



CHAMP
Coalition For Headache
And Migraine Patients

June 10, 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 value assessment framework for 2020. We appreciated the ability to work with ICER last year during its migraine assessment and look forward to continued interaction in the future.

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 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 value assessment framework, both in process and substance:

PROCESS

ICER Should Allow for Both an Appropriate Disease Specialist and Disease-Impact Patient to Serve as Voting Members for All Reviews.

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 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 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 that broadly and faithfully reflects the disease patient perspective.

ICER Should Allow More 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.

METHODOLOGY

The Use of the QALY in Value Assessments Impacting Chronic Diseases is Discriminatory.

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. We emphasize that 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.

ICER Should Give Substantial Weight to Real-World Evidence in its Quantitative Review.

Clinical trials data is important but represents a narrow set of information currently used by ICER in its value assessments – leading to an incomplete picture about the net health benefit (or not) of a particular therapy. ICER should instead provide a more comprehensive evaluation within its quantitative model that includes data relating to the societal burden of disease including the effects of inhibited productivity and absenteeism as well as expected reduction of costly ER visits associated with preventive therapy use. Data that includes patient experience is of particular interest to persons living with migraine and other chronic diseases. Burying this information in the qualitative section of the Final Report means that this type of data is not meaningfully considered by ICER and discounts the patient and provider perspective.

For example, over the past six years Migraine.com has conducted a large national survey called *Migraine in America*, which poses questions of people with migraine disease and provides unique insights into quality of life issues for migraine patients.³ The 2017 edition included responses from more than 4,500 Americans to 110 questions that spanned the full breadth of the migraine experience, providing a rich and up-to-date view into what it means to live with the disease.

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.⁴ This is currently not reflected accurately in ICER reviews.

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/1-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

³ Migraine in America 2017. (2017) Migraine.com. [Survey of more than 4,500 individuals currently diagnosed with migraine to better understand their symptoms, life impact and treatment experience]. Unpublished data.

⁴ Lampl et al, “Interictal Burden Attributable to Episodic Headache: Findings from the Eurolight Project,” *Journal of Headache and Pain*, Feb. 2016.

ICER Value Assessments Should Consider the Beneficial Cost Impact of Reducing Co-Morbid Conditions Where There is a Substantial and Interrelated Linkage to the Disease Impacted by the Therapy Under Review.

ICER’s cost assessment must 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 estimated at \$5.4 billion in the United States in 2015, total costs associated with migraine and co-morbid conditions *exceeded \$40 billion*.⁵ 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.⁶ 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 must be factored into the value assessment.

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

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.

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 or Kevin Lenaburg, Executive Director of the Coalition For Headache and Migraine Patients at (202) 365-7473.

⁵ Id.

⁶ 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/>