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August 3, 2023

Tamara Syrek Jensen, Director
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Coverage and Analysis Group
Centers for Medicare & Medicaid Services
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Baltimore, MD 21244

**RE: Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R8)**

Ms. Syrek Jensen and Dr. Chin,

The Society of Vascular and Interventional Neurology (SVIN) aims to advance vascular and interventional neurology to improve clinical outcomes of stroke and cerebrovascular disorders, including patients with carotid artery disease (CAD). For that reason, we have a keen interest in ensuring that the Medicare coverage policy for carotid artery stenting (CAS) aligns with the extensive available data and the current state of technology for the management of CAD. The Centers for Medicare & Medicaid Services' (CMS) Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting ("Proposed Decision Memo")[1] does just that, and we strongly urge CMS to finalize it. Below we respond to CMS's request for comments on its draft.

First, we enthusiastically support CMS's proposal to expand coverage to patients at standard surgical risk, patients with symptomatic carotid artery stenosis ≥50%, and patients with asymptomatic carotid artery stenosis of ≥70%, without further evidence development. As discussed in our February 2, 2023, comment letter with regards to the Request for Reconsideration of National Coverage Determination (NCD) 20.7, a deep bench of randomized clinical trials and other scientific literature supports coverage for these patients, and we are heartened that CMS has accepted our recommendation. We also support permitting Medicare Administrative Contractors (MACs) to make coverage determinations for patients who fall outside these parameters.

Second, as also discussed in our prior letter, we support the proposal to remove the operator and facility requirements for CAS. We agree that is best handled through hospital credentialing, medical society guidelines, and accreditation standards.

Third, we are writing to respond to CMS's request for comments on whether the shared decision-making (SDM) process described in the Proposed Decision Memo

[1] Proposed Decision Memo, Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R8), July 11, 2013, https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&ncaid=311

should require the use of a validated shared decision-making tool and/or if there are other options to achieve the goal of truly informed decision-making. As noted by CMS, no such tool currently exists. Therefore, it is our view that a robust and individualized SDM interaction that is documented in the patient's medical record can provide an adequate substitute for a validated SDM tool.

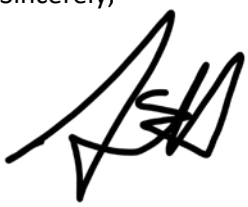
We agree with CMS that providers should document that their SDM conversation includes at least the following:

- Discussion of all treatment options for carotid stenosis to ensure the beneficiary is familiar with and aware of all treatment options including, but not limited to, procedures that fall within the parameters of this NCD.
- 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.

As described in the Proposed Decision Memo, an expanded body of clinical evidence now supports the equipoise between carotid endarterectomy (CEA) and CAS and therefore broader patient selection for CAS reimbursement. Waiting for the development of a validated SDM tool would delay patient access to their choice of an alternative treatment for carotid artery disease and, in so doing, undermine the very support for informed patient decision-making that CMS seeks to promote. CMS could promote development of a validated SDM tool by noting that, if and when such tool is developed, the tool can be used to comply with the documentation requirements.

We thank CMS for this opportunity to express our views. We continue to support CMS's rigorous consideration of the evidence and thoughtful expansion of coverage for CAS where the clinical evidence so warrants. We encourage CMS, after it considers the comments submitted, to largely finalize its excellent proposed draft.

Sincerely,



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