



November 29, 2017

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: Open Input Comments

Dear Dr. Pearson:

On behalf of the Institute for Patient Access, I thank you for the opportunity to provide comments regarding ICER's upcoming analysis of the cost effectiveness of Erenumab as a treatment for migraine.

About the Institute for Patient Access

The Institute for Patient Access (IfPA) is a physician-led policy research organization dedicated to maintaining the primacy of the physician-patient relationship in the provision of quality health care. To further that mission, IfPA produces educational materials and programming designed to promote informed discussion about the benefits of patient access to approved therapies and appropriate clinical care. IfPA was established in 2012 by the leadership of the non-profit Alliance for Patient Access, a national network of more than 800 physician advocates committed to patient access. IfPA is a 501(c)(3) public charity non-profit organization.

Cost and Value Considerations

The impact of migraine is multifaceted. Patients living with chronic migraine endure tremendous pain as well as other physical symptoms such as nausea, vomiting, and disturbances to their vision or hearing. Many also experience social stigma, upsets to their personal and professional lives, and strain on their relationships.

These patients incur substantial health care costs, too. By one estimate, the direct financial health care costs for the 4.2 million people living with chronic migraine are [\\$5.2 billion per year](#). Patients living with migraine also generate other health care costs due to the large number who have co-existing medical conditions, particularly depression, anxiety, and arthritis. In fact, according to the non-profit [Headache & Migraine Policy Forum](#), "nearly 90 percent of chronic migraine patients have at least one other chronic condition." When the costs of these comorbid conditions are included, the total health care costs of patients living with migraine increase to \$41 billion a year.

Impact on America's Opioid Abuse Crisis

Further, there is a connection between chronic migraine and the opioid crisis. Opioids currently account for nine percent of the total medications prescribed to treat chronic migraine headaches. A medicine that is explicitly designed to address migraine could be, potentially, a more effective alternative for patients who currently use prescription opioids to manage their migraine pain. Thus, a potential benefit of Erenumab could be the reduced number of opioid prescriptions written to treat migraine headaches. This reduction matters because reducing the total number of opioid prescriptions can help to address the opioid abuse crisis and to reduce its associated costs.

Effect on Productivity

Chronic migraine also takes a toll on patients' quality of life, and significantly reduce patients' workplace productivity. Consequently, accounting for any potential improvement in patients' quality of life is imperative.

IfPA urges ICER to incorporate robust estimates for all of the aforementioned costs associated with migraine.

Use of the QALY Metric

While it is imperative to incorporate robust estimates for these costs, the QALY metric used by ICER to evaluate the cost-effectiveness of the drugs raises concerns. The QALY metric is neither appropriate nor accurate to evaluate the effectiveness of medicines that treat diseases whose benefits are qualitative and, therefore, not easily quantified. As IfPA has noted to ICER previously, treatments for some disease states simply do not lend themselves to economic number crunching.

Timing & Data Constraints

I also want to express IfPA's concern regarding the timing of this cost-effectiveness evaluation. The FDA accepted the Biologics License Application for Erenumab for review as of July 20, 2017. Therefore, significant data constraints will limit the applicability of the results from any cost-effectiveness study.

Specifically, when conducting the analysis, it is likely that ICER will have access only to the clinical trial data, and (at best) initial post-marketing data. ICER will not be able to consider the more robust post-marketing data that will eventually be available. As is typically the case, the robust post-marketing data provides invaluable insights that enable researchers to more fully understand the value new drugs provide. This could include, for example, the impact that Erenumab may have on reducing the direct morbidities associated with migraine, as well as the numerous comorbidities associated with migraine such as depression and arthritis. It might also encompass the drug's potential side effects, both positive and negative.

As a consequence, IfPA anticipates that the findings of the ICER report will be unnecessarily limited due to the prematurity of the analysis.

Conclusion

IfPA has concerns that ICER is undertaking the cost effectiveness evaluation of Erenumab before sufficient data exists. However, should the evaluation proceed nonetheless, it is imperative that the evaluation incorporate effective estimates for all of the potential benefits associated with more effective treatment of migraine, which include: reduced health care costs associated with treating migraine headaches, reduced health care costs associated with treating the comorbid conditions, increased worker productivity, increased quality of life for patients, increased quality of life for family members or other caregivers, and the potential reduction in costs associated with the opioid abuse crisis.

Without a full accounting of all of these costs, the full potential benefit of Erenumab cannot be ascertained.

If IfPA can provide further detail or aid the Institute for Clinical and Economic Review in incorporating any of the above recommendations into its analysis, please contact me at 202-499-4114.

Sincerely,

A handwritten signature in cursive script, appearing to read "Brian Kennedy".

Brian Kennedy
Executive Director