CMS EXPANSION OF REIMBURSEMENT FOR CAS FOR ASYMPTOMATIC DISEASE:
AN EXPENSIVE, UNWARRANTED AND POTENTIALLY HARMFUL DECISION

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CONFLICT OF INTEREST

- I have no conflicts of interest related to this presentation.
- Member of IWGDF Classification Working Group
- Co-Chair of IWGDF/ESVS/SVS PAD and DFU Working Group
- Scientific Advisor, Biogen (consultant fees to BCM, not personal)
- Scientific Advisor, Humacyte bypass graft (fees to BCM)
- Consultant: Anges
- Immediate Past President of the Society for Vascular Surgery (SVS)

The opinions and perspectives expressed herein are my personal ones and not those of any society or group of which I am or have been a part.

WHAT IS THE CMS MISSION STATEMENT?

- "The CMS seeks to strengthen and modernize the Nation's health care system, to provide access to high quality care and improved health at lower costs."
- The recent CMS proposed coverage expansion of percutaneous transluminal angioplasty and stenting (NCD 20.7) is at striking odds with its mission statement.
- My views are shaped by my experience evaluating and treating carotid disease for over 40 years, a review of the available evidence, and having served as site PI for NASCET, ACAS and CREST trials.
- The coverage decision was premature and flawed, is likely to cause patient harm and is antithetical to the provision of "high quality care and improved health at lower costs."

MAJOR ISSUES WITH THE DECISION

- Letter of request came from a self-appointed group - the Multispecialty Carotid Alliance - that failed to disclose potential conflicts of interest.
- The decision was premature because the taxpayer funded trial (NINDS-CREST 2, NCT02089217), which could shed light on medical management alone compared to medical management in addition to CEA or CAS, has not been completed or published.
- The decision recommends the use of a decision-making tool, which does not currently exist, and which would take time to create and validate.

REMOVAL OF GUARDRAILS WHICH PROMOTED PATIENT SAFETY

- Important facility standards and approval requirements were removed WITHOUT recommendations for procedural or center certification or monitoring of outcomes.
- Removal of requirement to participate in a registry, such as the VQI (not a high bar), to monitor outcomes threatens patient safety. Broadening access mandates collection of real-world outcomes to maintain safety, especially since:
  - CAS outcomes are heavily operator dependent and require a prolonged learning curve
  - Experience and outcomes of "qualified physician" should have been defined through a careful process of stakeholder engagement, without which
  - Widespread expansion of CAS will predictably be associated with excessive stroke and death rates.

CAS IS NOT EQUIVALENT TO CEA

- TFCAS (CAS) is not equivalent to CEA. Large meta-analyses DEMONSTRATE that CAS is worse than CEA with respect to 30-day stroke, death and MI in symptomatic patients and that the difference is statistically significant. At least one additional study (VQIVision database) shows that the increased stroke risk in the real-world extends up to at least 5 years (CAS 15% higher) compared to CEA, and decreased survival up to 10 years.
- Meta-analyses of RCTs show that CAS is worse than CEA with respect to any stroke or any stroke and death in both asymptomatic and symptomatic patients. CAS is also demonstrably worse in terms of the long-term risk of stroke.

DECISION WILL INCREASE COSTS WITH NO BENEFITS, AND POTENTIALLY INCREASED STROKE RATE

- In contrast to other countries, most carotid interventions in the US are performed for asymptomatic disease; this is only justifiable in carefully selected patients when treated by practitioners and at facilities with verifiably low (< 3%) stroke and death rates, and has only been demonstrated by RCTs for CEA.
- There will be a predictable, initial increase in carotid stenting as a result of this decision, but due to lack of prospectively collected registry data, it will take years to sort out any possible impact on stroke reduction (or even an increase) in the Medicare population. It will lead to increased costs as physicians order imaging studies to evaluate asymptomatic patients, which will lead to more complex imaging studies, and in many cases, provoke an intervention rather than best medical therapy (BMT).

CONCLUSIONS:
THIS DECISION WAS FLAWED AND WILL BE HARMFUL AND WILL PREDICTABLY LEAD TO:

- Increase in the performance of costly screening tests (duplex, CTA, MRA) to identify asymptomatic carotid disease among asymptomatic individuals, a vulnerable patient Medicare subgroup with a relatively low stroke rate when managed with medical treatment alone, in whom CAS has never been shown to provide statistically significant benefit compared to BMT.
- Overtreatment of carotid disease, particularly in asymptomatic patients, based on lack of experience with and standardized, validated criteria for determining the degree of carotid stenosis by practitioners lacking substantial training and experience in the diagnosis treatment of carotid disease
- Increase in unregulated facilities and operators performing CAS without adequate training, credentialing or monitoring of outcomes with predictably increased stroke rates
- In short, testing and CAS procedures (and costs) will rise dramatically with an increase in the number of strokes, or at best, no overall reduction in stroke rate in the US.
- The decision will hinder further research to define who benefits from carotid revascularization.

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