May 15, 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 Proposed LCD – DL35170

Dear Dr. Oz:

On behalf of the Alliance for Patient Access, I am writing to request your reconsideration of proposed revisions to the Botulinum Toxin Injections Local Coverage Determination (LCD) DL35170, which present significant concerns regarding patients' ability to receive their prescribed medications.

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, promote personalized care and protect the clinician-patient relationship. Motivated by these principles, AfPA members participate in clinician working groups, advocacy initiatives, stakeholder coalitions and the creation of educational materials.

OnabotulinumtoxinA injections are a critical treatment option for multiple conditions including cervical dystonia, spasticity chronic migraine, and overactive bladder. The following sections summarize relevant clinical context and AfPA's specific requests for each condition.

Cervical Dystonia
Cervical dystonia is a painful neurological movement disorder in which the muscles controlling the neck contract involuntarily. This chronic condition can cause the head to twist, turn, or tilt with varying severity. It is the most common form of adult-onset focal dystonia, with women affected approximately two times more than men.[1] While there is no cure, treatments such as onabotulinumtoxinA injections are considered first line therapy to help reduce pain and abnormal movements.

OnabotulinumtoxinA injection is the current FDA-approved first-line treatment for cervical dystonia. Given its established clinical role, we request the following policy revisions to ensure timely and appropriate patient access:

(1) The **removal of "moderate to severe" terminology** from the policy, as it does not align with clinical guidance provided by the American Academy of Neurology or the FDA label for onabotulinumtoxinA. The FDA label does not make a distinction regarding severity, and onabotulinumtoxinA is recognized as a first-line treatment for

[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC3822401/

cervical dystonia regardless of severity.[2] Requiring a "moderate to severe" threshold is inconsistent with both the label and established clinical practice.

(2) The **addition of examples of acceptable assessment scales**, as the currently listed scales – and requirements for their use – are overly narrow. We would also urge you to consider the impact this requirement may have on community providers. As AAN stated in its previous letter, many clinicians, and particularly general neurologists, do not utilize these scales, and the requirements as currently stated may have unintended consequences on access. The policy should accommodate documented clinical assessment as an alternative to formal scale administration.[3]

While the above proposed changes focus specifically on cervical dystonia, similar concerns regarding severity terminology and assessment scale options apply equally to the other dystonia and related spasm indications listed in the LCD, including blepharospasm, hemifacial spasm, focal hand dystonia, oromandibular dystonia and laryngeal dystonia. We urge CMS to apply these revisions consistently across all related indications.

Spasticity

Spasticity is a condition that often results from illness or injury affecting the brain or spinal cord. It causes an involuntary increase in muscle tone and abnormal postures in the limbs and trunk. When present, spasticity can be painful and interfere with activities of daily living, undergarment change, nail care, hygiene, and dressing. OnobotulinumtoxinA injections are very effective in reducing the symptoms associated with spasticity.

OnabotulinumtoxinA injection is FDA approved for the treatment of spasticity in both adults and children. approved for spasticity presenting in adults and children. Given its established clinical role, we request the following policy revisions to ensure timely and appropriate patient access:

(1) **The removal or "moderate to severe" terminology** from the policy, as it does not align with current standards of practice. OnbotulinumtoxinA is the most widely used therapy for focal spasticity. Many of the commonly associated side effects of oral medications are avoided when utilizing onbotulinumtoxinA and limiting access to this therapy to "moderate or severe" cases of spasticity inappropriately limits care.

(2) The **addition of examples of acceptable assessment scales**, as the currently listed scales – and requirements for their use – are overly narrow. We would also urge you to consider the impact this requirement may have on community providers. Many clinicians, and particularly general neurologists, do not utilize these scales, and the requirements as currently stated may have unintended consequences on access. The policy should accommodate documented clinical assessment as an alternative to formal scale administration.[4]

Chronic Migraine

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[2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103000s5236lbl.pdf

[3] https://www.aan.com/siteassets/home-page/policy-and-guidelines/advocacy/comment-letters/24-Botulinum-Noridian-JF/

[4] https://www.aan.com/siteassets/home-page/policy-and-guidelines/advocacy/comment-letters/24-Botulinum-Noridian-JF/

Chronic migraine is a neurological disorder characterized by 15 or more headache days per month for at least 3 months, with at least 8 of those days meeting the full criteria for a migraine headache.[5] Over 4 million people in the United States are estimated to have chronic migraine.[6] Women are disproportionately affected, with a prevalence roughly 2-3 times higher than men. While there is no cure, several treatments - including preventive medications and onabotulinumtoxinA injections - injections can help manage the condition and improve quality of life.

OnabotulinumtoxinA injection is recognized as a first-line preventive therapy for chronic migraine per the 2024 AHS Position Statement and 2024 IHS Global Practice Recommendations.[7][8] To align the LCD with current clinical standards and reduce unnecessary barriers to care, we request the following revisions:

(1) **Removal of the step requirement**. The policy as written requires trials of agents from two separate drug classes for two months each before patients can access their originally recommended treatment. This delay increases the likelihood of adverse events, worsening of headache frequency, and disability, and the policy conflicts with current first-line treatment guidelines.

(2) **Recognition of combination therapy**. Some patients need to be able to initiate combination therapy (botulinum toxin + CGRP inhibitor) and the final LCD should recognize this regardless of which agent the patient began with. Additionally, the policy should accept the use of the term "headache days" in addition to "migraine days" as a valid metric.

(3) **Revise criteria language for subsequent dosing**. Rephrase the required outcome from a ">50% reduction in migraine headache episodes per month and migraine headache days per month" to more simply ">50% reduction in monthly headache days," as tracking both metrics is clinically unclear.

(4) **List examples of accepted assessment scales**. The policy requires the use of validated scales but does not identify which scales are acceptable. We urge CMS to align assessment requirements with those being used by clinicians in routine clinical practice.

Overactive Bladder Use

Overactive bladder is a common urological condition characterized by sudden urges to urinate that may be hard to control, including many times during the day and night. Patients may also experience loss of urine that isn't intended, known as urgency incontinence.[9] While there is no cure, treatments range from lifestyle changes, bladder training, and pelvic floor exercises to medications, onabotulinumtoxinA injections into the bladder, and nerve stimulation therapies.

To better reflect clinical practice and AUA guidelines for overactive bladder, we respectfully request the following revision:

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[5] https://ichd-3.org/1-migraine/1-3-chronic-migraine/

[6] https://pubmed.ncbi.nlm.nih.gov/38700185/#:~:text=CM%20prevalence%20is%200.91%25%20(1.3,%2C%20and%2042.4%25%20in%202018.

[7] https://pubmed.ncbi.nlm.nih.gov/38466028/

[8] https://pubmed.ncbi.nlm.nih.gov/39262214/

[9] https://www.mayoclinic.org/diseases-conditions/overactive-bladder/symptoms-causes/syc-20355715

(1) **Expanded dosing flexibility**. Appropriate dosing varies by patient; therefore those who are not experiencing the full therapeutic benefit should be able to receive doses ranging from 100 to 200 units at their clinician's discretion. This range is consistent with AUA guidelines, which allow dosing up to 200 units for patients with inadequate response and minimal side effects.[10]

It is for these reasons that the Alliance for Patient Access kindly requests CMS' reconsideration of the onabotulinumtoxinA injections proposed LCD. We appreciate the opportunity to provide comments. If you have any questions, please contact Casey McPherson at cmcpherson@allianceforpatientaccess.org.

Sincerely,

[10] https://www.auanet.org/guidelines-and-quality/guidelines/idiopathic-overactive-bladder