

# TREATMENT CHALLENGES FOR PEOPLE WITH HEADACHE AND MIGRAINE DISEASE

A WHITE PAPER FROM THE HEADACHE & MIGRAINE DISEASE WORKING GROUP

**T**oday, approximately 12 percent of the global population experiences migraine attacks.<sup>1</sup> And more than one third of these people have at least 15 migraine days per month.<sup>2</sup>

More than “just a headache,” migraine is a hereditary neurological disease that affects people both physically and mentally. In addition to the pain of migraine attacks, the disease negatively affects patients’ ability to work, social relationships with family and friends, and the

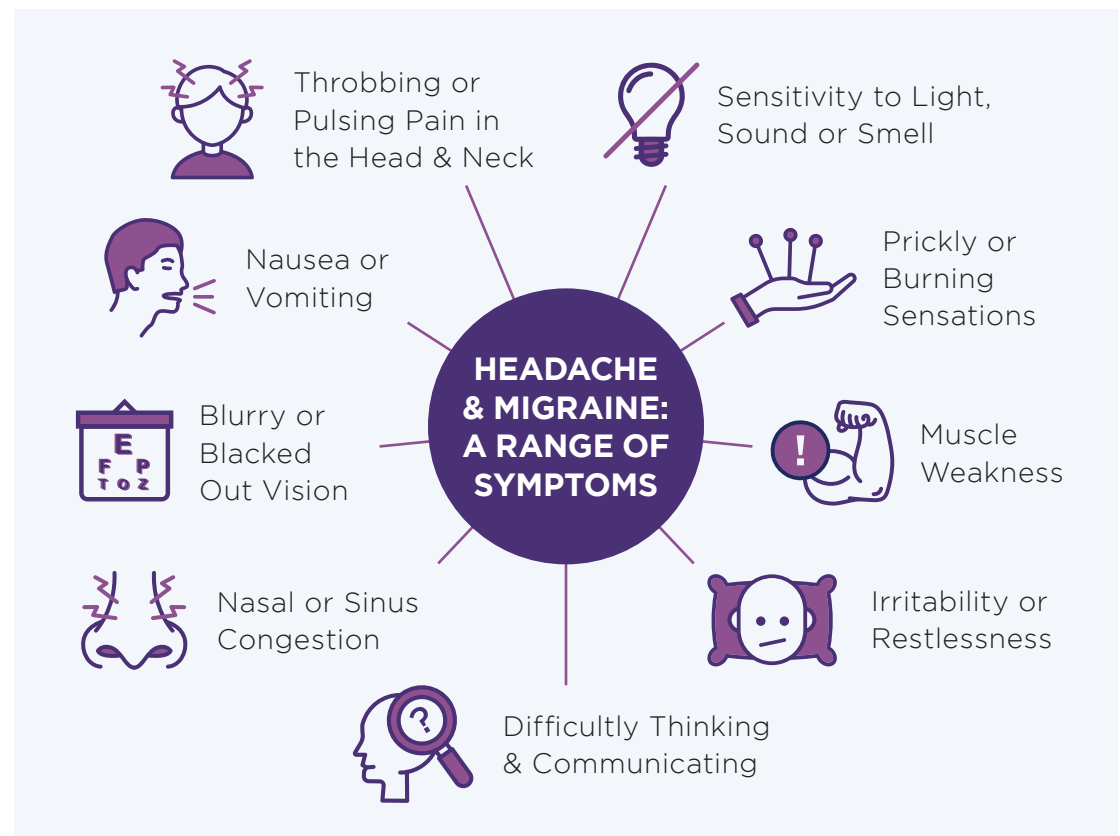
ability to provide basic self-care and to undertake normal life activities.

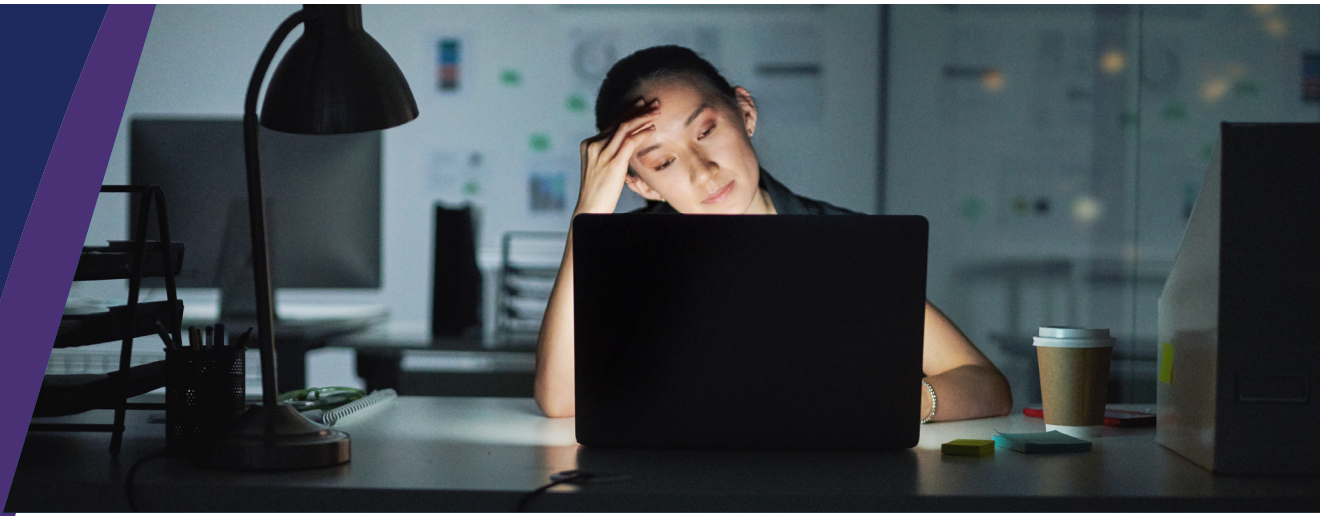
Researchers are just beginning to understand the indirect costs of migraine to society. By conservative estimates, migraine costs employers approximately \$4,000 per person per year and represents an economic loss of more than \$13 billion annually to employers.<sup>2</sup> There also exists a high burden on family and caregivers. Beyond the quantitative impact, migraine robs many people of a meaningful quality of life.



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## HEADACHE & MIGRAINE TREATMENT

A variety of medications exist to prevent and treat migraine. Managing migraine typically requires several of these treatments, often used concurrently.

Efficacy and side effects vary by patient and medicine. Opioids, for example, are widely prescribed because they are inexpensive and may temporarily block the pain. They can, however, be highly addictive, and they do not impact the underlying migraine process. In fact, they may also negatively affect the efficacy of some preventive treatments.<sup>3</sup> Yet, alarmingly, opioids account for nearly 10 percent of total medications prescribed to treat chronic migraine.<sup>4</sup> More than 15 percent of migraine patients have had an opioid prescription, according to a recent study.<sup>5</sup>

Research continues to improve migraine-specific treatments with the advent of botulinum neurotoxins and innovative biologics like calcitonin gene-related peptide (CGRP) inhibitors. And newer medicines are on the horizon. This should give hope to those living with headache and migraine disease and also should reduce the use of opioids by those living with migraine.

In addition to prescribing medications, health care providers should consider advising their patients with headache and migraine about complementary approaches like physical or talk therapy as part of a multimodal treatment strategy.

## IMPROVING ACCESS FOR HEADACHE & MIGRAINE PATIENTS

Timely access to appropriate treatment is critical for reducing the impact that headache and migraine attacks have on patients, loved ones, workplaces and communities. Effective control of this “invisible disease,” which has no biomarkers, requires a relationship of trust and communication between patients and health care providers.

But accessing treatment, or even a clinician who can help, can be difficult. In some cases, patients are challenged to identify which providers within their health plan’s network are headache specialists.

Insurance barriers can also impose a one-size-fits-all approach to the treatment of a complex disease across a heterogeneous population – disregarding the individual needs of each patient. Such insurance barriers to headache and migraine treatment take a variety of forms.

## TREATMENT & ACCESS BARRIERS

### *Prescriber Restrictions*

Some insurers allow only certain types of clinicians to prescribe certain types of medication. Restrictions may limit prescribing abilities for targeted medicines to neurologists, headache specialists or, in the most limiting cases, those with a certification from the United Council for Neurological Subspecialties.

But there are fewer than 500 UCNS specialists across the United States, and more than 36 million people living with migraine disease. In some states, such as Kansas, there are zero UCNS-certified headache specialists; patients whose insurance plans have put into place prescriber restrictions must travel to another state to seek an appointment.

The challenge of having so few clinicians to treat so many patients creates several access barriers. The time patients must wait for an appointment is the most obvious. In large metropolitan areas, the average wait time for an appointment at

a headache specialty center is more than 15 months.<sup>6</sup> In the time patients wait to see a specialist, their condition may worsen.

The distance between patients and specialists poses another challenge. Specialists are often clustered in metropolitan areas or academic research centers.<sup>7</sup> Not all patients can easily absorb travel costs including gas, hotels and food, in addition to time away from work and possible childcare expenses. Additionally, patients may not know on any given day if they will be well enough to travel for treatment.

Prescriber restrictions also increase pressure and patient load for UCNS-certified clinicians, increasing the likelihood of burnout. This creates an even smaller pool of “approved” providers – which further harms patients in need of treatment.

### *Non-Medical Switching*

Non-medical switching occurs when an insurer compels a stable patient to switch to a medication that’s less expensive for the health plan – regardless of medical factors.



Research shows this can actually lead to higher non-drug costs downstream, including expenditures for more physician visits, lab tests, ER visits and the like.<sup>8</sup> And for patients, the quality-of-life impact can be devastating. In one study, patients reported having trouble staying productive at work, feeling anxious and sad, and even abandoning their medication regimen after being switched.<sup>9</sup> For patients with acute conditions, switching to a less effective medication – one that could take weeks or months instead

of hours or days before its effectiveness is realized – can be particularly problematic.

Health plans may impose non-medical switching by abruptly changing their formulary of approved medications. Other non-medical switching techniques involve increasing patients' out-of-pocket costs for their medicine so much they can't afford it or forbidding co-pay coupons from counting toward patients' annual deductibles, making the medication unaffordable.



## A MIGRAINE PATIENT'S NON-MEDICAL SWITCHING NIGHTMARE

*A 68-year-old patient and her husband drove six hours from their rural community to see me, a headache specialist. The wife has suffered from migraine attacks since she was a teenager, but her symptoms had worsened to the point that she attempted suicide by walking into the desert with the goal of not walking back.*

*Now, months later, she and her husband sat in my office describing the myriad of medications that were once helpful but no longer provided any relief. Aiming for effective therapy fast, I prescribed a fast-onset CGRP inhibitor. And provided a sample so the patient could begin it immediately.*

*A month later she was thrilled to report the medicine worked well – just three migraine attacks since her last visit. But she had a new issue: Medicare wouldn't cover the medicine. And at a cost of more than \$650 a month, she couldn't afford it. I gave her another sample and filed an appeal.*

*She returned again a month later having had just one migraine attack. And her appeal was approved. Yet with a \$500 per month co-pay, she couldn't afford the medicine that kept her well. Her voice quivered as her eyes filled with tears. "I've been to the emergency room 18 times in the last year," she said, "Eighteen times!"*

*I had no choice but to switch her medication to one with a lower monthly co-pay. And hope that it worked enough to keep her out of the ER.*

Heather McCoy, DRNP, Scottsdale, Arizona

### *Restrictions on Combination Therapy*

Similar to treatment for other disease states, coping and managing migraine often requires multiple medications used concurrently. For example, patients routinely take preventive medications in combination with rescue medications. Some patients also benefit from taking multiple preventive medications together. Research shows that combination therapy is effective for treatment of migraine in children and adults.<sup>10, 11</sup>

However, insurers have begun limiting their approval of some treatment combinations. Take botulinum neurotoxins and CGRP inhibitors, for example. One national health plan's prior authorization form

goes so far as to require providers to explain in detail the rationale for using these two treatments concurrently. Yet, despite asking for this information, the health plan is denying coverage at an alarming rate, clinicians and patients report.

### *Prior Authorization and Punishment for Performance*

Headache and migraine patients also face treatment delays because of insurers' use of prior authorization and re-authorization. The practice requires that insurers approve drugs or therapies before patients can begin taking them. Typically, prior authorization requires that clinicians complete onerous multi-page forms detailing the patient's clinical and treatment history, and that they



## **“INVESTIGATIONAL” COMBINATION THERAPY**

*Many health plans have repeatedly rejected botulinum neurotoxin claims for patients whose medical files show they have been given a free sample of a CGRP, even when evidence shows the combination therapy has been more effective than either treatment in isolation.*

*Insurers justify denials by arguing that, because the two medicines weren't studied together in clinical trials, concurrent use is “investigational” and not covered. The rationale is disingenuous. In research, it's routine for patients to be excluded from a clinical trial because they are using another medicine. The reasoning is also inconsistently applied; health plans routinely cover other combination therapies.*

provide supporting documentation. Each insurer has its own forms, which can take hours to complete. Despite clinicians' efforts, insurers often deny the requested treatment anyway.

Exacerbating clinicians' frustration with the prior authorization process is the need for re-authorization of the same treatment. This often occurs with the use of botulinum neurotoxin. Some insurers require a new authorization for every injection, which can occur as frequently as every 12 weeks.

Aside from the paperwork and time it takes clinicians, the process puts patients on an emotional rollercoaster. If the treatment is working, they will experience fewer migraine days per month. But, paradoxically, if they have too few migraine days, insurance won't cover the treatment that's keeping them well. A patient may be considered "episodic," meaning he or she has zero to 14 headache days per month, rather than "chronic," characterized as having 15 or more headache days

per month.<sup>12</sup> This "punishment for performance" denies treatment for a patient based on its effectiveness, resulting in denials and patients cyclically returning to a higher number of headache days and a chronic migraine status.

Patients can also be punished in another way: if their medicine works, but not well enough, according to their insurance. The medicine may effectively reduce the number of headache days or the severity of attacks that a patient experiences, but the decrease may not be significant enough for insurance to continue covering the treatment. Making matters still more complicated, insurers' thresholds can change on a whim.

The level of frustration and pain these situations causes patients is unfathomable. And those patients who are not given the opportunity to manage their disease may be forced to seek Social Security disability status, resulting in additional costs to the health care system.



## CONCLUSION

Headache disorders and migraine disease steal dreams, destabilize families and cut careers short. Meanwhile, workplaces in the United States lose an estimated \$50 billion dollars annually in absenteeism, lost productivity and medical expenses caused by migraine.<sup>13</sup> Yet restrictive insurance policies keep patients from the very medications that can prevent and treat these conditions.

Policymakers, patients, advocates, insurers and clinicians must come together to find solutions that mitigate barriers to treatment. Only then can patients achieve optimal health, improving their lives and enhancing the lives of those around them.

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*Please note that the views expressed in this document do not necessarily reflect those of the institutions with which working group members are affiliated.*

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## ABOUT THE HEADACHE & MIGRAINE DISEASE WORKING GROUP

*The Headache & Migraine Disease Working Group is a unique network for clinicians and advocates interested in public policy related to access to therapies for headache and migraine disease. Working group members collaborate in the development of educational resources and participate in advocacy initiatives that promote informed policymaking, particularly relating to state access to innovative medical therapies.*

*To learn more, visit [AllianceforPatientAccess.org/headache-migraine](https://AllianceforPatientAccess.org/headache-migraine)*



**Headache & Migraine  
Disease Working Group**