultrasound), surgical risk factor, and symptomatic status. Definitions: CAS – Carotid Artery Stenting, CEA – Carotid Endarterectomy, CTA – Computed Tomography Angiography, DSA – Digital Subtraction Angiography, HCP – Healthcare Professional, MRA – Magnetic Resonance Angiography, NIHSS – National Institutes of Health Stroke Scale, OMT – Optimal Medical Therapy, US – Ultrasound

Disclaimer: This is a high-level summary of the final decision memo. Please refer to the ENROUTE® Transcarotid Stent and Neuroprotection Systems Instructions For Use (IFU) for detailed indications, contraindications, warnings, and precautions. Visit the CMS webpage for the final decision memo: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=311.

[1] NCD - Percutaneous Transluminal Angioplasty (PTA) (20.7). Cms.gov. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=201

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If you have any additional questions regarding TCAR Medicare coverage please contact the Silk Road Medical Team by email at reimbursement@silkroadmed.com or visit their website.

Q: UNDER WHAT CIRCUMSTANCES ARE THE NEW NCD20.4 REQUIREMENTS ENFORCED?

A:
1. All carotid stent approaches including but not limited to: Femoral, brachial, radial, open and percutaneous carotid approach not using a flow reversal protection device.
2. TCAR procedures not entered in the VQI CAS Registry.

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Q: WHAT MUST BE INCLUDED IN A SHARED DECISION-MAKING DISCUSSION IF TSP PATHWAY B3 IS NOT FOLLOWED?

DISCLAIMER: SVS PSO recognizes that following the TSP pathway does not require a shared decision discussion, a SDM discussion is considered best practice.

A: Components of a Shared Decision Discussion:

a. Discussion of all treatment options including carotid endarterectomy (CEA), CAS (which includes Transcarotid artery revascularization (TCAR), and optimal medical therapy (OMT).
b. Explanation of risks and benefits for each option specific to the beneficiary's clinical situation.
c. Integration of clinical guidelines (e.g., patient comorbidities and concomitant treatments).
d. Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Q: WHAT DOES VQI MEMBERSHIP TO THE CAS REGISTRY PROVIDE?

A: VQI remains the premiere tool for centers to develop and maintain a dedicated carotid stent program for the safety of their patients, regardless of whether a center decides to join the TSP. Even with the changes resulting from NCD 20.7, you still need to collect data, track outcomes, and establish a quality improvement program. VQI participation offers centers…

- Ability to track provider and center performance and compare to national benchmarks. Identification of areas for quality improvement and addressing length of stay.
- Robust Quality Improvement program, including quality improvement toolkits, quality charters, webinars, and one-on-one mentoring for members.
- Networking opportunities, including regional and national meetings, for participating centers to review outcomes data, foster collaboration, and spark innovation.

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Q: WHO DO I CONTACT IF I AM INTERESTED IN PARTICIPATING?

A: To sign up for the VQI or for the TSP, contact vqi@fivoshealth.com or call (603) 298-5509.

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