

February 9, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

On behalf of the Society for Vascular Surgery (SVS), we appreciate the opportunity for engagement and stakeholder comment regarding the request to the Centers for Medicare & Medicaid Services (CMS) for reconsideration of the [National Coverage Determination \(NCD\) 20.7](#). As you are aware, the SVS is a professional medical specialty society composed primarily of vascular surgeons, that seeks to advance excellence and innovation in vascular health through education, advocacy, research, and public awareness.

CMS is currently reconsidering NCD 20.7 and is soliciting public comments regarding coverage for PTA concurrent with CAS including transcrotid artery revascularization (TCAR) procedures. Under the current NCD 20.7 for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting, Section B4 covers PTA of the carotid artery concurrent with the placement of a Food and Drug Administration (FDA) approved carotid stent with embolic protection for:

- Patients at high risk for carotid endarterectomy (CEA) with symptomatic carotid artery stenosis $\geq 70\%$
- Patients at high risk for CEA with symptomatic carotid artery stenosis between 50 and 70% in accordance with the Category B Investigational Device Exemption (IDE) clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (NCD 310.1), or in accordance with the NCD on carotid artery stenting (CAS) post-approval studies (NCD 20.7, B3)
- Patients at high risk for CEA with asymptomatic carotid artery stenosis $\geq 80\%$ in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (NCD 310.1), or in accordance with the NCD on CAS post-approval studies (NCD 20.7, B3)

As CMS begins the process for potential reconsideration of NCD 20.7, the SVS respectfully offers the following comments.

The SVS published its current clinical practice guidelines for management of extracranial cerebrovascular disease in January 2022.¹ These recommendations guide the management of extracranial carotid disease among vascular surgery providers.

¹ [AbuRahma et al. SVS clinical practice guidelines for management of extracranial cerebrovascular disease. JVS. 75\(1S\): 4S-22 S. Jan 2022](#)

The SVS does not recommend any change in the current policy.

SVS recommends MAC discretion for CAS procedure not described in the NCD. Such flexibility allows providers the ability to use their best independent medical judgment to determine the appropriateness of specific interventions tailored to the needs of individual beneficiaries.

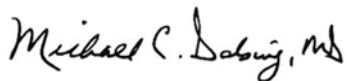
SVS supports continued CMS standards to which facilities must comply in order to perform CAS procedures. Section B4 of the NCD includes standards that facilities must meet and requires facilities to be approved by CMS and recertify every two years to perform CAS procedures. These requirements involved data submissions to CMS, however in 2017 CMS placed a moratorium on the data submission requirement.

In addition, the SVS stresses the importance of thorough analysis relating to patient safety and the downstream impacts of the proposed NCD reconsideration. The procedures covered within NCD 20.7 are not without significant risk for patients, even when provided by a highly experienced vascular surgeon. If CMS moves forward with this reconsideration, we strongly encourage an emphasis on the collection of real-time data, paired with the continuation of the credentialing process and requirements for reporting standards. These elements are critical for ensuring a high degree of patient safety.

Again, the SVS appreciates the opportunity to comment on CMS' potential reconsideration of NCD 20.7. We also note the importance of comments submitted by the SVS-affiliated Vascular Quality Initiative (VQI). The mission of the VQI is to improve the quality, safety, effectiveness and cost of vascular healthcare by collecting and exchanging information.

If you have questions regarding these comments, please contact the SVS' Director of Advocacy, Megan Marcinko, at mmarcinko@vascularsociety.org.

Sincerely,



Michael C. Dalsing, MD MBA
President, SVS



Matthew J. Sideman, MD
Chair, SVS Advocacy Council

cc: Ken Slaw