Step Therapy Fails Patients

A POLICY PANEL DISCUSSION

HEADACHE ON THE HILL

The Headache & Migraine Policy Forum

AHDA ALLIANCE FOR HEADACHE DISORDERS ADVOCACY
INTRODUCTION

Timely access to care is critical for people living with migraine and other headache disorders. But far too often, it’s unattainable—often because of a practice known as step therapy, or “fail first.”

In fact, more than 90% of people who receive treatment for migraine encounter step therapy, with many having to try multiple medications before getting the one their doctor prescribed.

Health plans hope the practice, which requires that patients try an insurer-preferred medication before being approved for the one prescribed by their health care provider, will cut costs. In reality, step therapy delays—and sometimes outright prevents—people from getting optimal care.

For people living with migraine and other headache disorders, step therapy can be frustrating and painful.

Step therapy was front and center at the eighth annual Capitol Hill Policy Forum, hosted in March 2024 by The Headache & Migraine Policy Forum (HMPF) and the Alliance for Headache Disorders Advocacy (AHDA).

The policy panel discussion coincided with the annual AHDA Headache on the Hill fly-in, which brought together more than 200 patients from all 50 states to Capitol Hill. Advocates, health care providers and policymakers used the opportunity to explore migraine patients’ experience with step therapy and consider opportunities for legislative reform.

Julienne Verdi, Executive Director AHDA
FEATUERD SPEAKER

U.S. SENATOR
LISA MURKOWSKI

U.S. Senator Lisa Murkowski (R - Alaska), a longtime champion of utilization management reform and patient-centered care, kicked off the event.

Sen. Murkowski thanked patients and advocates for attending the event and applauded their dedication to pushing back against onerous insurance barriers.

For Sen. Murkowski, reducing burdens like step therapy is particularly important for people in rural states such as Alaska. It’s also essential to ensuring patient access to optimal care and treatment.

“As you all know, step therapy protocols often delay necessary treatment and create impacts that actually increase health care costs. We’ve all seen the harm that the ‘fail first’ approach to medicine can cause. It’s time for Congress to address that, which is why I’ve introduced the Safe Step Act.

I think this legislation is long overdue. But I’m happy to share that the Health Committee has now favorably reported it as part of [pharmacy benefit manager] reform. We’re one step closer to ensuring patients suffering from migraine can get the care they need when they need it.”

ABOUT THE SAFE STEP ACT

The Safe Step Act, S.652 /H.R. 2630, is bipartisan legislation that would require health plans to allow patients to skip certain insurer mandated steps in their medication plan if needed. For example, if a medicine isn’t working and could harm patients or stop them from doing daily tasks, they must be given an exception. The legislation would also require the health plan to clearly explain how to ask for this exception and to respond quickly.

Sen. Murkowski is among 39 bi-partisan cosponsors and one of the original 18 co-sponsors of the bill.
A patient with a long history of migraine, Karla illustrated how the condition can impact a person's life. Her journey with headache and migraine began in middle school. Since then, she has traveled a daunting treatment path that, because of step therapy, has entailed 50 treatments.

“A lot of decisions in my life are made for me by my disease,” Karla said.

Her attempt to access infusion therapy was particularly arduous. Karla was a new mother at the time. She stopped breastfeeding and endured nine months of different injectable treatments before being approved for infusion therapy. The prolonged process, she said, took a major toll on her mental health.

Karla also highlighted how migraine has affected her family life. Migraine makes being a mother difficult, Karla explained. Her experience underscores the emotional and psychological impact of navigating the insurance system while also dealing with the relentless burden of migraine.

Dr. Khoury added a medical professional’s perspective to the discussion. He emphasized how frustrating the barriers imposed by insurance companies, particularly step therapy, can be.

The process of step therapy, he said, not only delays effective care but also strains the patient-physician relationship. He added that this practice can seriously compromise migraine patients’ health.

“That's the thing about insurance companies,” Dr. Khoury said. “They don't care about the patient. They care about not paying.”

By delaying access to critical treatment management, he said, patients are often driven to emergency rooms. Among all disease-state groups, migraine patients are the fourth highest utilizers of the emergency room. This method of care can lead to disease mismanagement and ultimately chronic migraine. It’s costly for both patients and the health care system.

Dr. Khoury’s insights illustrated the physician's dilemma and challenges of advocating for patients in a profit-driven insurance landscape.
CHARLOTTE PINEDA
HEALTH POLICY DIRECTOR, OFFICE OF SENATOR ROGER MARSHALL (R-KS)

Charlotte provided background on the Safe Step Act. The legislation, she explained, offers a glimmer of hope for migraine patients and others with headache disorders struggling to access effective treatment.

“If you’re already stable - formulary change or not - you shouldn’t have to fail first” Charlotte said.

The Safe Step Act seeks to place reasonable limits on step therapy. For instance, if patients are already stable on a treatment, they should not be forced off it because of formulary changes.

Charlotte also emphasized the importance of advocacy. She encouraged attendees to tell policymakers their step therapy stories and describe the financial and emotional toll they endured. Highlighting the hidden costs, she explained, allows budget-minded policymakers to see the long-term benefit of the Safe Step Act.

SARAH BUCHANAN
SAFE STEP COALITION

The Safe Step Coalition has galvanized patient advocates around the passage of the Safe Step Act. Sarah described how the group’s advocacy began at the state level, where advocates learned just how pervasive and pernicious step therapy was.

Sarah described one event where “every patient in the room stood up and said, ‘Me too.’ To hear the cracks in their voice,” she recalled, “it was just so devastating.”

These findings spurred the group to push for the nation’s first-ever step therapy laws, but they were confined to the state level. The challenge with state-based laws, Sarah explained, is that regulations apply only to some commercial plans – but not all. The Safe Step Coalition saw a need for reform at the federal level.

Sarah shared a few tips with attendees about how to best advocate for step therapy reform, particularly the importance of meeting and following up with policymakers. The more-than-200 people attending the Capitol Hill Policy Forum were scheduled to have nearly 300 meetings that same day with legislators and staff.

Since the group’s Capitol Hill day, the Safe Step Act has received additional co-sponsors.

The panel discussion was moderated by Amaal Starling, MD, of the Mayo Clinic in Scottsdale, Arizona.
POLICY RECOMMENDATIONS

This year’s Capitol Hill Policy Forum underscored the importance of the Safe Step Act.

Federal policymakers can support people living with migraine and other headache disorders by:

• Co-sponsoring and passing the Safe Step Act, which would allow migraine patients to bypass certain health plan-mandated medication steps and access the correct treatment with as little delay as possible.

Advocates can further support passage of the Safe Step Act by:

• Engaging and amplifying the Safe Step Coalition’s resources on the legislation.

To learn more about topics discussed at the event, as well as HMPF’s and AHDA’s policy priorities and advocacy initiatives, visit:

• www.headachemigraineforum.org
• www.allianceforheadacheadvocacy.org

ABOUT THE HEADACHE & MIGRAINE POLICY FORUM

The Headache & Migraine Policy Forum advances public policies and practices that promote accelerated innovation and improved treatments for persons living with headache disorders and migraine disease.

ABOUT THE ALLIANCE FOR HEADACHE DISORDERS ADVOCACY

The Alliance for Headache Disorders Advocacy is an umbrella organization uniting headache advocates nationwide. The organization’s ongoing mission is to make life better for the millions of Americans living with headache disorders in our country.