August 31, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1850-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1850-P, Calendar Year 2027 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule — Prior Authorization for Additional Botulinum Toxin Injection Services

Dear Administrator Oz,

Thank you for the opportunity to respond to the Center for Medicare & Medicaid Services' (CMS) proposed CY 2027 Hospital Outpatient Prospective Payment System proposed rule. On behalf of the Alliance for Patient Access' (AfPA) clinician members and the Movement Disorders Policy Coalition (MDPC), we are writing specifically to provide feedback on the proposed plan to increase the hospital outpatient department prior authorization process to additional botulinum toxin injection services. Botulinum toxin injections are a critical treatment option for multiple medical conditions including cervical dystonia, spasticity, chronic migraine, and overactive bladder. CMS asks about the potential for "unintended clinical consequences," which is what this letter will respond to.

Founded in 2006, AfPA is a national network of policy-minded health care providers who advocate for patient-centered care. AfPA supports health policies that reinforce clinical decision-making and promote personalized care to protect the provider-patient relationship. MDPC serves as a platform from which stakeholders, including health care providers and patients, can provide input on policy decisions impacting patient-centered care for those living with movement disorders and advocate at the state, federal, and health plan levels.

We understand and appreciate that CMS is looking to control unnecessary increases in the volume of covered services and agree with the goal of protecting the program from fraud, waste, and abuse. Our concern reflects the fact that the proposed codes treat serious, chronic medical conditions for which botulinum toxin is an FDA-approved, guideline-recommended therapy.

CMS characterizes the 42.8 percent growth in utilization of these codes between 2017 and 2024 as evidence of "unnecessary" volume. We respectfully disagree with that characterization as applied here. As detailed below, the growth is substantially explained by legitimate clinical drivers that CMS'

own analysis acknowledges but does not fully credit. Most notably, CMS does not give the appropriate level of credence to the expansion of FDA-approved indications during the same period as a driver of significant growth in utilization.[1] This reflects expected clinical uptake of the use of these medications in manners the FDA has reviewed and recommended. As a result, CMS is making flawed conclusions about the level of fraud, waste, and abuse that is present in the prescribing of these needed and life-changing medications.

Potential for Unintended Clinical Consequences

We are concerned that prior authorization applied to these codes in the manner proposed will delay medically necessary care for patients whose conditions require treatment on a strict, recurring schedule. Botulinum toxin's therapeutic effect is temporary, and when a scheduled injection is delayed, symptoms recur.[2] These treatments cannot be deferred without direct clinical consequence, as outlined below and separated by code.

1. Cervical dystonia and related focal dystonias (64616, 64617):
   Cervical dystonia is a painful neurological movement disorder in which the neck muscles contract involuntarily. This chronic condition can cause the head to twist, turn, or tilt with varying severity and 90% of people with cervical dystonia experience pain associated with the condition.[3] It is the most common form of adult-onset focal dystonia, with women affected approximately two times more than men.[4] While there is no cure, botulinum toxin injections are considered first line therapy to help reduce pain and abnormal movements.[5] Laryngeal dystonia (spasmodic dysphonia) impairs the ability to speak. For both conditions, botulinum toxin is administered at regular intervals to maintain control of symptoms. A delay as a result of prior authorization increases means the return of pain, abnormal movement, or loss of voice during the gap in treatment.
2. Spasticity in adults and children (64642, 64644, 64646, 64647):
   Spasticity results from illness or injury affecting the brain or spinal cord and causes an involuntary increase in muscle tone and abnormal postures in the limbs and trunk. It can be painful and can interfere with activities of daily living, hygiene, dressing, and care. Botulinum toxin is the most widely used therapy for focal spasticity and avoids many of the systemic side effects associated with oral medications.[6] A prior authorization delay directly impairs function and comfort.

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[1] U.S. Food & Drug Administration. Prescribing information: Xeomin (incobotulinumtoxinA), chronic sialorrhea, 2018; Myobloc (rimabotulinumtoxinB), chronic sialorrhea, 2019; Daxxify (daxibotulinumtoxinA-lanm), cervical dystonia, 2023.
[2] U.S. Food & Drug Administration. Myobloc (rimabotulinumtoxinB) prescribing information, 2019.
[3] Charles, P.D., Adler, C.H., Stacy, M. et al. "Cervical Dystonia and Pain: Characteristics and Treatment Patterns from CD PROBE (Cervical Dystonia Patient Registry for Observation of OnabotulinumtoxinA Efficacy)." Journal of Neurology vol. 261. https://doi.org/10.1007/s00415-014-7343-6
[4] Defazio, G., Jankovic, J., Giel, J.L. et al. "Descriptive Epidemiology of Cervical Dystonia." Tremor and Other Hyperkinetic Movements vol. 3. https://doi.org/10.7916/D80C4TGJ
[5] Simpson, D.M., Hallett, M., Ashman, E.J. et al. "Practice Guideline Update Summary: Botulinum Neurotoxin for the Treatment of Blepharospasm, Cervical Dystonia, Adult Spasticity, and Headache." Neurology vol. 86. https://doi.org/10.1212/WNL.0000000000002560
[6] Ibid.

3. Chronic sialorrhea (64611):
   Sialorrhea is a common and burdensome symptom of many conditions such as Parkinson's disease, ALS, cerebral palsy, and stroke.[7] Beyond its social and quality-of-life impact, uncontrolled sialorrhea carries clinical risks including skin breakdown and aspiration.[8] The therapeutic effect of injection very effective but is also temporary, meaning that delayed reauthorization allows these symptoms and risks to return.

Recommendations

We ask that CMS:

1. Reconsider or narrow the proposed additions, particularly for codes where the observed growth is attributable to the expansion of FDA-approved indications and products during the analysis window (for example, code 64611 for chronic sialorrhea and drug code J0589).

2. Publish the code-level data underlying the utilization and spending analysis so that stakeholders can meaningfully evaluate whether the growth reflects unnecessary volume or appropriate uptake of newly available, FDA-approved therapies.

3. If CMS proceeds, adopt patient-protective safeguards, including: continuity-of-care protection for patients already established on therapy; expedited review timelines appropriate to the recurring treatment schedule of these conditions; a provider exemption pathway for clinicians with demonstrated high rates of appropriate use; and transparency regarding approval criteria, denial rates, and processing times.

We appreciate the opportunity to provide comments and welcome the chance to serve as a resource to CMS on these issues. If you have any questions please contact Adina Lasser, Director of the Movement Disorders Policy Coalition at alasser@allianceforpatientaccess.org.

Sincerely,

American Brain Coalition
American Parkinson Disease Association
Aimed Alliance
The Alliance for Patient Access
Caregiver Action Network
Clinical Neurological Society of America
The Davis Phinney Foundation for Parkinson's
Dystonia Medical Research Foundation
The Michael J. Fox Foundation for Parkinson's Research
Parkinson Association of Northern California
Parkinson & Movement Disorder Alliance

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[7] Jost, W.H., Friedman, A., Michel, O. et al. "SIAXI: Placebo-Controlled, Randomized, Double-Blind Study of IncobotulinumtoxinA for Sialorrhea." Neurology vol. 92. https://doi.org/10.1212/WNL.0000000000007368
[8] Ibid.

Tourette Association of America

Shadi Barbu, MD
Knoxville, TN

Calli Cook, DNP, APRN, FNP-C
Emory Brain Health Center
Atlanta, GA

Mary Feldman, DO MBA, FAAN
Dartmouth-Hitchcock
Lebanon, NH

Fay Gao, MD
The Queen's Health Systems
Honolulu, HI

Rashmi Halker Singh, MD
Mayo Clinic
Scottsdale, AZ

Julie Kurek, MD
Augusta University
Augusta, GA

Robert Nahouraii, MD
AMC/ Flourish Charlotte
Charlotte, NC

Gaurang Palikh, MD, PC
Kings Mountain, NC

Amita Patel, MD
Amita R. Patel MD INC
Dayton, OH

Meghan Piccinin, DO
Allegheny Health Network
Pittsburgh, PA

Jared Pomeroy, MD, CMD, MHA, CPE
Corewell Health
Grand Rapids, MI

Bal Sharma, MD, PharmD
Ascension Hope
Wichita, KS

Bhavna Singla, MD
Erie County Medical Center
Buffalo, NY

Michael Soileau, MD, FAAN
Texas Movement Disorder Specialists
Georgetown, TX

Kathleen Woschkolup, MD
Carolina Neurology
Spartanburg, SC