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October 1, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician Owned Hospitals [CMS-1736-P]

Dear Administrator Verma,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 36,000 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.

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

The AAN urges the Centers for Medicare and Medicaid Services (CMS) to remove the finalized requirement for additional prior authorization (PA) requirements for botulinum toxin injections in the HOPD setting. In CMS's recent Final Rule, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; CMS-1717-FC, the agency finalized its proposal to implement an outpatient PA program on five different services when performed in the hospital outpatient department. Included in these procedures are several codes related to the administration of botulinum toxin. The AAN believes an expansion of PA requirements associated with administering botulinum toxin is unwarranted and notes that there are several clinical indications within neurology that necessitate utilizing botulinum toxin, including migraine, dystonia, blepharospasm,

spasticity, and axillary hyperhidrosis. Given the medical necessity of botulinum toxin injections within the field of neurology, the AAN believes that implementation of additional prior authorization requirements is unduly burdensome on practicing neurologists, even without accounting for the ongoing public health emergency (PHE).

During the PHE, the AAN believes that prior authorizations should be reduced as much as possible. Prior authorization is one of the most time consuming and expensive administrative requirements preventing physicians from spending more time with patients. 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 during the PHE by appropriate post-service audits and by screening for potentially inappropriate changes in practice patterns among providers and health care systems. The AAN notes that new PA requirements are especially burdensome during the ongoing PHE. Many practices are operating with significantly reduced staff capacity and most practices are urgently developing telehealth services, learning new E/M coding criteria, and adapting to frequent changes in guidance from the Centers for Disease Control and Prevention and local health authorities. Most have taken staff and funding from other practice activities to adapt to these emergency changes. Additional PA requirements will unnecessarily strain neurology practices that are already operating with reduced capacity and reduced staffing and will be especially problematic for small departments. The AAN notes that the new PA requirements may eliminate the ability of many clinicians to administer botulinum toxin during the same visit as the initial examination and diagnosis, resulting in an unnecessary return visit which is burdensome for patients and increases the risk of transmission of Covid-19.

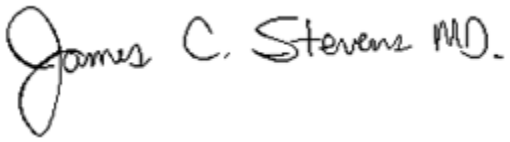
Furthermore, the AAN disagrees that additional PA requirements are necessary due to an increase in inappropriate utilization of botulinum toxin. The increase in utilization observed by CMS is likely attributable to an increase in migraine awareness and subsequent diagnosis as there have been national campaigns to reduces 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 all other choices on the market for 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. Furthermore, injections in limbs or necks are highly unlikely to be cosmetic.

There are many alternative solutions to address the observed increase in utilization, without requiring costly and time-consuming PAs. PA requirements could be limited to those who do not treat clinical indications that necessitate utilizing botulinum toxin, but are unlikely to be cosmetic like migraine, dystonia, spasticity, and other neck and limb injections. CMS could also provide education to Medicare eligible providers to ensure that physicians understand relevant agency criteria and documentation requirements. CMS could also work to modify relevant CPT code descriptions to ensure that cosmetic procedures would not meet the relevant code requirements. The AAN also recommends that CMS work with relevant specialty groups to minimize PA-related burdens, including by ensuring that PA requirements are standardized.

Conclusion

Regulatory relief is a top priority for the AAN. The AAN appreciates CMS' commitment to relieving the regulatory burdens faced by physicians across the country and urges the agency to reverse its decision to increase PA-related burdens on physicians administering botulinum toxin. 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 Government Relations Manager at mkerschner@aan.com or Daniel Spirn, the AAN's Senior Regulatory Counsel at dspirn@aan.com, with any questions or requests for additional information.

Sincerely,



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President, American Academy of Neurology