



**Institute for
Patient Access**

June 4, 2018

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 for Severe Asthma Therapies

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 severe asthma therapies.

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 patient access to approved therapies and appropriate clinical care. IfPA was established in 2012 by the leadership of the 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.

Draft Scoping Document Comments

As noted in ICER's scoping document, uncontrolled asthma is a substantial problem that, according to the Centers for Disease Control and Prevention, afflicts 38.4 percent of children with asthma and 50 percent of adults with asthma.¹ It is not clear from the scoping document, however, that ICER will adequately incorporate into its analysis several key issues associated with uncontrolled asthma.

These issues include:

- (1) The fundamental differences among alternative long-term asthma control medicines
- (2) Both the quantifiable and unquantifiable costs that uncontrolled asthma imposes on patients
- (3) The income and demographic characteristics of the disease.

¹ https://www.cdc.gov/asthma/asthma_stats/uncontrolled_asthma.htm.

IfPA requests the following as ICER evaluates biologic medicines for long-term asthma control.

(1) Account for the different causes of asthma that these medicines are designed to address

It is imperative to account for the clinical differences among long-term asthma medicines when ICER is preparing its draft evidence report. For example, omalizumab (Xolair) is designed to treat allergic asthma patients, while mepolizumab (Nucala) and reslizumab (Cinqair) are designed to target eosinophils, a specific white blood cell linked to severe asthma.

Patients who require a long-term asthma controller that targets eosinophils will not achieve long-term control by taking an asthma controller designed to treat allergic asthma, no matter the cost-effectiveness differences between the medicines. Similarly, patients who require long-acting beta-agonists (designed to open patients' airways) cannot interchange their bronchodilator medicine with a medicine that treats asthma related to allergies or inflammation caused by the immune system.

These clinical differences among medications present a real challenge for ICER's comparative evaluation. Because different long-term asthma medicines are designed to treat different types of uncontrolled asthma, comparing these drugs is imprecise and therefore problematic. The cost-effectiveness of a long-term asthma medicine that is inappropriate for a patient's specific condition is simply irrelevant when evaluating the benefits created by the medicine that does actually address the patient's asthma condition.

Instead of attempting to compare these medicines against one another, ICER may find it more effective to judge each medicine individually based on symptom relief and the reduction in both quantifiable and non-quantifiable costs of uncontrolled asthma.

(2) Fully account for the socioeconomic costs of uncontrolled asthma

Patients with uncontrolled asthma drive the large quantifiable and unquantifiable costs associated with asthma, including:

- 3,615 annual deaths due to asthma
- 1.7 million ER visits per year
- 14.2 million doctor's office visits per year
- 439,000 hospitalizations per year.²

In total, asthma imposes nearly \$82 billion in quantifiable socio-economic costs annually, including the costs from lost productivity and absences from work.³ The annual, per-person medical cost of asthma is estimated to be \$3,266, including the costs for prescriptions, office visits, hospitalizations, outpatient visits and emergency department care.

Some costs that are disproportionately borne by the uncontrolled asthma population are not quantifiable. These include the inability to engage in typical daily activities, the inability to exercise, inability to sleep and diminished productivity while at work or school. Uncontrolled

² <https://www.cdc.gov/nchs/fastats/asthma.htm>, and <http://www.aafa.org/page/asthma-facts.aspx>.

³ <https://www.thoracic.org/about/newsroom/press-releases/journal/asthma-costs-the-us-economy-more-than-80-billion-per-year.php>

asthma has also been linked to comorbidities, such as psychiatric diseases and cardiac diseases, particularly in seniors.

Since the new biologics target the uncontrolled asthma population, these drugs will be particularly effective at reducing these socioeconomic costs. It is imperative that ICER's draft evidence report accounts for these impacts. It should also reflect the reality that these costs (and the resulting benefits) will be concentrated in the subset of asthma patients who have uncontrolled asthma.

(3) Account for income and ethnic disparities

Important income and ethnic disparities exist with respect to treating asthma. For example, asthma prevalence and mortality are highly related to poverty. Ethnicity also plays a role. African Americans are three times more likely to be hospitalized due to asthma and three times more likely to die from asthma. African American women have the highest mortality rate due to asthma. Hispanics and Puerto Ricans are also at higher risks to environmental hazards leading to allergic or asthmatic responses.

Since these groups disproportionately suffer asthma-related consequences, they will also disproportionately benefit from medicines that more effectively control asthma symptoms. ICER should attempt to account for these income and ethnic disparities in its draft evidence report.

Conclusion

IfPA urges ICER to account for these considerations when compiling its draft evidence report. The report will provide an inaccurate picture of the benefits created by these new biologic medicines for the treatment of asthma if the wide differences in patients' asthma conditions, the large quantifiable and unquantifiable costs, and the income and ethnic disparities that exist are not fully incorporated into the analysis.

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

Sincerely,



Brian Kennedy
Executive Director