



March 31, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: [Botulinum Toxin Injections \(L35170\)](#)

Dear Dr. Oz,

On behalf of the 1.2 million people living with Parkinson's disease, the American Parkinson Disease Association (APDA) is writing to respectfully request that you reconsider recent revisions to the Botulinum Toxin Injections Local Coverage Determination (LCD) L35170. While we appreciate the Centers for Medicare and Medicaid Services (CMS) efforts to reduce waste, fraud and abuse in the Medicare system, the revised LCD requires the use of an "objective clinical scale" as an indication of coverage which is having unintended consequences resulting in unnecessary burden on physicians and delays in the delivery of care.

Blepharospasm, Blepharospasm Associated with Orofacial Dystonia, Cervical Dystonia, Focal Hand Dystonia, Hemifacial Spasm/Facial Dystonia, Laryngeal Dystonia (Spasmodic Dysphonia), Sialorrhea, and Upper and Lower Spasticity are symptoms that can exist as independent neurological conditions but are also frequently associated with a Parkinson's disease diagnosis. Botulinum Toxin Injections (BTI) are used to provide patients suffering from symptoms associated with these diagnoses by temporarily relaxing overactive muscles and blocking nerve signals that cause involuntary muscle spasms, stiffness, and excessive saliva production. BTI injections can be very effective for symptom control, but require repeat treatments, typically every three months. Muscle selection and dose often need to be adjusted to achieve optimal symptom control.

The new application of an "objective clinical scale" as an indication of coverage in the revised policy has been very puzzling to physicians since many of the diagnoses described above do not have scales that are currently used in clinical practice. This new requirement, therefore, has physicians searching for scales online that they have never used before and then attempting to implement them in an office visit. This exercise does not improve patient selection for the treatment involved, nor does it improve patient care.

Additionally, since the effects of BTI last about three months, these injections are typically performed every three months. The goal is to re-inject BTI before symptoms return, ensuring continued symptoms management. Presumably the purpose of performing the scales is to capture the “before” and “after” effect of the BTI and demonstrate that the treatment is useful. However, for patients receiving injections over a long period of time to keep their symptoms under control, there is neither a “before” nor “after”. It is therefore unclear when the scales should be performed to capture the information that is required by CMS.

The addition of an “objective clinical scale” indication of coverage requirement is an added administrative burden on physicians, subjecting them to comply with a policy that is of little value and reducing the already limited amount of time they are able to spend with patients. For patients, this requirement results in unnecessary denials or delays in care if a scale is not documented or does not determine that the treatment is as effective as CMS requires or does not fully capture the benefit of BTI to the patient.

Finally, without regular access to BTI treatment, many people living with Parkinson’s would not be able maintain the levels of exercise and physical activity necessary to benefit their quality of life after a Parkinson’s diagnosis—improving mobility, balance, and cognitive function.

The APDA urges you to reconsider the required inclusion of an “objective clinical scale” indication of coverage associated with the diagnoses listed above. We appreciate the opportunity to collaborate with you on identifying ways to improve the lives of people living with Parkinson’s while at the same time protecting the Medicare system. Please reach out to Emma Plourde, APDA Director of Health Policy, at emplourde@apdaparkinson.org or 202-763-6801 with any questions or to further discuss this issue.

Sincerely,



Leslie A. Chambers
President & CEO

cc:

Kimberly Brandt, Centers for Medicare and Medicaid Services, Deputy Administrator & Chief Operating Officer