

August 4, 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

**Re: Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting; CAG-00085R8**

Dear Administrator Brooks-LaSure:

The Society for Vascular Surgery (SVS), 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, in collaboration with its Patient Safety Organization (PSO) Vascular Quality Initiative (VQI), offer the following comments regarding CMS' proposed decision memo for NCD 20.7, Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting. For the sake of clarity, we will distinguish percutaneous transfemoral carotid artery stenting (TF-CAS), where a catheter is inserted percutaneously through a groin artery and uses a cerebral protection device, from trans-carotid artery revascularization (TCAR), which requires a small neck incision followed by carotid stenting with reversal of flow in the carotid artery.

Currently the Centers for Medicare & Medicaid Services (CMS) has a [National Coverage Determination \(NCD 20.7\)](#) for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting (specifically TF-CAS). Section B4 of the NCD 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)

On July 11, CMS released a proposed decision memo regarding its reconsideration of NCD20.7, which included the following adjustments in coverage for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting:

- Expanding coverage to individuals previously only eligible for coverage in clinical trials;
- Expanding coverage to standard surgical risk individuals by removing the limitation of coverage to only high surgical risk individuals;
- Removing facility standards and approval requirements;
- Adding formal shared decision-making with the individual prior to furnishing CAS; and
- Allowing MAC discretion for all other coverage of PTA of the carotid artery concurrent with stenting not otherwise addressed in NCD 20.7.

The SVS and its affiliated PSO remain concerned with the expansion of coverage outlined in CMS' Proposed Decision Memo regarding NCD 20.7. We respectfully submit the following comments for consideration in advance of issuing a final decision memorandum.

#### Proposed Coverage Expansion Will Negatively Impact Patient Safety

Based on data from 100% fee-for-service Medicare claims, carotid artery stenosis is prevalent in approximately 6.6% of Medicare beneficiaries, equivalent to 36 million people. Only a fraction of people with carotid artery stenosis undergo carotid revascularization; in 2022, 23,667 carotid endarterectomy (CEA) and 12,691 carotid artery stenting (CAS) procedures were performed.

Based on data for all Medicare fee-for-service beneficiaries undergoing carotid artery revascularization between 2016 and 2022, the risk of perioperative stroke is significantly higher for CAS compared to CEA (3.4% vs. 2.7%,  $P < 0.001$ ). After a median follow-up time of 3.3 years, CAS is associated with a 15% higher risk of stroke compared to CEA (HR 1.15, 95% CI 1.11, 1.18).

#### Premature Decision; Prior to CREST-2

The CREST-2 trial (NCT02089217) is still underway and represents a major investment by NINDS. Its information should provide improved Level 1 evidence to support treatment of asymptomatic carotid artery disease or management with optimal medical therapy (OMT). It would seem to be premature to expand the use of carotid artery stenting until this randomized trial comparing three treatment arms has reported its results.

#### Impact to the Elderly Patient Population

Multiple studies have demonstrated inferior outcomes with TF-CAS in elderly patients. The CREST lead-in study noted this and subsequently restricted use of CAS in the CREST RCT to those under age 80 (PMID 15622363). This was noted in other series as well including CAPTURE-2 (PMID 21349464). In the CREST RCT itself age was noted to have a significant impact on outcomes with stroke or death being significantly higher after TF-CAS compared to CEA for those above age 73. This should be

concerning for CMS as most beneficiaries with carotid stenosis would therefore be expected to have better outcomes with CEA than TF-CAS.

The previous requirements for a local credentialing committee, outcome review, and submission to CMS or to a national registry likely led to improved patient selection and outcomes. Doing away with the requirements for outcome reporting will likely do a disservice to all Medicare beneficiaries as well as those with other insurance. We may never know the full extent of this disservice without collecting the data.

### Learning Curve

NCD 20.7 removes relevant facility standards and approval requirements. However, TF-CAS procedures should be performed by a qualified physician. A qualified physician is a physician with demonstrated competency in TF-CAS and who has staff privileges to perform these interventions in a hospital that participates in the Medicare program. The removal of these requirements creates a misalignment in relation to standards included in other coverage decisions.

Multiple analyses have demonstrated a substantial and lengthy learning curve for TF-CAS (PMID: 11747955, 17050898, 21954477). Early RCTs were criticized for not having rigorous training/experience requirements for interventionalists. Alternatively, CREST only allowed interventionalists who submitted case reports and discharge summaries for 10-30 patients and then had to go through a lead-in phase where outcomes were not included and were only allowed to participate following satisfactory completion of the lead-in phase. ACT 1 similarly had rigorous requirements for experience and demonstration of appropriate outcomes in recognition of the learning curve. All studies that have analyzed the learning curve for TF-CAS have shown that more than 50-200 procedures are needed for acceptable outcomes. (PMIDs 16110374, 11787965, 10842380, 8798126, 21349464, 22645102)

A systematic review of TF-CAS has defined that 72 procedures are needed for an operator to achieve a stroke or death rate of  $\leq 3\%$  and that active carotid transfemoral stenting centers need 2 years to achieve a S/D rate below 5%. (PMID 21050404). In addition to an elevated mortality early in an operator's experience with TF-CAS in Medicare patients, Birkmeyer et al found that annual volume was also important for optimal outcomes. (PMID 3208144). Similar findings were noted in the CAPTURE 2 registry. (PMID 21349464). It has been felt that policies that would restrict the use of TF-CAS to highly experienced operators might ensure safety but would come at the cost of limited access. (PMID 28582158) However, if expanded access comes at the cost of an increased stroke risk, the benefits of expanded access will be lost. A prophylactic procedure designed to reduce the future stroke risk may not be worthwhile if patients would be exposed to a higher risk of stroke than for non-interventional management.

Unrestricted access to TF-CAS can be predicted to result in an increase in the number of operators performing the procedure at a low annual rate, slowly making their way through the learning curve, and struggling to achieve annual procedure numbers, with less-than-acceptable results for Medicare beneficiaries. Based on the considerations above, this coverage decision will likely increase the

number of strokes in the United States in the near future since the stroke and death rate for carotid intervention must be <3% to confer any benefit when treating asymptomatic patients.

#### Lack of Registry Participation Requirement

In the CMS proposed decision summary, it is stated “Analysis of data from large registries support the conclusion that benefits and harms of CAS compared to CEA seen in trials are generalizable to broad community practice.” While this may be true, at the time of data collection, interventionalists had been advised by previous credentialing documents and expert consensus statements that TF-CAS is an advanced endovascular procedure and should only be done by proceduralists with advanced training and expertise – leading one to believe that this is an elite and select group of interventionalists. In addition, providers were aware that their data would be collected for review and hence would be under scrutiny. With the proposed decision that is “leaning toward access”, many new providers who will offer TF-CAS will be inexperienced and low volume. **In the proposed decision summary, there is no recommendation or requirement for procedural or center certification and no requirement for monitoring outcomes.** None of the RCT’s or studies referenced in the proposed decision provide any evidence that the previous lengthy (estimated >50-200) learning curve has decreased over time. The influx of a large volume of inexperienced, inadequately trained, low volume providers may well lead to an increased rate of post-TF-CAS stroke. It is important to consider whether the proposed decision will lead to better care for patients with carotid stenosis. In the proposed decision, they state that “a standardized, nationwide registry – for all carotid artery procedures – would be helpful to monitor procedural safety, further evolve patient risk stratification, and to facilitate auditing and quality improvement, including comparison of local outcomes to national and other benchmarks.” We fully agree and wonder why this was not required and would encourage CMS to reconsider. It is also important to remember that there are varied criteria for estimating the degree of stenosis resulting in wide variation in estimates for the degree of stenosis. As such, it would be important for any registry to collect critical diagnostic criteria, e.g., the peak systolic velocity and end diastolic velocity recorded on pre-intervention diagnostic ultrasound.

The leadership for the SVS/PSO would propose a construct similar to the current CMS sponsored VQI TCAR Surveillance Project. The VQI TF-CAS Surveillance Project would be designed to capture the real-world experience of TF-CAS. The project will collect the real-world data and outcomes of TF-CAS to include all users, all sites, and all patients without exclusion criteria, run-in period, or restrictions on credentialing. Data could be analyzed and reported to CMS on a periodic basis. In doing so, CMS and the medical community would have real-time evidence on the risks, benefits, safety and one-year outcomes following TF-CAS. This surveillance project will provide data to better define and refine the role of different carotid interventions in the treatment of carotid stenosis.

Monitoring procedural outcomes, sharing information, and reducing variation is embedded within the mission of the VQI. The VQI is uniquely positioned to discern early signal detection of adverse outcomes with the use of DELTA (Data Extraction and Longitudinal Trend Analysis). Through DELTA (ClinicalTrials.gov NCT04110288), VQI refuted a suspected late mortality increase with Paclitaxel products very early in 2020 following initial concerns raised by Katsanos et al meta-analysis in 2018. This reinforces the value of real-world evidence by timely directed analysis of procedural data which

is only possible through registry participation. With razor thin margins of benefit on carotid intervention over medical therapy, it remains paramount that ongoing monitoring continue in CAS with guideline adherence to reduce practice variation and not parallel harbingers of disparate outcomes as seen in PVI interventions.

**Due to these concerns, particularly relating to patient safety, we urge CMS to revise its proposed decision memo relating to NCD 20.7 to reflect the following:**

**Recommendation 1.** *Mandate utilization of a standardized “Shared Decision Making” tool that would be designed in collaboration with applicable medical specialty societies and/or other relevant stakeholders.*

Shared decision-making is a vital component of allowing patients to receive a carotid treatment plan that best aligns with their wishes and values. Unfortunately, currently there is no validated carotid decision tool that captures the options offered in contemporary practice that are the subject of this NCD.

There are four primary studies that have sought to develop decision tools for patients with carotid stenosis (PubMed IDs: 21477967, 22218277, 31101429, 34297713). Only two of these studies included patients with known carotid stenosis. Perhaps the most important limitation of these available instruments is that none of them included transcrotid artery revascularization (TCAR), the primary modality of placing carotid stents from the transcrotid approach. This is important, since TCAR has added important nuances into the decision-making process that could be guided by a decision aid. Specifically, TCAR appears to have a lower perioperative risk of stroke than transfemoral carotid stenting (TF-CAS) and has a faster recovery than carotid endarterectomy (CEA). However, no large studies have yet published long-term data on TCARs durability or expected stroke rates. Furthermore, no level 1 evidence exists to support TCARs use. These tradeoffs can be challenging to understand and would be greatly aided by a validated shared decision-making tool that includes best medical therapy, CEA, TF-CAS, and TCAR. To date, this does not exist.

**Recommendation 2.** *Revise the proposed decision memo to emphasize 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.*

Given the recent decision of CMS on Transfemoral Carotid Artery Stenting (TF-CAS), the SVS/PSO which oversees the Vascular Quality Initiative believe the ongoing collection of real-world data to assess the clinical impact and safety of the CMS coverage decision is imperative.

The VQI CEA and CAS registries represent the combined efforts of the SVS and the ACC NCDR to better understand and improve the care of patients with carotid disease. Currently over 1000 centers enter data into the VQI and within the CEA/CAS registries ---- procedures, outcomes and one year follow up have been captured. This makes these registries the ideal tool for accrual of additional data to assess the real-world outcomes following the recent CMS decision.

**Recommendation 3.** *Revise the proposed decision memo to include a definition for “Qualified Physician” and demonstrated core competency standards relating to PTA of the carotid artery concurrent with stenting. CMS should work with relevant stakeholders to develop the core competency standards.*

### **Conclusion**

The SVS believes the coverage expansion in CMS’ proposed decision memo regarding NCD20.7 is premature and jeopardizes patient safety. If the agency moves forward to finalize the proposed expansion of coverage, the finalized memorandum should reflect the outlined recommendations. SVS will continue to actively promote quality and safety for vascular patient care through its published guidelines, appropriate care documents, PSO-VQI Registry and Initiatives such as the Vascular Verification Program. All practitioners caring for patients with vascular disease are encouraged to become familiar with and to utilize them. SVS will continue to develop these resources and make them available.

If you have questions regarding these comments, please contact Jim Wadzinski, SVS Deputy Executive Director/Executive Director PSO ([jwadzinski@svspsso.org](mailto:jwadzinski@svspsso.org)) or Megan Marcinko, SVS Director of Advocacy ([mmarcinko@vascularsociety.org](mailto:mmarcinko@vascularsociety.org)).

Sincerely,

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