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September 2, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
U.S. Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating [CMS-1772-P]

Dear Administrator Brooks-LaSure,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 38,000 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 (AD), Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

Physicians in the United States complete an average of 41 prior authorization (PA) requests every week, taking an average of 13 hours to process.[1] PA is one of the most time-consuming and expensive administrative requirements preventing physicians from spending more time with patients. Over 90% of clinicians reported that PA requirements have a negative impact on patient clinical outcomes and 82% of clinicians reported that issues associated with PA can lead to patients abandoning a recommended course of treatment.[2] Burdens associated with PA are often cited as a top concern among AAN members. The detrimental impact of PA

[1] "2021 AMA Prior Authorization (PA) Physician Survey." American Medical Association, 2022, https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[2] Id.

burden predates the Covid-19 Public Health Emergency (PHE) and has been magnified by stressors stemming from the PHE including staffing shortages.

The AAN remains quite concerned with the Centers for Medicare and Medicaid Services' (CMS) incorporation of PA – traditionally a utilization control process used by managed care organizations – into the Medicare Fee-for-Service (FFS) Program. The initial adoption of hospital outpatient PA requirements in the CY 2020 Hospital Outpatient Prospective Payment System (OPPS) Final Rule constituted a significant departure from historic Medicare policies. The AAN believes this expansion was adopted without adequate transparency regarding the standards used to select the services that would be subject to these burdensome new requirements. Additionally, physicians who have been subject to PA requirements since July of 2020 continue to experience significant challenges in obtaining timely approval, which directly impact the patient's access to timely proper medical care. The AAN understands that CMS has an interest in protecting program integrity and ensuring that Medicare funds are not spent on unnecessary services, but the AAN believes that Medicare program integrity can be adequately protected by appropriate post-service audits and by screening for potentially inappropriate changes in practice patterns among providers and health care systems.

The AAN has previously provided CMS with a number of recommendations[3] to address PA-related burdens and reiterates the following recommendations:

- CMS must closely monitor the implementation of the current Medicare FFS PA requirements to ensure that decisions are made promptly and, when they are not, clarify that the PA requirements are not barriers to payment for these services.
- Release Medicare Administrative Contractor PA data to improve transparency.
- Clarify the process for removing existing services from the PA requirements.
- Suspend the use of PA for any additional services under all Medicare FFS programs.

The AAN is highly concerned with the proposed expansion of hospital outpatient PA requirements to include facet joint interventions (CPT Codes 64490-64495 and 64633-64636) starting on March 1, 2023. The AAN believes that requiring PA for these services poses substantial risks of limiting patient access to care. Currently there are no better diagnostic injections to test for facet arthropathy. The AAN is concerned that PA requirements may exclude patients' access to care based on requirements that are not data driven and not in alignment with clinical expertise. There are substantial limitations associated with both physical exam findings and radiographic studies. Neurologists use the diagnostic block when the history and physical examination are suggestive. Completing this diagnostic injection yields substantial benefits to patients when it results in a radiofrequency ablation (RFA) that can result in sustained relief. Before doing the permanent RFA, it is common practice to do a set of two diagnostic blocks. Recent data suggests that only one diagnostic block may be needed, which may reverse the trend towards increased utilization observed by CMS. Given the potential impacts on patient access to care, and the likelihood that recent findings will decrease observed service utilization, the AAN believes that these new requirements will be unnecessary.

[3] See AAN/RRC comments found here: https://www.regrelief.org/wp-content/uploads/2021/09/RRC-comments.-HOPPS-Proposed-2022.-D0910997-2.docx

Furthermore, the AAN urges CMS to remove the finalized requirement for additional PA requirements for botulinum toxin injections in the hospital outpatient department (HOPD) setting. In the 2020 OPPS Final Rule, the agency finalized policies to implement an outpatient PA program on several codes related to the administration of botulinum toxin. The AAN believes an expansion of PA requirements associated with administering botulinum toxin continues to be unwarranted and notes that there are several clinical indications within neurology that necessitate utilizing botulinum toxin, including migraine, dystonia, blepharospasm, spasticity, clonic hemifacial spasm, medically refractory upper extremity tremor, and axillary hyperhidrosis. Botulinum toxin is considered to be the first line treatment for cervical dystonia, blepharospasm, and clonic hemifacial spasm. The increase in utilization observed by CMS that justified subsequent PA requirements is likely attributable to an increase in migraine awareness and diagnosis, as there have been national campaigns to reduce stigma, alongside patient and provider education related to the availability of new medications. The AAN notes that botulinum toxin has been found to be arguably more effective and safer than most other choices on the market for management of chronic migraine. Additionally, it is unlikely that neurologists are providing cosmetic services and there is no basis to believe that botulinum toxin injections for dystonia or spasticity are cosmetic. Additionally, injections in limbs or necks are highly unlikely to be cosmetic.

There are many alternative solutions to address the observed increases in utilization, without requiring costly and time-consuming PAs. PA requirements for botulinum toxin could be eliminated specifically for those who treat clinical indications like migraine, dystonia, spasticity, and other neck and limb injections that necessitate utilizing botulinum toxin but are unlikely to be cosmetic. The observed increase in facet joint interventions may be reduced due to findings from recent data. In lieu of new PA requirements, CMS could also provide education to Medicare eligible providers to ensure that physicians understand relevant agency criteria and documentation requirements.

The AAN appreciates CMS' attention to the need to balance program integrity with the need to relieve the administrative burdens faced by physicians across the country. The AAN urges the agency to heed our recommendations regarding the HOPD PA program and reverse its decision to increase PA-related burdens on physicians administering botulinum toxin and facet joint interventions. The AAN believes that reducing PA-related burdens will reduce costs and improve patient outcomes by ensuring that paperwork does not interfere with clinically necessary care. Please contact Matt Kerschner, the AAN's Director, Regulatory Affairs at mkerschner@aan.com or Max Linder, the AAN's Government Relations Manager at mlinder@aan.com, with any questions or requests for additional information.

Sincerely,

Orly Avitzur MD

Orly Avitzur, MD, MBA, FAAN
President, American Academy of Neurology