August 9, 2023

SUMMITTED ELECTRONICALLY

RE: Comment on Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R8)

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 40 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.

SCAI has 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 (CAD). SCAI appreciates the opportunity to comment on this national coverage determination.

SCAI strongly supports the analysis by CMS in the proposed decision memo and the conclusion to expand coverage to include patients at standard surgical risk, patients with symptomatic carotid artery stenosis of at least 50%, and patients with asymptomatic carotid artery stenosis of at least 70%. SCAI confirms that no specific physician, care team, or facility requirements are needed as standards adequately exist in our societal guidelines and outcomes at local facilities can be audited or reviewed by appropriate entities, just as those requirements are managed for other well-established procedures.

SCAI supports the proposal that the treating provider has primary responsibility for care management. Requiring a patient to see multiple physician specialists as a condition for coverage could delay or limit patient access and may be unavailable in certain regions thus limiting care access to vulnerable patients if made mandatory. All qualified treating physicians, regardless of specialty, are well-versed in providing patients with up-to-date information and personalized advice on all treatment options and their associated risks and benefits even if they do not personally offer all possible treatment options. This practice and level of physician education is true of all established areas of medicine with multiple treatment options and is commonly performed by the SCAI membership in discussions of endovascular PCI versus surgical CABG revascularization.

While SCAI supports the continued advancement of care through clinical research, SCAI concurs with no requirement for participation in a national registry as a condition for coverage. Clinical equipoise between CAS and carotid endarterectomy (CEA) has been supported by 4 RCTs reported since 2010, consistently demonstrating equivalence in procedural outcomes, long-term stroke prevention, and durability. Each hospital system locally monitors its outcomes through quality assurance and peer-review processes. To limit patient access to carotid stenting to those centers participating in national registries could prevent availability of care expansion to patients located in care deserts where treatment access and systems of care require the most development.

Diagnostic Imaging

Regarding diagnostic imaging, SCAI recommends some modifications to the language in the proposal to reflect the current standard of care and its continued advancement over time. Additional magnetic resonance angiography (MRA) and computed tomography angiography (CTA) imaging may be clinically contraindicated in clinical scenarios including in the presence of chronic renal failure or in patients with implants that are not MRI-conditional. Intra-arterial digital subtraction (catheter) angiography is not recommended for first-line imaging, but it can be useful for further imaging of carotid stenosis when there is (1) significant discrepancy between non-invasive imaging results,

(2) clinical contraindications to non-invasive imaging, or (3) when additional information can be provided to inform optimal patient care. With advances in technology and techniques, physicians can now perform selective angiography with an exceptionally low risk of complications compared to previous approaches.

Shared Decision Making

SCAI supports a shared decision-making (SDM) interaction with all patients and concurs with the four core elements outlined by CMS:

- Discussion of all treatment options for carotid stenosis to ensure the beneficiary is familiar with and aware of all treatment options.
- Explanation of risks and benefits for each option specific to the beneficiary's clinical condition.
- Integration of clinical guidelines (e.g., patient life-expectancy).
- Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Patient awareness of all treatment options and their risks and benefits and consideration of patient personal preference are key to informing appropriate patient selection and achieving optimal outcomes for patients and their families. SCAI recommends the patient specific SDM interaction be documented in the medical record by the treating physician as an alternative to requiring use of a validated SDM tool. A validated SDM tool does not exist currently for patients considering any intervention for carotid artery stenosis. Development of such a tool would be a multi-year process and must evolve with advances in clinical evidence and standard of care. If CMS were to require use of a validated tool, the NCD would have no effect on coverage until such a tool could be developed.

In other national coverage analyses, such as the analyses of Artificial Hearts and Related Devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N), Transcatheter Mitral Valve Repair (CAG-00438R), and Transcatheter Aortic Valve Replacement (CAG-00430R), CMS has recognized the value of SDM but not required use of a specific tool when no validated tool existed at the time of the coverage determination. CMS should apply the same reasoning to this proposed decision. Requirement of a validated tool for coverage would significantly delay or deny patient access to treatment.

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. Thank you for your consideration, and should you have any questions or need more information, please contact SCAI's director, regulatory affairs Monica Wright at mlwright@scai.org.

Sincerely,

George Dangas, MD, PhD, MSCAI
President