
Update: NCD 20.7

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Caroline Morgan, RN

Director Clinical Operation SVS SPO

NCD 20.7 Paths

NCD 20.7: Pick Your Path to Compliance and Quality Care



In October 2023, the Centers for Medicare & Medicaid Services (CMS) released their final NCD 20.7, which pertains to coverage for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting.

While the [final CMS determination](#) was that participation in a registry is not mandated for coverage, CMS made it clear in the ruling that centers **must** establish and maintain institutional and physician standards to support a dedicated carotid stent program—and registry participation remains the most fitting route to do so. **Here's how you can rely on the The Society for Vascular Surgery® Vascular Quality Initiative® (SVS VQI) to satisfy CMS requirements and maintain your commitment to quality care for your vascular patients...**

PATH A VQI TSP PARTICIPATION (THE DIRECT ROUTE)

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.

PATH B VQI MEMBERSHIP

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

In this time of change, one thing remains certain: it has become more imperative than ever to monitor and maintain quality across your *full* carotid program. We're ready to be your guide. Learn more about your options [here](#) or reach out to us at vqi@fivoshealth.com.

CONTACT US TO LEARN MORE > www.vqi.org



Society for Vascular Surgery



American Venous Forum



Society for Vascular Medicine



SVU

SVS VQI Transcarotid Revascularization Surveillance Project (VQI- TCAR)

The VQI TCAR Surveillance Project (VQI TSP)

- Designed to monitor safety & effectiveness of stents placed directly into the carotid artery while reversing blood flow within the carotid artery to reduce stroke risk
 - Compare this less-invasive surgical procedure with standard carotid endarterectomy in centers that participate in the SVS VQI
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- Started 11/2016
 - Estimated Completion 12/2026 Procedure with LTFU completion 2027
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- Clinical Trials Number = NCT02850588

RECRUITING ⓘ

SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR)

ClinicalTrials.gov ID ⓘ NCT02850588

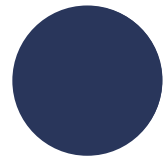
Sponsor ⓘ Society for Vascular Surgery Patient Safety Organization

Information provided by ⓘ Society for Vascular Surgery Patient Safety Organization (Responsible Party)

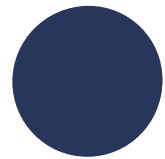
Last Update Posted ⓘ 2022-10-07

<https://clinicaltrials.gov/study/NCT02850588>

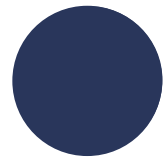
VQI TCAR Surveillance Project (VQI TSP)



Data entry into VQI CAS Registry



Billing using the Clinical Trails Number
- NCT02850588



Any FDA-cleared proximal embolic protection device and FDA-approved carotid artery stent system indicated for the Transcarotid approach will be included in the registry.

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:

- 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 10/11/2023)
Clinical Criteria			
Surgical Risk Factor	<ul style="list-style-type: none"> • Standard Risk & High Risk 		<ul style="list-style-type: none"> • High Risk
Symptom Status & Degree of Stenosis	<ul style="list-style-type: none"> • Symptomatic & ≥50% stenosis** • Asymptomatic & ≥70% stenosis** 		<ul style="list-style-type: none"> • Symptomatic
Additional Criteria			
Facility Requirements	<ul style="list-style-type: none"> • Facility standards and approval 	<ul style="list-style-type: none"> • Facility and physician standards for carotid stent program 	<ul style="list-style-type: none"> • CMS facility accreditation
Registry or Data Collection	<ul style="list-style-type: none"> • Registry participation (VQI-TSP) 	<ul style="list-style-type: none"> • Not required for coverage 	<ul style="list-style-type: none"> • Data collection
Neurological Assessments	<ul style="list-style-type: none"> • Not specified 	<ul style="list-style-type: none"> • Pre & post-op neurological assessments by a neurologist or NIHSS certified HCP 	<ul style="list-style-type: none"> • Not specified
Imaging Guidelines	<ul style="list-style-type: none"> • Not specified 	<ul style="list-style-type: none"> • Duplex US and CTA/MRA or • Duplex US and DSA when non-invasive imaging is inconclusive or CTA/MRA are contraindicated 	<ul style="list-style-type: none"> • Not specified
Shared Decision Making	<ul style="list-style-type: none"> • Not specified 	<ul style="list-style-type: none"> • Shared decision-making with patients about CEA, CAS (including TCAR), and OMT before treatment 	<ul style="list-style-type: none"> • Not specified

*Medicare coverage for VQI TSP is based on the study protocol ([clinicaltrials.gov \(NCT02850588\)](https://clinicaltrials.gov/ct2/show/study/NCT02850588)). **Stenosis requirements vary depending on the diagnostic imaging type (angiogram or ultrasound), surgical risk factor, and symptom 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, 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>

Shared Decision Making

As mandated by CMS, the shared decision-making interaction should include:

1. Discussion of all treatment options for carotid stenosis to ensure the patient is familiar with and aware of all treatment options. Including Carotid Endarterectomy and endovascular Carotid Artery Stenting (Transfemoral and TCAR) and optimal medical therapy
2. Explanation of risks and benefits for each option specific to the beneficiary's clinical condition.
3. Integration of clinical guidelines (e.g., patient comorbidities and concomitant treatments).
4. Discussion and incorporation of the patient's personal preferences and priorities in choosing a treatment plan.

Shared Decision Making Documented Interaction

No

Yes

The SDM interaction/discussion can be provided at an office/clinic visit, telehealth visit, or at the bedside, but must be documented in the medical record. All interactions/discussions should occur prior to entering the preoperative area or initiation of any anesthesia. SDM documentation is in addition to and does not replace informed patient consent.

CMS Final Coverage Determination Document link

- <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=311>

For questions related to the CAS NCD, please contact

- Sarah Fulton at sarah.fulton@cms.hhs.gov

Thank You
