



ALLIANCE FOR HEADACHE
DISORDERS ADVOCACY

June 14, 2026

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

Re: Request for Information on Step Therapy in Proposed Rule for Interoperability Standards and Prior Authorization for Drugs

Submitted via [regulations.gov](https://www.regulations.gov)

Dear Administrator Oz,

The Alliance for Headache Disorders Advocacy (AHDA) appreciates the opportunity to comment on CMS's proposed rule addressing prior authorization for drugs, interoperability standards, transparency, and related reforms. 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.

Headache disorders are among the most prevalent and disabling neurological diseases in the United States. Migraine alone affects approximately 39 to 40 million Americans and is a leading cause of disability, particularly among women during prime working and caregiving years (Cohen et al., *Headache*, 2024). Yet despite the significant burden of disease, people living with headache disorders routinely face barriers to timely, evidence-based treatment. Prior authorization, repeated reauthorization, opaque step therapy requirements, and abrupt formulary changes are among the most common and harmful obstacles reported by our community.

We commend CMS for recognizing that prior authorization processes for drugs require modernization and greater accountability. We strongly support the agency's efforts to extend interoperability requirements to drugs, improve access to prior authorization information, establish decision timeframes, and publicly report utilization management metrics. These

reforms have the potential to meaningfully reduce administrative burden and improve patient access.

At the same time, we urge CMS to strengthen the final rule to more directly address continuity of care, step therapy abuse, clinician notification of coverage changes, and the real-world burden of repeated utilization management on patients with chronic neurological disease.

I. Prior Authorization Delays Cause Real Harm for People with Headache Disorders

For people living with migraine and other headache disorders, treatment delays are not benign administrative inconveniences. Delayed access to preventive or acute therapy can mean additional attacks, worsening symptoms, lost productivity, missed school, inability to care for children or family members, mental health deterioration, and avoidable emergency department visits — migraine and headache account for more than 4 million ED visits annually at a direct cost of approximately \$4.2 billion (Rhudy et al., *Headache*, 2024). It can also result in progression of disease, with increased attacks leading to chronic migraine or even disability — without adequate preventive treatment, approximately 2.5% of people with episodic migraine progress to chronic migraine each year (Lipton, *Neurology*, 2009).

Many headache therapies are time-sensitive. A patient whose preventive treatment is delayed may experience a cascade of worsening attacks that can be difficult to reverse. A patient who loses access to an effective acute therapy may rely on less effective rescue treatment, increasing suffering and potentially increasing downstream healthcare costs.

We support CMS's proposal to establish and clarify prior authorization decision timeframes for drugs. Timeliness protections are essential. However, we urge CMS to ensure that these standards are meaningful in practice and not undermined by repeated requests for additional documentation, administrative ping-pong, or non-transparent pauses in the review process.

CMS should consider:

- strict limits on unnecessary requests for duplicative documentation
- clear definitions of when a clock begins and ends
- monitoring plans that routinely delay decisions through technicalities
- requiring plans to honor approvals for a reasonable duration absent material clinical change
- ensuring expedited review pathways are accessible for neurological conditions where treatment interruption may cause rapid deterioration

II. Step Therapy Is a Core Access Barrier and Must Be Addressed Directly

We appreciate that CMS specifically requested comment on step therapy and prior payer determinations. This is one of the most important aspects of the proposal.

Step therapy, or fail-first protocols, often force patients to try medications that are ineffective, poorly tolerated, contraindicated, or previously unsuccessful before receiving access to the treatment recommended by their treating clinician. A 2026 peer-reviewed study of 7.7 million patients with migraine found that one in five actively treated individuals (20.6%) experienced payer blocking — defined as denial of prescribed branded migraine medications two or more times due to step therapy or prior authorization — and that patients who experienced blocking had significantly higher rates of emergency department and inpatient admissions (Buse et al., *Headache*, 2026). In headache care, patients may be required to cycle through multiple therapies over months or years despite extensive treatment history. This practice persists despite the 2024 American Headache Society consensus statement endorsing CGRP-targeting therapies as a first-line option for migraine prevention, without requirement for prior failure of older preventive classes (Charles et al., *Headache*, 2024).

We urge CMS to make clear in the final rule that step therapy should be treated as part of the broader utilization management burden subject to transparency and reform.

CMS should strongly consider:

- requiring plans to recognize documented prior treatment failures, including if they occurred under a previous payer
- requiring plans to recognize prior step therapy determinations when a patient changes coverage
- protecting continuity of care for patients stable on therapy from having to repeat fail-first protocols solely because of insurance churn
- requiring accessible, timely override processes when a clinician determines step therapy is medically inappropriate
- requiring public reporting of step therapy approval, denial, and override metrics
- discouraging protocols that require failure on therapies with poor tolerability or no meaningful clinical rationale for the individual patient
- set reasonable limits on the amount of steps required to access prescriber prescribed therapies
- limit requirements for additional prior authorization requests for simply changing the dosage or frequency of an approved therapy

Patients should not have to restart years of failed treatment history every time they change jobs, move states, age into Medicare, or experience another coverage transition.

III. Continuity of Care for Stable Patients Must Be a Central Priority

We strongly encourage CMS to more explicitly center continuity of care in the final rule.

Across the headache community, one of the most damaging experiences is losing access to a treatment that is working because of a formulary change, a new prior authorization requirement, a payer transition, or a new step edit. Patients who have finally achieved some degree of stability after years of trial and error can quickly relapse when treatment is interrupted.

This is particularly concerning in chronic migraine and cluster headache, where stability may represent the difference between functional daily life and severe disability.

CMS should establish stronger protections for stable patients, including:

- grandfathering protections for individuals stable on therapy for a defined period
- streamlined renewals or auto-renewals where no material clinical change has occurred
- recognition of prior approvals during payer transitions
- temporary continuation coverage during appeals or transition periods
- limits on non-medical switching for chronic neurological disease absent compelling justification

Continuity protections would reduce harm, lower administrative burden, and likely prevent higher-cost downstream care.

IV. Transparency Through APIs Is Valuable but Must Be Meaningful and Usable

We support CMS's proposal to require broader access to prior authorization information through patient and provider APIs. Patients and clinicians should be able to understand where a request stands, what was approved or denied, what documentation is missing, and what steps come next.

However, transparency alone is insufficient if the information is incomplete, overly technical, or delayed.

We encourage CMS to require that prior authorization status information be:

- updated in real time or as close to real time as operationally feasible
- presented in plain language for patients
- actionable for clinicians and practices
- specific enough to understand the exact reason for denial
- inclusive of appeal rights and next steps
- interoperable across EHR and practice management systems, not merely technically available

For patients living with disabling headache disease, uncertainty itself can be harmful. Weeks of not knowing whether a treatment will be approved can produce stress, delayed scheduling, and treatment gaps- challenges that are compounded by a severe shortage of headache specialists

— fewer than 900 physicians hold board certification in headache medicine through the United Council for Neurologic Subspecialties, against a projected need of approximately 3,700 (Begasse de Dhaem et al., *Headache*, 2020) — which already limits timely access to appropriate care.

V. Advance Notice of Coverage Rule Changes Is Essential

One of the least visible but most disruptive burdens on patients and practices is the lack of timely notice when plans change formularies, prior authorization requirements, step therapy criteria, preferred products, quantity limits, or site-of-care rules.

Too often, clinicians discover these changes only when:

- a patient arrives for treatment and coverage has changed
- a prescription is rejected at the pharmacy
- staff must urgently resubmit paperwork
- a stable patient suddenly loses access to a longstanding therapy

We urge CMS to add explicit notification requirements in the final rule.

Plans should be required to provide timely electronic notice to affected in-network clinicians and participating practices regarding material utilization management or formulary changes, including:

- new or removed prior authorization requirements
- new step edits or changes to step criteria
- formulary removals or preferred product shifts
- quantity limit changes
- site-of-care restrictions
- changes affecting physician-administered drug coverage

At minimum, notice should occur promptly after finalization and sufficiently in advance of implementation whenever feasible.

This reform would reduce surprise denials, avoid treatment disruption, and allow clinicians to proactively transition or reauthorize care.

VI. Coverage Decisions Should Reflect Current Clinical Evidence and Appropriate Expertise

We continue to hear from clinicians and patients that denials often rely on outdated criteria that do not reflect current evidence or individualized care needs.

Headache medicine has evolved substantially in recent years, with new preventive and acute therapies expanding options for patients who previously cycled through older treatments with limited success or poor tolerability. Medical societies have recognized the rapidly evolving therapeutic landscape for patients and have updated their clinical guidance and position statements several times in recent years to reflect new treatment options and standards of care.

We urge CMS to encourage plans to use transparent, evidence-informed review criteria aligned with updated clinician guidelines from trusted medical associations and to ensure that reviewers evaluating complex neurological cases have appropriate expertise.

CMS should consider requiring:

- publicly available medical necessity criteria
- periodic review and updating of coverage criteria
- specialty consultation pathways for complex cases
- individualized review rather than rigid algorithmic denial pathways

Patients with neurological disease deserve decisions grounded in current medicine, not stale templates.

VII. Physician-Administered Therapies Require Special Attention

Many headache treatments are delivered in clinical settings and can be uniquely vulnerable to scheduling and authorization disruption.

When physician-administered therapies are delayed, patients may miss treatment cycles that were carefully timed, leading to symptom escalation and avoidable disability. Similarly, such administrative burdens or delays can have a real negative impact on clinical decision-making and the clinician-patient relationship; when a clinician believes prescribing a specific therapy may trigger multiple rounds of prior authorization, appeals, or step edits - even when that therapy is clinically appropriate - the expected burden (including staff time and paperwork) can push providers toward therapies that are easier to get approved, but not necessarily better for the patient. The scale of this burden is well-documented: a 2024 American Medical Association survey found that 93% of physicians reported that prior authorization delays patient care, 82% reported that patients abandon recommended treatments due to prior authorization, and 29% reported prior authorization contributed to a serious adverse event for a patient (American Medical Association, 2024).

Likewise, physician-administered therapies have some inherent financial risk under a “buy-and-bill” model. Since those therapies are purchased upfront by the practice, if authorization is delayed or denied, the provider may be stuck holding expensive inventory, reimbursement timing becomes unpredictable, and smaller or community practices will

undoubtedly face economic strain. This risk alone can discourage providers from stocking or offering the therapy at all if there are too many scheduling or authorization disruptions.

We therefore urge CMS to ensure that the final rule fully captures physician-administered drugs and associated workflows, including:

- timely review standards
- clear approval duration rules
- coordination between medical and pharmacy benefit systems
- reduced repeat authorization for stable regimens
- protection against mid-cycle disruption caused by administrative changes

VIII. Public Reporting of Metrics Should Include What Patients Need to Know

We support public reporting of prior authorization metrics. Transparency can drive accountability and illuminate patterns invisible to the public.

We encourage CMS to ensure reporting is consumer-friendly and includes:

- approval and denial rates
- appeal overturn rates
- average and median decision times
- frequency of requests for additional documentation
- rates of repeat prior authorization for previously approved therapies
- step therapy override approval rates
- metrics by therapeutic category where feasible

Patients should be able to compare plans not only on premiums and networks, but also on how often medically necessary care is delayed and/or denied.

Conclusion

AHDA applauds CMS for undertaking this important rulemaking. Prior authorization reform is urgently needed, and the proposed rule contains several meaningful steps forward.

We respectfully urge CMS to strengthen the final rule by:

- treating step therapy as a core utilization management issue
- protecting continuity of care for stable patients
- requiring recognition of prior determinations across payer transitions
- mandating timely notice of formulary and utilization management changes
- ensuring transparency tools are usable and actionable
- promoting evidence-informed review criteria

- strengthening protections for physician-administered therapies
- expanding meaningful public reporting of metrics

For the approximately 39 to 40 million Americans living with migraine and other headache disorders (Cohen et al., *Headache*, 2024), these issues are not theoretical. They shape whether patients can work, care for family, remain in school, and live with dignity. Only 11.5% of people with migraine successfully reach consultation, diagnosis, and minimally appropriate treatment — and among those with chronic migraine, that figure drops to 2.7% (Lanteri-Minet et al., *J Headache Pain*, 2024). Prior authorization and step therapy are measurable contributors to that failure rate.

We appreciate the opportunity to comment and stand ready to be a resource to CMS as it finalizes this rule.

With Appreciation,

Alliance for Headache Disorders Advocacy
American Headache Society
Chronic Migraine Awareness
Clusterbusters, Inc.
Danielle Byron Henry Migraine Foundation
Facial Pain Association
Great Lakes Regional Headache Society
National Headache Foundation
Headache Cooperative of the Pacific
Miles for Migraine
National Headache Foundation
US Pain Foundation