

PLAN 2025

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Message From the Community

In recent years, the migraine community has been called to action with increased frequency.

- Advocates have addressed complex value assessments, raised awareness with an increased support from Capitol Hill and broken down payer access challenges to innovative treatment options.
- We have partnered with like-minded advocates in other communities, such as the veterans' population.
- We have acknowledged disparities in care and sought to address them.

At every turn, our community has risen to the occasion, set record levels of patient and clinician engagement, and created change.

As advocacy efforts have deepened, there has also been an increased need to have a network to serve as strategic counsel. No single group can do this work alone. But we can find more ways

to cross-collaborate, maximize resources and get to goals faster.

The Headache Disease Policy Advocacy Network, or HDPAN, was formed in early 2021 with an ambitious goal: launching a four-year strategic plan that would guide advocacy toward real and strategic gains. We've had individual successes addressing state-based issues as they arise, but we know policy changes come from the top down. We must focus on system-wide change.

It is our sincere hope that Plan 2025 will help guide, drive and accelerate us forward to do all we can for the millions of patients living with headache disorders and migraine disease.

While this plan is the first of its kind, it certainly won't be the last. We intend to hold ourselves accountable by reviewing our promises and renewing our efforts each year.

Thank you for your commitment and passion as we embark on this new journey.



Overview

Plan 2025 is the result of an in-depth, multi-organization-wide process that represents vital input from patients, clinicians, advocacy groups and fellow stakeholders. The strategic planning process required the community to ask some critically important questions, including:

- How can we drive policy advocacy goals rather than react to challenges?
- How will we secure the necessary support and policy backing we need to succeed?
- How can groups work together better?

The strategic plan reaffirms the community's mission and core values of advancing public policies that provide more research and federal support for headache and migraine disease as well as promote innovation and improve access to patient-centered treatment.

The plan centers on three key focus areas:

- Access, Payers & State Policy
- Federal Outreach & Research
- Health Technology Assessments

The strategies associated with these focus areas are not meant to stand in silos, but to reinforce and strengthen each other across mission priorities to create greater impact.

Toward that end, the plan envisions the next four years by identifying measurable outcomes, achievable by diligent interconnectedness and purposeful advocacy.

Core Values

The efforts outlined in this plan are rooted in several core values that motivate and bind the migraine community.



Patient-Centered Care

Patients are individuals with unique experiences, and migraine and headache disorders are spectrum diseases necessitating a tailored approach to care and treatment. The primacy of clinician-patient decision making must remain a priority without third-party intervention. As a network, we advocate for equitable access to patient-centered care.



Multidisciplinary Collaboration

As a community, we must align on common goals and work together in the best interest of the patients we serve. Strategic partnerships with patient advocacy groups, medical societies, and policy organizations are critical. Together, we think “big picture” and ensure everyone has a voice in policy advocacy.



Patient & Clinician Empowerment

In health care decision making, patients must be allowed to work in partnership with clinicians. To achieve successful shared decision making, patients need effective educational tools to support discussions with their clinicians, decide their treatment goals and navigate their treatment journey.



Solutions & Accountability

We intend to revisit the plan at the end of each year to identify measurable progress and to consider how we may need to pivot to effect change. We will hold ourselves accountable and remain focused on moving forward.



2021-2025

Focus Areas & Measurements

FOCUS AREA ONE Access, Payers & State Policy

The treatment advancements of recent years hold little value unless they are adequately covered by health plans and made accessible to people living with migraine disease and headache disorders.



Making the Cost-Benefit Case for Effectively Managed Migraine Disease

Payer operations have historically been specific and siloed — separate budgets for pharmacy benefits and hospital benefits, for example. Claims are viewed as absolute cost drivers and not compared for cost-effectiveness. That is, payers don't ask, "If I approve this pharmacy benefit claim, will emergency care claim costs go down?"

Payers are just beginning to use a long-term view to drive strategic value by better understanding the relationship between preventive and hospital care. Given that people with migraine are the fourth highest users of the ER, there is a compelling and data-driven case that preventive and acute treatment can lead to overall cost savings for payers. They also offer strategic value for patients.

Building upon the initial conversations between payers and migraine advocacy organizations, we envision strategic outreach to:

- Blue Cross Blue Shield Association
- National Association of Managed Care Physicians
- America's Health Insurance Plans
- Large commercial market payers in CA, FL, TX and NY



Fighting Overly Burdensome Utilization Management Restrictions

With all of the innovative treatment options, including devices, that have come to market in the past several years, payers have responded by restricting access. Utilization management techniques include prescriber restrictions,

step therapy protocol, prior authorization, and refusal to cover combination therapy. The migraine community has been well organized to effectively respond to some of the most egregious restrictions through sign-on letters, social media campaigns, and patient education about how to overcome these barriers. However, challenges remain.



State Medicaid P&T Committee Reviews

Individual states administer Medicaid programs. Each quarter, pharmacy and therapeutics, or P&T, committees meet to determine coverage policy, including whether both new and existing therapies and devices should be covered. Determinations typically occur without any clinician or patient input, despite the fact that decisions affect a significant number of covered lives. We aspire to provide regular input to these committees.



State Utilization Reform Legislation

Across the nation, groups seek to reform onerous and restrictive utilization management tactics. In years past, The Headache & Migraine Policy Forum has circulated sign-on letters and advocated with state legislatures on step therapy and prior authorization reform. There is also a need to mobilize advocates on a state level to engage in grassroots efforts such as testifying, meeting with state legislators, and taking advantage of opportunities to draft op-eds and undertake earned media efforts.

Yearly Measurements

2021

- **UM Restrictions:**
Identify data gaps and resources required to marshal evidence (claims data) on cost effectiveness of preventive treatment and well-managed care
- **State Medicaid P&T Committees:**
Identify top 5 states for engagement and determine how to track quarterly board meetings

2022

- **UM Restrictions:**
Create educational materials including “Model Insurance Coverage for Migraine Patients” and cost-effectiveness report cards. Begin outreach with insurance stakeholders
- **State Medicaid P&T Committees:**
Track quarterly meeting agendas and identify opportunities for engagement; cultivate patient and clinician advocates and facilitate engagement

2023

- **UM Restrictions:**
Set meetings and begin advocacy with select national and state-based payers
- **State Medicaid P&T Committees:**
Add additional states to dashboard

2024

- **UM Restrictions:**
Communicate positive coverage policies with employer groups and generate earned media opportunities

FOCUS AREA TWO

Federal Outreach & Research

Building upon past successes, federal advocacy will take a multi-phase approach that includes all three branches of government: legislative, executive and judicial.

GOALS INCLUDE:

- Additional federal research funding
- Access to oxygen treatment
- Inclusion and equity on disability and disparity issues
- Passage of a first-ever congressional resolution on migraine disease and headache disorders.



Federal Research Funding

Federal funding for migraine disease research is still meager considering the disease burden. The Alliance for Headache Disorders Advocacy, AHDA, has identified funding streams through the Department of Defense, VA and NIH to close this gap. It has also achieved success through the appropriations process to ensure that NIH prioritizes some of the \$500M Helping to End Addiction Long Term initiative funding toward research on headache disorders.

The community has also strived to improve specialty care for U.S. veterans with chronic headache disorders,

working with Congress to secure appropriations to establish Headache Disorders Centers of Excellence within the VA health care system.



Oxygen Access for Cluster Headache

The Centers for Medicaid and Medicare Services does not cover home-use oxygen for cluster headaches. However, newly appointed leadership within CMS presents new opportunities for the migraine and headache community to engage with decision makers to appeal the national coverage decision.



Disability, SSA, Accommodations & Health Disparities

Engagement with all three branches of government will be critical to making lasting policy changes for the migraine and headache community. Through education and advocacy, the HDPAN will:

- Empower the new administration to recognize the disparities and discriminations headache and migraine patients face in health care access and everyday living

- Identify legislative champions to elevate these issues in Congress and introduce policy solutions
- Pursue legal remedies to ensure headache disorders and migraine disease are recognized as a serious disability with qualifying benefits.



Congressional Resolution on Migraine Disease and Headache Disorders

The inaugural Advocacy Day of Action will culminate with migraine and headache community advocates contacting their representatives in Congress to request support of a House Resolution (H.Res), designating June as Migraine and Headache Awareness Month. The resolution will broaden congressional support for the migraine and headache community and educate representatives about the impact of the disease.

Accomplishments in federal advocacy are measured incrementally given the slow-moving timetable of Congress and change in priorities of administrations. Therefore, annual measurements will not be as simple and easily identifiable.

Yearly Measurements

2021

- **Congressional Resolution:** Introduction by Rep. Madeleine Dean, June 2021; significant number of co-sponsors by year's end
- **Oxygen Access:** Anticipate decision from CMS on the AHDA-initiated appeal for coverage of home-use oxygen. Letter to CMS administrator requesting further review of national coverage decision if necessary
- **Federal Research Funding:** Strengthen relationships with veteran community

2022

- **Disability, SSA, Accommodations & Health Disparities:** Identify and begin outreach to like-minded stakeholders who are also shut out of the list of qualifying conditions for IDEA and other federal disability programs
- **Federal Research Funding:** Headache on the Hill appropriations requests; develop new congressional champions. Strengthen relationships with veteran community
- **Congressional Resolution:** Increase co-sponsors and work with champions to have resolution brought to a floor vote

2023

- **Disability, SSA, Accommodations & Health Disparities:** Pursue strategic policy and necessary legal remedies to include migraine disease
- **Federal Research Funding:** Continue Headache on the Hill appropriations requests; reach \$25 million in funding for VA Headache Disorders Centers of Excellence

2024

- **Federal Research Funding:** Continue Headache on the Hill appropriations requests



FOCUS AREA THREE

Health Technology Assessments

Though the Affordable Care Act prohibits Medicare from making drug coverage decisions based on cost-effectiveness,² nearly half of insurance companies “strongly agree” that an independent health technology assessment body is needed to counterbalance the perceived strain of innovative medicines on their budgets.³ Insurance plans representing 88% of pharmacy lives intend to use Institute for Clinical and Economic Review, ICER, assessments in their decision-making.⁴ Without question, this topic will continue to impact whether persons living with migraine and headache disorders can access innovative therapies and devices to manage their disease.

To that end, the community can continue to provide new information to groups like ICER to encourage a more fulsome economic model. The community can also weigh in on state legislation on “value” as more states consider using the quality adjusted life year, or QALY, and similar measures that have been found discriminatory to patients living with chronic diseases like migraine.



Diversity & Representation in Clinical Trials

Groups like ICER use economic models that are imbalanced and incomplete in many ways, but in particular lack key data from communities of color. By focusing solely on clinical trials data, ICER value assessment outcomes do not reflect the real world yet have very real impacts on communities without a voice in the process.

Manufacturers and advocacy groups continue to raise awareness of the importance of including more persons of color in clinical trials. But it is still imperative that groups like ICER

acknowledge the current disparity by changing their economic modeling to offset this lack of critical data. Typically, ICER has included some disparity data in its qualitative modeling but not in ways that meaningfully affect outcomes.



Real-World Evidence for ICER Input, AHRQ & PCORI

Along with closing the gap in disparities data, real-world evidence needs to be brought to ICER — and a policymaking audience as well. The mission of the Agency for Healthcare Research and Quality, or AHRQ, is to produce evidence to make health care safer, higher

quality, more accessible, equitable and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. AHRQ requests that researchers, patient advocacy groups, and other stakeholders get involved by suggesting topics, commenting on key questions and draft reports, submitting supplemental evidence and data to make sure evidence is used and understood. The migraine community should devise a plan to actively engage with AHRQ.



Value in the States & Ensuring Equitable Access

Since 2020, 60 state bills have been proposed or enacted to address drug pricing in the United States. ICER's model and use of the QALY has served as a platform to introduce value-based design into state decision-making through the creation of prescription drug affordability review boards that would set prices for certain therapies and potentially result in loss of access to innovative medicines. HMPF is a member of the Value in the States Coalition, which seeks to engage on these bills.

1. <https://healthcare.mckinsey.com/next-generation-member-engagement-during-care-journey/>
2. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 subsection 6301, 124 Stat. 119, 740 (2010) (codified at 42 U.S.C. subsection 1320e-1), <https://www.govinfo.gov/content/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>
3. <https://www.tandfonline.com/doi/pdf/10.1080/1396998.2019.1632203?needAccess=true>
4. <https://www.eversana.com/insights/icers-unsupported-price-increase-assessment/>

Yearly Measurements

2021

- **Diversity in Clinical Trials:** Identify like-minded disease states who wish to engage ICER on this topic
- **Value in the States Coalition:** Continue to participate in coalition activities; invite other members within the migraine community to join

2022

- **AHRQ:** Compile list of research topics submitted to AHRQ for consideration for a technical brief or systematic review
- **Diversity in Clinical Trials:** Publicly amplify patient narratives from communities of color on issue of access to groups like ICER
- **Value in the States Coalition:** TBD

2023

- **AHRQ:** Provide input to research during public input periods
- **Diversity in Clinical Trials:** Submit letter to ICER with suggested changes to their framework to increase meaningful representation

2024

- **Strategically Disseminate to Migraine Community Stakeholders** Including clinicians, health care systems, policymakers and others who need and want to use evidence for decision-making

Appendix

BUILDING ON POLICY ADVOCACY SUCCESSES

The headache community has made tremendous strides in recent years.

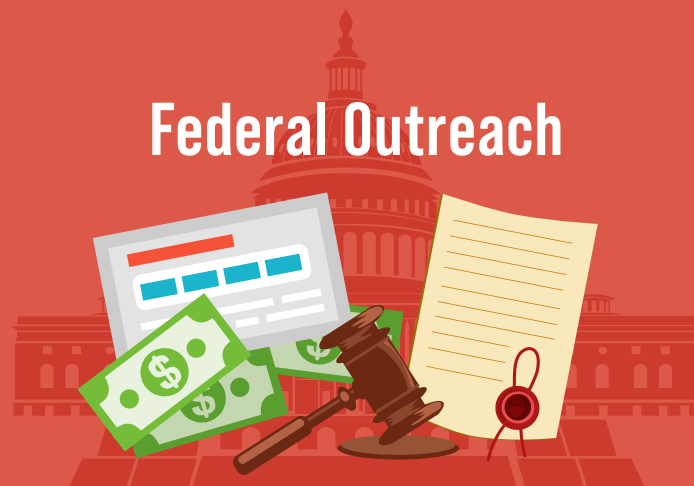


State Access Challenges

Advocates have challenged:

- Prescriber restrictions
- Prior authorization
- Step therapy
- Medicaid P & T committee decisions

Federal Outreach



Headache on the Hill has:

- Grown from 45 to 217 advocates
- Contributed to establishing VA Centers for Excellence in headache
- Encouraged increased funding for National Institutes of Health

Health Technology Assessments

Headache advocates have:

- Contributed record numbers of patient comments for the 2018 ICER review of CGRP inhibitors
- Spurred positive outcomes for 2018 and 2020 ICER review of migraine therapies



HDPAN
Headache Disease Policy Advocacy Network

Bound by a shared vision and coordinated approach to advocacy, the migraine community is poised to build on past successes by effecting measurable change by 2025.