AMERICAN ACADEMY OF NEUROLOGY®

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Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R8)

Dear Ms. Syrek Jensen,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 40,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease, Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The AAN is pleased to provide comments on the proposed decision memorandum on Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R8). We commend the Centers for Medicare & Medicaid Services (CMS) for proposing to update the national coverage determination (NCD) for this procedure, including ending the requirement for some patients to participate in clinical trials, following successful completion of the evidence development activities required by the current version of the NCD. The AAN supports the goal of Coverage with Evidence Development (CED) to provide access to promising technologies while collecting data on how they work in Medicare beneficiaries. At the same time, we have been concerned about coverage policies that become outdated and cannot be adapted easily as standards of practice evolve. We have urged CMS to be nimble and allow access to care without CED requirements quickly when newly acquired evidence supports broader coverage. We greatly appreciate the thoughtful analysis CMS applied to the clinical evidence for carotid artery stenting (CAS).

We also support the specific elements of this proposed decision, namely:

- Covering PTA of the carotid artery concurrent with stenting with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries with symptomatic carotid artery stenosis ≥50% or with asymptomatic carotid artery stenosis ≥70%;
- Covering CAS for standard surgical risk patients;
- Covering CAS without requiring patients to participate in clinical trials;

- Allowing the Medicare Administrative Contractors (MACs) to determine coverage for patients not described in the proposed decision;
- Removing facility standards and approval requirements; and
- Requiring formal shared decision-making (SDM) with the patient prior to the procedure.

We ask CMS to finalize this proposed decision. To ensure that the final decision allows timely access to appropriate care for Medicare beneficiaries, we recommend that CMS revise two parts of the decision.

First, CMS should not require use of a validated SDM tool prior to the CAS procedure because there is no such tool now. SDM is critically important, and CMS appropriately identifies elements that must be included in the SDM interaction:

- Discussion of all treatment options for carotid stenosis to ensure the beneficiary is familiar with and aware of all treatment options including, but not limited to, procedures that fall within the parameters of this NCD.
- Explanation of risks and benefits for each option specific to the beneficiary's clinical condition.
- Integration of clinical guidelines (e.g., patient life-expectancy).
- Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

These elements should be finalized, and CMS should encourage development of a validated tool that includes these elements. Until such a tool is available, physicians should be able to satisfy the NCD's requirements by documenting in the medical record that the SDM interaction occurred. CMS also could specify in the final decision that use of a validated SDM tool would provide adequate documentation of the interaction.

Second, CMS should not require use of CTA and MRA to evaluate the extent and severity of carotid artery stenosis in all patients. These procedures are contraindicated for some patients due non-MR safe implants, allergies or other comorbidities. The final decision should allow physicians to use catheter-based angiography when CTA and MRA are not appropriate for the patient.

In conclusion, the AAN applauds CMS for proposing an updated coverage policy for CAS that is based on the currently available evidence. We urge CMS to implement this decision, with the two revisions discussed above, to expand Medicare beneficiaries' access to care.

The AAN appreciates the opportunity to provide input on this coverage decision. Please reach out to Matt Kerschner, the AAN's Director, Regulatory Affairs and Policy at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

Carlayne E. Jackson, MD, FAAN
President, American Academy of Neurology