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February 7, 2023

Tamara Syrek Jensen, Director
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SUBJECT: Request for Reconsideration of CMS National Coverage Determination (NCD) 20.7: Percutaneous Transluminal Angioplasty (PTA)

Dear Ms. Syrek 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 Section on Cerebrovascular Neurosurgery, we appreciate the opportunity to comment on the reconsideration of National Coverage Determination (NCD) 20.7: Percutaneous Transluminal Angioplasty (PTA). Neurosurgeons perform carotid artery stenting (CAS) and carotid endarterectomy (CEA), positioning us to objectively evaluate the clinical evidence for treating carotid artery disease.

In 2009, the AANS and CNS disagreed with proposals to expand coverage for CAS to asymptomatic patients based on the available evidence. Since the last reconsideration of NCD 20.7, multiple randomized controlled trials (RCTs) have been published, physicians from several different specialties have amassed extensive real-world experience, and data have been collected as part of national registries. Significant clinical trials — CREST, ACT-1, SPACE-2 and ACST-2 — have all demonstrated equivalence in outcomes and long-term stroke prevention between CAS and CEA for a broad range of patients in randomized studies.[1-7] As such, we support updating the patient selection criteria in the NCD to reflect the evidence demonstrated over the last 12 years and parallel CEA access by including patients at standard surgical risk, patients with symptomatic carotid artery stenosis of at least 50% and patients with asymptomatic carotid artery stenosis of at least 70%.

We agree that the asymptomatic standard should be changed to at least 70% as opposed to at least 80%, as the most frequent means of surveillance measurement, carotid dopplers, utilize a 70% stenosis as a dichotomizing standard and other ongoing major trials which may alter future guidelines are employing these cutoffs. Specifically, this difference is less than 0.5mm in most carotid arteries and, therefore, not material to making decisions. We also recommend that specific requirements for training and tracking of procedures that are routinely covered in our clinical guidelines and ongoing quality efforts should not be mandated by CMS. Therefore, given the vast clinical experience and evidence validating CAS, the physician and facility requirements can now be removed and handled through hospital credentialing and medical society guidelines that are in place, as with other well-established procedures.

The current NCD had its purpose as the CAS technology and medical evidence to support its routine use developed. However, it has far outlived that purpose and has become an unnecessary burden on the

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optimal care of Medicare beneficiaries. The decision on how to best treat carotid stenosis should be based on optimizing medical therapy, clinical presentation, co-morbidities, life expectancy, anatomical, lesional attributes, societal guidelines, physician expertise and patient preferences. The standing NCD is outdated and is preventing optimal care.

We thank CMS for consideration of expanded reimbursement for CAS. If we can provide any additional information or answer any questions, please do not hesitate to contact us.

Sincerely,

Ann R. Stroink, MD, President
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Elad I. Levy, MD, President
Congress of Neurological Surgeons

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