

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 indications¹:

- 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) NCT02850588	B4. Carotid Stent Placement (Updated 10/11/2023)	B4. Carotid Stent Placement (Original thru 10/10/2023)
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 & ≥70% stenosis
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 approval and certification
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 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/nca.aspx?NCDId=201>