

AMERICAN ASSOCIATION OF  
NEUROLOGICAL SURGEONS

KATHLEEN T. CRAIG, *CEO*  
5550 Meadowbrook Drive  
Rolling Meadows, IL 60008  
Phone: 888-566-AANS  
Fax: 847-378-0600  
info@aans.org



American  
Association of  
Neurological  
Surgeons



Congress of  
Neurological  
Surgeons

CONGRESS OF  
NEUROLOGICAL SURGEONS

REGINA SHUPAK, *CEO*  
10 North Martingale Road, Suite 190  
Schaumburg, IL 60173  
Phone: 877-517-1CNS  
FAX: 847-240-0804  
info@cns.org

*President*  
ANTHONY L. ASHER, MD  
Charlotte, North Carolina

*President*  
ELAD I. LEVY, MD  
Buffalo, New York

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Tamara Syrek Jensen, Director  
Joseph Chin, MD, Deputy Director  
Coverage and Analysis Group  
Centers for Medicare & Medicaid Services  
7500 Security Blvd.  
Baltimore, Maryland 21244

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

Dear Ms. Jensen and Dr. Chin:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Cerebrovascular Section, we appreciate the opportunity to comment on the Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting Proposed Decision Memo. Neurosurgeons perform carotid artery stenting (CAS) and carotid endarterectomy (CEA), positioning us to objectively evaluate the clinical evidence for treating carotid artery disease.

We support the rigorous analysis by the Centers for Medicare & Medicaid Services (CMS) in the Proposed Decision Memo and the proposal to expand coverage to include (1) patients at standard surgical risk; (2) patients with symptomatic carotid artery stenosis of at least 50%; and (3) patients with asymptomatic carotid artery stenosis of at least 70%. We agree with the agency's proposed approach, which recognizes that specific requirements for training and tracking procedures are routinely covered in clinical guidelines and ongoing quality efforts and should not be mandated by CMS. Thus, given the vast clinical experience and evidence validating CAS, the physician and facility requirements should be handled through hospital credentialing and medical society guidelines that are in place — as is the case with other well-established procedures.

In addition, we support the agency's proposal to give the treating provider primary responsibility for care management. Requiring a patient to see multiple physician specialists as a condition for coverage could delay or limit patient access. As is true of all other well-established areas of clinical practice, qualified treating physicians, regardless of specialty, routinely provide 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 provide all available treatments.


Finally, we support a shared decision-making (SDM) interaction with all patients and agree with the four core elements CMS has included in the Proposed Decision Memo. Treating physicians must ensure that patients understand the risks and benefits of all treatment options. They must also understand patient preferences to provide appropriate recommendations to patients and their families. We recommend documenting the details of these conversations with patients in the medical record by the treating physician. However, we do not believe a validated SDM tool should be required. As CMS notes in the Proposed Decision Memo, a validated SDM tool does not exist, it would take multiple years to develop

and validate such a tool, and requiring a validated tool for coverage would significantly delay or deny patient access to this critical treatment. In other national coverage analyses, CMS recognized the value of SDM but did not require 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.

In the end analysis, we encourage CMS to support decisions about how to best treat carotid stenosis based on optimizing medical therapy, clinical presentation, co-morbidities, life expectancy, anatomical, lesional attributes, societal guidelines, physician expertise and patient preferences.

Thank you for considering expanded coverage for CAS. Please do not hesitate to contact us if we can provide any additional information or answer any questions.

Sincerely,



Anthony L. Asher, MD, President  
American Association of Neurological Surgeons



Elad I. Levy, MD, President  
Congress of Neurological Surgeons



Adam S. Arthur, MD, Chair  
AANS/CNS Cerebrovascular Section

**Staff Contact:**

Catherine Jeakle Hill  
Director, Regulatory Affairs  
AANS/CNS Washington Office  
25 Massachusetts Avenue, NW, Suite 610  
Washington, DC 20001  
Phone: 202-446-2026  
E-mail: [chill@neurosurgery.org](mailto:chill@neurosurgery.org)