The Headache & Migraine
POLICY FORUM

October 18, 2019

Submitted electronically to: publiccomments@icer-review.org

Steven D. Pearson, MD, President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Migraine Community Input for ICER's 2020 Value Assessment Framework

Dear Dr. Pearson:

On behalf of the Headache and Migraine Policy Forum (HMPF), thank you for the opportunity to provide input as ICER considers improvements to its revised value assessment framework for 2020.

HMPF recognizes that health insurers and policymakers today are increasingly committed to defining value based upon medical therapies' clinical effectiveness and rely upon groups like ICER to help make such preliminary assessments. Your ability to employ methodology that is fair, patient-focused, and comprehensive is important and we applaud your willingness to improve upon your process. HMPF asks that you remember that, more than any other stakeholder, it is patients and caregivers who will feel the impact when value assessments influence health plans' formulary, coverage and cost-sharing decisions.

With that in mind, HMPF proposes the following recommendations for improving ICER's revised value assessment framework regarding methodology, deliberation, and process:

METHODOLOGY / MODEL

The Use of the QALY in Value Assessments Impacting Chronic Diseases Like Migraine is Discriminatory and Should be Replaced by a Patient-Centered Methodology.

We urge ICER to apply methodologically sound and clinically useful techniques – but that does not include usage of the QALY. For heterogeneous populations like migraine patients, indirect comparisons are infeasible. ICER should consider important prognostic factors, such as age, previous treatment history, baseline pain levels, and the fact that migraine attacks do not have a static start and end point, making determination of the exact number of headache days challenging to determine.

QALYs also result in lower ICER valuations for regenerative or life-enhancing therapies. Fort he migraine community, any therapy that improves outcomes for the migraine patient population that is chronic or high/medium-episodic or poorly responds to existing therapies has tremendous value to this community.

Finally, translation of a QALY-based value assessment to coverage and access has been found to be discriminatory against people with disabilities by the U.S. Department of Health and Human Services.[1] Migraine patients are more than twice as likely as those not living with migraine disease to be disabled.[2] Applying a single rigid framework across many chronic diseases is therefore problematic and should be adjusted or disregarded in favor of usage of the DALY for certain diseases.

Future ICER Value Assessments Should Consider the Beneficial Cost Impact of Reducing Co-Morbid Conditions and Use Real World Evidence in Such Considerations.

HMPF supports ICER's recent recognition of the importance of real-world evidence (RWE) and looks forward to its use in future reports in order to more accurately represent value to the patient. We agree that RWE is a better source in actual model input data rather than randomized clinical trials that include a largely unrepresentative subtype of younger patients without a diversity of backgrounds and ethnicities or comorbidities.

With that in mind, ICER's cost assessment must also consider the cost impact of any reduction of co-morbid conditions that would be positively impacted by a therapeutic option for an interrelated condition. For example, while medical costs for treating chronic migraine were

---

[1] Sullivan, Louis W. M.D. Secy. of Health and Human Services, Washington, (Aug. 13, 1992). Oregon Health Plan is Unfair to the Disabled, *New York Times*. Retrieved at http://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html

2 Steiner, Tim, et.al, Headache Disorders Are Third Cause of Disability Worldwide, *J Headache Pain*. 2015; 16: 58. Retrieved at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4480232/; *Also*: http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_white_paper_-_measuring_value_in_medicine_-_uses_and_misuses_of_the_qaly.pdf estimated at $5.4 billion in the United States in 2015, total costs associated with migraine and co-morbid conditions *exceeded $40 billion*.[3] Research has shown that migraine disease is linked to both depression and anxiety, with up to 80 percent of chronic migraine patients exhibiting symptoms of depression.[4] In fact, persons living with migraine are about five times more likely to develop depression than someone without migraine. Further, depression is associated with worsened migraine-related disability and reduced quality of life – even suicide. For many, depression or anxiety begins months or years after their migraine attacks start—partially because migraine can be so debilitating. Therefore a reasonable extrapolation of the cost impact of related co-morbidities – using real world evidence - must be factored into the value assessment.

ICER Should Recognize the Reality of a Multi-Modal / Combination Therapy Approach for Certain Chronic Diseases.

Likewise, where certain disease states (like migraine) *exist on a spectrum*, ICER should consider additional data that shows a clear distinction within the subgroup of certain chronic conditions. For example, patients who experience a high frequency of episodic migraine (headache days of 10-14 per month) are poorly reflected when pooled within either the episodic (fewer than 14 days) or chronic (15 days or more) categories. There also exists a substantial burden attributable to episodic headache where patients are not symptom free in-between attacks.[5] This is currently not reflected accurately in ICER reviews.

The reality for many patients with chronic diseases like migraine is that they will be using therapies in combination to further reduce symptoms (or headache days). When ICER assesses one therapy in a vacuum, it cannot discount the fact that a therapy, when used with another, may for example help a patient move from a "chronic" to "episodic" category, thereby increasing the quality of life for a person living with migraine disease and therefore substantially increasing *both* therapies' overall value.

The Revised Framework Continues to Inadequately Address Vulnerable Patient Populations Like Persons Living with Cluster Headache.

HMPF was greatly disappointed by ICER's seemingly arbitrary limitation of the proposed framework to assess the value of rare disease therapies to include those diseases with 10,000 patients or less. This patient population cohort size corresponds to no accepted definitions of rare or ultra-rare diseases but was justified by ICER stating that it was "modestly higher than the threshold used in the EU."[6]

---

[3] Id.

[4] The Link Between Migraine, Anxiety, and Depression, American Migraine Foundation May 2, 2018 available at: https://americanmigrainefoundation.org/resource-library/seeking-patient-input-for-new-migraine-medication/

5 Lampl et al, "Interictal Burden Attributable to Episodic Headache: Findings from the Eurolight Project," Journal of Headache and Pain, Feb. 2016.

6 ICER Revised Framework.

Of particular interest to the migraine community is the impact this might have on therapeutic options available to cluster headache (CH) patients. Cluster headache is a primary headache syndrome that is under-diagnosed and in many instances under-treated. The pain produced during a cluster headache is more severe than that generated by any other primary headache. Cluster headache is very stereotyped in its presentation and is fairly easy to diagnose with an in-depth headache history.

Cluster headache is also recognized by the National Organization of Rare Diseases (NORD) as an uncommon form of primary neurovascular headaches. CH are the most painful form of headaches, described as searing, burning, and stabbing. CH is divided into both episodic and chronic, where episodic cluster headache patients experience 1 to 4 short headaches per day that can individually last between 15 and 120 minutes per attack. These attacks (cluster periods) last for weeks or months and are separated by months or years of remission periods where the patients are pain-free. Chronic cluster headache patients suffer without remissions for 1 year or more or with remissions so brief they do not even span a month. Less than 20% of cluster headache patients have the chronic form. There is no cure, and treatment is determined on an individual basis – making access to a wide variety of treatment options critically important to this population.

PANEL COMPOSITION / DELIBERATION / INPUT

ICER Should Allow for Both an Appropriate Disease Specialist and Disease-Impacted Patient or Caregiver to Serve as Voting Members.

During the 2018 ICER Migraine Review, HMPF noted that the Voting Panel initially included an OBGYN to represent the clinician expert; upon questioning, we understand this specialist was included because migraine disease disproportionately affects women. Medical students undergo approximately *one hour* of education on *all* topics related to neurology – an insufficient amount of training required to fully understand the specialty let alone the sub-specialty of headache disorders. HMPF was appreciative that ICER recognized this concern and at least included a neurologist on the Voting Panel during its final review. However, broadly speaking, this is a continuing challenge and we would recommend ICER take a more inclusive approach by specialty with subsequent reviews for all disease states.

Similarly, we strongly request that a disease-impacted patient or caregiver be allowed to serve as a member of the Voting Panel. While it is positive that ICER allows for testimony opportunities for impacted patients, designating a patient or caregiver Voting Panel member with voting power would reflect a more substantial commitment to patient input. Furthermore, we request ICER commit to working with the leading patient advocacy organizations in any reviewed disease state to collaboratively select a patient representative or caregiver that broadly and faithfully reflects the patient perspective in the assessed disease state.

Finally, with regard to process we do not agree that voting should occur prior to the roundtable discussion portion of the public meeting. The discussions in the afternoon, after the voting took place, informed several voting members who indicated during last year's migraine review that they would have reassessed their vote had they had the additional information gleaned in the afternoon session. To vote prior to that testimony makes such testimony moot and inconsequential to the outcome. We encourage ICER to allow voting members to vote only after all information is provided at the conclusion of the public meeting.

ICER Should Provide Greater Time for Patient Groups to Respond to Various Stages of the Open Input Process.

Patient advocacy groups have substantially fewer resources than industry or ICER to evaluate and respond to open comment periods or drafts of information from ICER. To ensure that patient advocacy organizations have enough time to meaningfully participate in the ICER review process, we request that ICER extend the comment/review periods so there is more time to digest, collectively discuss and provide important patient-perspective feedback.

Thank you in advance for your consideration. If you have questions or if we can provide further information, please contact Lindsay Videnieks, Executive Director of the Headache Migraine Policy Forum at (202) 299-4310 / Lindsay@headachemigraineforum.org.

Alliance for Balanced Pain Management
Alliance for Patient Access
Association of Migraine Disorders
Clusterbusters
Coalition For Headache And Migraine Patients (CHAMP)
Danielle Byron Henry Foundation
Global Healthy Living Foundation
GoldenGraine
Hope for Migraine Community
The Migraine Diva
Migraine Meanderings
Miles for Migraine
National Headache Foundation
SoldierStrong Access
U.S. Pain Foundation