



The Society for Cardiovascular Angiography and Interventions (SCAI) has dedicated its work to advancing the profession and is the designated society for guidance, representation, professional recognition, education, and research opportunities for invasive and interventional cardiology professionals. For more than forty years, SCAI has personified professional excellence and innovation globally, fostering a trusted community of more than 5000 members dedicated to medical advancement and lifesaving care for adults and children with cardiovascular disease. This includes interventional cardiologists with expertise in carotid artery disease that is treated with optimized medical therapy, and when appropriate to reduce risk, carotid artery stenting (CAS).

Such comprehensive management of atherosclerotic vascular disease has become standard practice in contemporary cardiovascular medicine and interventional cardiology fellowship training programs, and CAS is an integral part of the therapeutic armamentarium. SCAI promotes excellence in invasive and interventional cardiovascular medicine through education, advocacy, and the advancement of quality standards to enhance patient care. For that reason, we have a strong interest in ensuring that Medicare coverage policy for CAS aligns with the available and voluminous data and the current state of technology for the management of atherosclerotic bifurcation carotid artery disease.

SCAI strongly supports updating NCD 20.7 to broaden Medicare beneficiary access to PTA and CAS and to remove facility and operator requirements consistent with the current state of the published literature and standard clinical practice. The current CAS NCD was last reconsidered in 2009 and does not reflect the significant advances that have occurred. Consequently, the current coverage is limiting access for many patients who would potentially benefit from CAS. The limitation forces some patients into higher-risk surgical procedures and negatively impacts clinical outcomes.

Since the decision was made by the Centers for Medicare & Medicaid Services (CMS) to restrict the NCD for CAS in 2009, randomized clinical trials (RCTs) including the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST), Asymptomatic Carotid Trial (ACT-1), Stent Protected Angioplasty versus Carotid Endarterectomy-2 (SPACE-2) trial, and Asymptomatic Carotid Surgery Trial-2 (ACST-2); all have demonstrated comparable outcomes for periprocedural complications (stroke, death, and MI), reduction in long-term stroke risk, and durability of CAS in comparison to carotid endarterectomy (CEA)^{1,2,3,4}. Furthermore, advances in carotid artery stenting strategies including better patient selection, refined techniques, and improving technology have resulted in steady improvement in peri-procedural outcomes during last 20 years⁹. We believe that the patient selection criteria in the NCD should reflect the recent data supporting the efficacy and safety of CAS in standard surgical risk patients and revise the patient selection criteria for PTA and CAS with embolic protection to cover patients who have asymptomatic carotid artery stenosis $\geq 70\%$ and symptomatic carotid artery stenosis $\geq 50\%$. CAS is no longer a novel procedure but now has become a widely performed procedure with robust clinical evidence to support widening the coverage by CMS.

In addition, the restrictive coverage requirements by the CMS including minimum standards for facility are not relevant in modern era given the increasing experiences with CAS across the country and growing evidence supporting the safety of the procedure⁹. Like other established procedures, medical societies have developed guidelines/recommendations for monitoring facility and operator requirements for local facilities. Recently, SCAI and the Society of Vascular Medicine (SVM) have published a multidisciplinary expert consensus statement on physician training and credentialing guidance along with encouraging data collection on quality metrics.

Institutions that perform CAS should be encouraged to have regular participation in peer review processes, such as patient safety or quality improvement conferences, random case review, and quality registries, but these should not be mandatory. Furthermore, CAS is now an established procedure, and data collection for coverage of CAS by CMS is no longer applicable. Monitoring the quality metrics with CAS should be managed at societal and local level given that the institutional participation in a quality assurance registry is already encouraged and facilities already handle quality assurance at the institutional level. Therefore, credentialing for CAS should be addressed at each individual facility, similar to other invasive procedures (eg, percutaneous coronary interventions) and not be part of the determination for CMS coverage.

We look forward to working with you to expand Medicare beneficiary access to this widely performed procedure that has well-established safety and health outcomes. Let us know if you have any questions or comments on our recommendation. Feel free to contact Monica Wright at mlwright@scai.org or 202-327-5451. Thank you for your time and consideration.

References:

1. Rosenfield K, Matsumura JS, Chaturvedi S, Riles T, Ansel GM, Metzger DC, Wechsler L, Jaff MR, Gray W and Investigators AI. Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis. *N Engl J Med*. 2016;374:1011-20.
2. Matsumura JS et al KR, Bret Hanlon, Jenifer Voeks, George Howard, Gary Roubin, Thomas Brott on behalf of the ACT I and CREST Investigators Treatment of Carotid Stenosis in Asymptomatic, Non-Octogenarian, Standard Risk Patients with Stenting versus Endarterectomy: A Pooled Analysis of the CREST and ACT I Trials *Journal of Vascular Surgery*. 2021.
3. Reiff T, Eckstein HH, Mansmann U, Jansen O, Fraedrich G, Mudra H, Bockler D, Bohm M, Bruckmann H, Debus ES, Fiehler J, Lang W, Mathias K, Ringelstein EB, Schmidli J, Stingele R, Zahn R, Zeller T, Hetzel A, Bodechtel U, Binder A, Glahn J, Hacke W and Ringleb PA. Angioplasty in asymptomatic carotid artery stenosis vs.endarterectomy compared to best medical treatment: One-year interim results of SPACE-2. *Int J Stroke*. 2019:1747493019833017.
4. Halliday A, Bulbulia R, Bonati LH, Chester J, Craddock-Bamford A, Peto R, Pan H and Group A-C. Second asymptomatic carotid surgery trial (ACST-2): a randomised comparison of carotid artery stenting versus carotid endarterectomy. *Lancet*. 2021:1065-73.
5. Silver FL, Mackey A, Clark WM, Brooks W, Timaran CH, Chiu D, Goldstein LB, Meschia JF, Ferguson RD, Moore WS, Howard G, Brott TG and Investigators C. Safety of stenting and endarterectomy by symptomatic status in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST). *Stroke*. 2011;42:675-80.
6. Aronow HD, Collins TJ, Gray WA et al. SCAI/SVM expert consensus statement on carotid stenting: Training and credentialing for carotid stenting. *Catheter Cardiovasc Interv* 2016;87:188-99.
7. Yadav JS, Wholey MH, et al. Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Investigators. Protected carotid-artery stenting versus endarterectomy in high-risk patients. *N Engl J Med*. 2004; 351:1493–1501.
8. Brott TG, Hobson RW 2nd, Howard G, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med*. 2010;363(1):11–23.
9. White CJ, Brott TG, Gray WA, et al. Carotid Artery Stenting: JACC State-of-the-Art Review. *J Am Coll Cardiol*. 2022 Jul 12;80(2):155-170.