May 14, 2020

Ms. Connie Leonard
Acting Director
Program Compliance Group

Ms. Tiffany Swygert
Director
Hospital Ambulatory Payment Group
Center for Medicare and Medicaid Services
7500 Security Boulevard
(Sent electronically)

Dear Ms. Leonard and Ms. Swygert:

We are writing to request that CMS delay the planned July 1 implementation for certain procedures 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-P* , the agency finalized its proposal to implement an outpatient PA program on five different services when performed in the hospital outpatient department. Our organizations would like to request a conference call at the earliest opportunity to discuss these and other concerns regarding how the policy is being implemented and requesting a delay.

During the open comment period, concerns were articulated by our groups with the proposed outpatient PA process. Key to preserving access for patients is the definition/understanding of medical necessity. Nowhere in the rule, however, did CMS provide guidance to hospitals or MACs on what constitutes medical necessity for the services proposed for PA. Many MACs do not have LCDs on one or more of the procedures discussed below, and it is unclear who becomes the arbiter for approvals. The prior authorization approval process, now more than ever, consumes valuable physician and administrative time, places financial burden on providers and may negatively impact patients by delaying much-needed treatment.

In response to the Proposed Rule to the above captioned Final Rule, AAO wrote to the agency to express our concern over unnecessarily burdening ophthalmologists with a PA for certain blepharoplasty, eyelid surgery, brow lift and related services. The AAN and the AAO-HNS additionally have concerns over burdens related to important medically necessary botulinum toxin injections.

To reiterate, Medicare's claims data does not support CMS' statement in the proposed rule that utilization for these procedures increased 48.9% between 2011 and 2012. Similarly, CMS also intends to require PA for CPT 64612 (Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral, eg, for blepharospasm, hemifacial spasm) yet, since 2008, Medicare claims data for this procedure across several years reflect no growth or declining utilization for claims associated with CPT 64612.

On April 21, 2020 CMS issued revised guidance to Medicare Advantage and Part D plans which enabled these plans,

“*to waive or relax PA requirements at any time for other formulary drugs in order to facilitate access with less burden on beneficiaries, plans, and providers*[1].

The current pandemic has taken its toll on physicians, their staff and patients as the majority of practices report severe financial disturbances which require physicians to do more under constrained resources. During this public health emergency, we want to thank CMS for the extraordinary steps it has taken to help health care providers including our members. The recent Medicare Advantage and Part D plan flexibility to ease Prior Authorization (PA) requirements[2] were one important piece of those efforts. However, we strongly believe that the agency should delay the implementation date of its own planned outpatient PA program originally scheduled for implementation on July 1, 2020.

Sincerely,

The American Academy of Ophthalmology

The American Academy of Neurology

The American Academy of Otolaryngology-Head and Neck Surgery

The American Society of Ocular Plastic and Reconstructive Surgeons

[1] https://www.cms.gov/files/document/updated-guidance-ma-and-part-d-plan-sponsors-42120.pdf
[2] IBID