December 8, 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: Draft Scoping Document

Dear Dr. Pearson:

On behalf of the Institute for Patient Access, I thank you for the opportunity to provide comments regarding ICER's draft scoping document for a review of CGRP inhibitors for migraine prevention.

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 nonprofit 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 nonprofit organization.

Draft Scoping Document Comments

The Institute for Patient Access raised several concerns during ICER's open input period. Based on the methodology described in the draft scoping document, however, it does not appear that ICER's cost-effectiveness evaluation will adequately address these issues. To reiterate, these concerns include:

(1) The vast majority of migraine patients experience comorbid conditions, such as depression, anxiety, and arthritis, in addition to the symptoms associated with migraine. The direct health care costs associated with migraine, therefore, should include the cost to treat migraine as well as the cost to treat these comorbid conditions. It is imperative that

ICER include the estimated reduction in health care costs across migraine and the comorbid conditions when evaluating the reduction in direct health care costs that the CGRP inhibitors can provide.

(2) Although the scoping document fails to discuss the connection between migraine and the current 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 the pain caused by migraine headaches could be, potentially, more effective at treating migraine headache patients who currently use prescription opioids to manage their pain. If this is the case, then the CGRP inhibitors may meaningfully reduce the costs associated with the current opioid abuse crisis by reducing migraine patients' need for opioids. These benefits will include reductions in: the direct health care costs associated with opioid abuse; the work/productivity costs associated with opioid abuse; and the criminal justice costs associated with the opioid abuse crisis.

(3) The scoping document focuses on estimating the direct health care cost savings for the base-case analysis, with workplace productivity considerations relegated to a separate analysis. Focusing solely on the direct health care cost savings in the base case may underestimate (perhaps significantly) the benefit of CGRP inhibitors. As ICER's scoping document notes, episodic and chronic migraines take a large toll on patients' quality of life and significantly reduce patients' workplace productivity. Additionally, there are costs imposed on caregivers and family members living with a migraine patient.

From a patient perspective, reducing these costs is one of the primary benefits of more effectively managing migraine symptoms. It is therefore imperative to incorporate values for these "quality of life improvements" into the base model, which tends to drive ICER's overall cost-effectiveness conclusions.

(4) The scoping document confirms that ICER intends to use the QALY metric to evaluate the cost effectiveness of the CGRP inhibitors despite evidence that the metric is not appropriate for evaluating the effectiveness of medicines that treat diseases whose benefits are qualitative and, therefore, not easily quantified.

(5) The timing of this cost-effectiveness evaluation is problematic. As the ICER scoping document notes, the FDA is not expected to make a decision regarding these medicines until the second and third quarters of 2018. Therefore, significant data constraints will limit the applicability of the results from ICER's 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 insight that enables researchers to more fully understand the value new drugs create. That could include the impact that CGRP inhibitors have on reducing the direct morbidities associated with

migraine, as well as the numerous comorbidities associated with migraine headaches such as depression and arthritis. It could also include the drug's potential side effects, both positive and negative.

As a consequence, IfPA remains concerned that the ICER report's findings will be unnecessarily limited due to the timing of the analysis.

Conclusion

Should ICER's evaluation of CGRP inhibitors proceed despite the problematic timing of the analysis, it is imperative that the evaluation incorporate effective estimates for all of the potential benefits associated with more effective treatment of migraine. Those include: reduced health care costs associated with treating migraine headaches, reduced health care costs associated with treating comorbid conditions, increased worker productivity, improved quality of life for patients, improved 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 these costs, the full potential benefit of CGRP inhibitors 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, please contact me at 202-499-4114.

Sincerely,

Brian Kennedy
Executive Director