



ALLIANCE FOR HEADACHE
DISORDERS ADVOCACY

May 15, 2026

CGS

Meredith Loveless, MD
Attn: Medical Review
26 Century Blvd., Ste ST610
Nashville, TN 37214-3685

Re: Comments on Proposed Local Coverage Determination (LCD): Botulinum Toxin Injections (DL39857)

Dear Dr. Loveless,

On behalf of the Alliance for Headache Disorders Advocacy and our member organizations, thank you for the opportunity to provide comments on the proposed Local Coverage Determination (LCD) DL39857 regarding botulinum toxin injections for migraine treatment.

The Alliance for Headache Disorders Advocacy (AHDA) is a national coalition representing patients, care partners, clinicians, researchers, patient advocacy organizations, medical societies, and other stakeholders committed to improving the lives of people living with migraine, cluster headache, facial pain, and other disabling headache disorders.

AHDA appreciates the Centers for Medicare and Medicaid Services' focus on reducing the burden of utilization management tools such as prior authorization and step therapy across items, services, and medicines. However, AHDA is concerned that this LCD proposal regarding migraine-related coverage criteria may inadvertently restrict access to medically necessary care for Medicare beneficiaries living with chronic migraine. This LCD, and other recent coverage policies for access to migraine treatment, would increase utilization management requirements, undercutting the direction that CMS is urging across disease states.

1. Overly Stringent Response Criteria May Exclude Clinically Meaningful Improvement

The proposed LCD requires documentation of $\geq 50\%$ reduction in migraine days and episodes, along with improvement in disability and functioning, to support continued therapy. Response criteria in existing LCDs are already causing denials in outpatient settings, and these proposed criteria may further restrict access compared to current practice.

Notably, a 50% reduction does not reflect the full spectrum of meaningful clinical benefit observed in real-world patients. Many patients experience substantial improvements in severity, duration, or responsiveness to acute treatment - even without reaching a 50% reduction threshold. These improvements can significantly enhance quality of life and functional capacity but would not qualify under the proposed criteria. OnabotulinumtoxinA received FDA approval

for chronic migraine prophylaxis based on the PREEMPT 1 and PREEMPT 2 clinical trials.¹² The PREEMPT trials were designed to establish whether onabotulinumtoxinA reduces headache days compared to placebo - not to define a threshold for determining who should continue treatment. FDA labeling for onabotulinumtoxinA does not require or reference a $\geq 50\%$ reduction as a condition for continued use. A coverage criterion more restrictive than FDA labeling and not grounded in clinical trial evidence is scientifically unjustified and risks denying coverage to patients who are clearly benefiting from therapy.

Under the Indications for Coverage for chronic migraine, the current LCD requires that headaches be “moderate to severe in intensity with typical migraine headache characteristics.” However, migraine attacks may occur with minimal or even absent headache pain while still producing disabling symptoms such as dizziness, weakness, cognitive impairment, nausea or vomiting, aura, phonophobia, and photophobia. These non-headache manifestations can significantly impair functioning and quality of life, and patients may still benefit from botulinum toxin therapy. Accordingly, migraine attacks should be evaluated based not only on headache intensity, but also on the presence and severity of associated migraine symptoms.

The American Headache Society (AHS) has raised similar concerns in its comments on this proposed LCD, emphasizing that clinically meaningful improvement may include reductions in headache severity, improved response to acute medications, decreased disability, and overall patient-reported benefit, even when frequency-based thresholds are not met. This position is consistent with published AHS clinical guidance supporting individualized, patient-centered treatment assessment.³

Strict adherence to a $\geq 50\%$ reduction threshold therefore risks discontinuing effective therapy for patients who are clearly benefiting but fall short of an arbitrary numerical cutoff.

Accordingly, we urge MACs to revise the reasonable and necessary criteria for subsequent botulinum toxin injections to better reflect clinical practice and individualized patient response. At minimum, continued therapy should be supported when a patient demonstrates any of the following: a $\geq 50\%$ reduction in headache days, a $\geq 50\%$ reduction in migraine attacks, **or** meaningful improvement in headache-related disability and functioning. We further encourage the MACs to recognize that lower thresholds of improvement over an appropriate treatment period may still represent substantial clinical benefit for many patients living with chronic migraine.

Additionally, under the *Subsequent Botulinum Toxin Injections* section of the LCD, the following language is stigmatizing and we therefore request that CMS consider its removal: “Clinicians must be aware and address the importance of cognitive-affective processes in headache disorders and address the potential for hypervigilance to bodily sensations and anxiety regarding the symptoms of headache pain when managing chronic migraine headaches.” Such language risks framing patients with chronic migraine as psychologically overreactive, anxious, or excessively focused on their symptoms rather than recognizing migraine as a complex neurologic disease with well-established biologic mechanisms. The use of terms such as “hypervigilance to bodily sensations” and “anxiety regarding the symptoms of headache pain”

¹Aurora SK, Dodick DW, Turkel CC, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. *Cephalalgia*. 2010;30(7):793–803.

²Diener HC, Dodick DW, Aurora SK, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. *Cephalalgia*. 2010;30(7):804–814.

³Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61(7):1021–1039. <https://doi.org/10.1111/head.14153>

may be interpreted as implying that patients' symptom burden is amplified by maladaptive behavior or emotional processing, rather than reflecting the legitimate and often debilitating experience of chronic migraine. We appreciate CMS' shared interest in breaking down such stereotypes.

2. Utilization Management Requirements May Delay Access to Appropriate Therapy

The current LCD for initial botulinum toxin treatment requires beneficiaries to fail at least two months of therapy in two medication classes, despite the fact that none of the listed agents are FDA-approved for chronic migraine. By contrast, both onabotulinumtoxinA and several CGRP-targeting therapies are FDA-approved for chronic migraine, yet CGRP therapies are not reflected in the policy. The American Headache Society has recognized that a trial of onabotulinumtoxinA may be an appropriate alternative to multiple oral medication failures.⁴ We encourage CMS to better align the LCD with the current therapeutic landscape and society guidance by including CGRP-targeting therapies and considering a requirement to fail only one preventive agent rather than two in order to prevent delay in access to appropriate therapy for patients with chronic migraine.

Moreover, rigid two-class failure requirements do not account for variability in patient tolerance, contraindications, or partial but meaningful responses.

In practice, enforcing a fixed number of required failures may result in patients cycling through therapies that are poorly tolerated or unlikely to be effective, delaying access to evidence-based options such as botulinum toxin. This can prolong disability, increase acute medication use, and contribute to higher overall healthcare utilization. Allowing flexibility in how prior treatment experience is evaluated - including clinician attestation of intolerance, contraindication, or inadequate response - would better align coverage policy with real-world clinical care and reduce unnecessary barriers to treatment.⁵

The LCD also proposes a requirement to adhere strictly to 12-week treatment intervals. This may not reflect real-world clinical practice, where some patients experience waning benefit prior to 12 weeks and may require individualized dosing intervals to maintain consistent symptom control.

3. Combined Therapy Requirements May Limit Appropriate Use of CGRP Agents and OnabotulinumtoxinA

The LCD introduces requirements for patients receiving concurrent CGRP-targeting therapies and onabotulinumtoxinA, including demonstration of additional reduction in migraine days compared to monotherapy.

Even though combination therapy is supported in clinical practice for refractory chronic migraine, the LCD would require clear additive benefit relative to monotherapy that may be difficult to document and may not reflect the individualized nature of treatment response. Patients who improve from severe chronic migraine (e.g., 25 headache days per month) to a lower but still disabling frequency (e.g., 12–14 days per month) may still require combination therapy to maintain function. In addition, many patients who began onabotulinumtoxinA therapy prior to the availability of CGRP inhibitors are not covered by the current LCD's framework for concurrent therapy.

⁴Charles A, et al. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024. doi:10.1111/head.14692

AHS has specifically noted that combination preventive therapy, including CGRP-targeting agents with onabotulinumtoxinA, is appropriate in patients with persistent disability despite monotherapy. AHS guidance supports clinician judgment in layering therapies based on patient response rather than requiring rigid comparative documentation of incremental benefit.⁶

Policies that require proof of additive reduction beyond monotherapy risk penalizing patients whose condition improves but remains disabling, thereby limiting access to necessary adjunctive treatment.

4. Behavioral Therapy Documentation Requirement May Create Administrative Barriers

The LCD requires that behavioral therapies (e.g., cognitive behavioral therapy, biofeedback, mindfulness-based therapies) be assessed and implemented as appropriate.

While these interventions are valuable components of migraine care, access to such therapies is often limited by geography, cost, and provider availability - particularly for Medicare beneficiaries. Requiring documentation of implementation may create an administrative barrier unrelated to medical necessity and could delay or deny access to pharmacologic treatment.

AHS supports a multimodal approach to migraine management, including behavioral therapies; however, AHS guidance does not suggest that lack of access to or documentation of these therapies should preclude initiation or continuation of evidence-based pharmacologic treatments.⁷ Notably, the PREEMPT clinical trials, which established the evidence base for FDA approval of onabotulinumtoxinA for chronic migraine, did not require biobehavioral therapy as a condition for treatment.⁸⁹ Making biobehavioral therapy a documentation prerequisite adds a requirement not grounded in the regulatory approval evidence base.

5. Emphasis on Objective Functional Measures May Not Reflect Clinical Practice

The proposed policy emphasizes “objective improvement in functioning” and use of disability measures. However, many clinicians - particularly those in general neurology settings - do not routinely use standardized disability scales in a way that is easily documented for coverage purposes. Rigid documentation requirements may therefore disadvantage both providers and patients without improving care quality.

AHS acknowledges the importance of functional outcomes but supports the use of clinician judgment and patient-reported outcomes when assessing treatment response, rather than mandating strict reliance on specific instruments.¹⁰ If functional documentation requirements are retained, AHS has identified validated tools commonly used in headache medicine - including the Headache Impact Test (HIT-6), Migraine Disability Assessment (MIDAS), and Patient Global Impression of Change (PGIC) - as appropriate measures. Clinician attestation of functional improvement supported by medical record documentation should be permitted as an equally valid alternative.

6. Risk of Reduced Access for Patients with Persistent but Improved Disease

Chronic migraine is a fluctuating and heterogeneous condition. Patients often transition along a spectrum of disease severity rather than achieving complete or near-complete remission. Policies that require near-threshold improvements risk excluding patients who remain significantly impaired despite partial response to therapy. Patients who improve yet continue to experience disabling migraine should not lose access to effective treatments simply because they do not meet rigid numeric thresholds.

7. Administrative Documentation Burden Falls on an Already Strained Specialist Workforce

The cumulative documentation requirements in this proposed LCD - including the $\geq 50\%$ threshold for coverage continuation, biobehavioral therapy documentation, combination therapy criteria, and standardized outcome measures - fall disproportionately on a small and already overburdened specialist workforce.

There are currently fewer than 900 board-certified headache medicine specialists in the United States, against a projected need of approximately 3,700, rising to 4,500 by 2040.¹¹ The majority of Medicare beneficiaries with chronic migraine are managed by general neurologists and primary care providers who lack the bandwidth to navigate complex, multi-criterion documentation requirements for a single treatment. Excessive administrative burden does not improve quality of care, but it does increase the risk that patients lose access to an effective, well-tolerated treatment due to documentation failures that have nothing to do with clinical appropriateness.

Recommendations

To ensure that the LCD supports appropriate access to care while maintaining program integrity, AHDA respectfully recommends:

- Allowing continued coverage based on clinically meaningful improvement - including reduction in severity, duration, or acute medication use - not solely $\geq 50\%$ frequency reduction thresholds
- Removing excessive step therapy failure provisions and including CGRP-targeting therapies as recognized preventive options, with consideration to require failure of only one agent rather than two
- Providing flexibility in evaluating combination therapy, consistent with AHS guidance supporting layered preventive treatment for patients with persistent disability
- Clarifying that behavioral therapy assessment should not serve as a coverage barrier when access is limited or when the treating clinician does not believe it is clinically appropriate
- Permitting clinician attestation of functional improvement in lieu of strict standardized instrument requirements
- Recognizing the continuum of chronic migraine severity and ensuring that patients with persistent disability retain access to therapy even when partial improvement has been achieved

National Scope and Policy Coordination

Multiple Medicare Administrative Contractors have released nearly identical proposed LCDs, indicating a coordinated national trend. AHDA urges CMS to conduct a centralized review with input from neurologists, pain specialists, and patient organizations before finalizing these restrictions.

¹¹Begasse de Dhaem OB, Robbins MS, Starling AJ, et al. Headache medicine workforce shortage: a call to action. *Headache*. 2020;60(2):478–481.

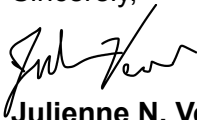
Conclusion

As currently written, the migraine-related provisions of this LCD risk limiting access for patients who derive real, meaningful benefit from treatment but do not meet the narrowly defined criteria required. Aligning the policy with current clinical practice will ensure that Medicare beneficiaries with chronic migraine receive appropriate and timely care.

CMS should ensure that migraine patients benefit from the current effort to reduce the burden of utilization management rather than permitting additional barriers and rigid assessment requirements. AHDA also looks forward to providing public comment on CMS' proposed rule to streamline prior authorization requirements for prescription drugs, as the cumulative effect of this proposed LCD and that which CMS has proposed regarding peripheral nerve blocks (see DL40267, DL40300, DL40261, DL40263, and DL40265) risks creating an increasingly burdensome prescribing and utilization management environment for clinicians treating migraine, while imposing additional access barriers and administrative burden on Medicare beneficiaries living with chronic headache disorders.

Thank you for your consideration of these comments.

Sincerely,



Julienne N. Verdi, Esq.

Executive Director

Alliance for Headache Disorders Advocacy