February 16, 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: Feedback on ICER's Rheumatoid Arthritis Draft Evidence Report

Dear Dr. Pearson:

On behalf of the Institute for Patient Access, I thank you for the opportunity to provide feedback on the Institute for Clinical and Economic Review's draft report regarding the cost-effectiveness of alternative Targeted Immune Modulators (TIMs) for rheumatoid arthritis (RA).

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 healthcare. 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.

Feedback on Draft Report

As ICER's draft report acknowledges, rheumatoid arthritis is the most common autoimmune inflammatory arthritis. It affects approximately 1.5 million Americans. Resulting joint swelling and stiffness can lead to permanent damage, even deformity. Yet TIMs have enhanced patients' ability to cope with the disease on a day-to-day basis, improving functioning as well as duration and quality of life.

IfPA is pleased that ICER's analysis recognizes the value of TIMs as a treatment option for patients with rheumatoid arthritis.

IfPA does have concerns, however, with ICER's conclusion that the price of TIMs exceeds ICER thresholds for cost effectiveness. Health plans may use this conclusion to limit patients' options for RA treatment, despite the fact that ICER's model for calculating cost effectiveness is, arguably, ill-suited for arthritis treatments. IfPA finds

ICER's model particularly unfitting for rheumatoid arthritis treatments given the following four points:

1. *ICER's homogeneous cohort does not reflect the reality of treating rheumatoid arthritis' heterogeneous patient population*.

   As ICER notes, "modeling a homogeneous RA patient cohort limits the ability to account for the diverse nature of RA treatment." This limitation is significant.

   Cost-effectiveness estimates based on a homogeneous patient cohort are, in reality, applicable only to the patient population that matches the estimated cohort. Any variability in the actual patient population could create results that deviate from those predicted by ICER's model.

   Thus, cost-effectiveness estimates should, at minimum, come with a caveat specifying to whom the results apply.

2. *ICER's lifetime horizon for calculating cost effectiveness overestimates the duration of patients' treatment with any given therapy.*

   ICER's model simulates the use of therapies over "a lifetime time horizon." Yet one important variability across the RA patient cohort is the length of time patients will use a given treatment. For many patients, the timeframe used in a clinical setting would vary dramatically from ICERs assumptions, significantly altering ICER's cost estimates.

   The average age of a simulated person in the model is 55 years, yielding a lifetime horizon span of 20 to 25 years on average. In reality, TIMs are typically first prescribed for a limited timeframe – six months, for instance. Then, if the patient's arthritis symptoms improve, a doctor will prolong treatment. If patients achieve remission, doctors may slowly phase out the medications.

   Likewise, treatment with traditional DMARDs such as methotrexate are equally unlikely to continue for the time span simulated by ICER's model. Having begun treatment on these therapies, many patients discover that they must progress to a biologic treatment to achieve the response they want. Others find that they cannot tolerate the side effects and must examine additional or alternative treatment options.

   Thus, a substantial gap exists between the time horizon actual RA patients will use a given therapy in a clinical setting and the time horizon that simulated patients use in the ICER model. This gap reduces the reliability of derived estimates. The sensitivity analysis evaluates the "results over short-term horizons," and ICER's simulation partially accounts for some, but not all, of these factors. To yield more realistic results, however, ICER should account for this shorter timeframe in its base model for determining cost-effectiveness.

3. *ICER's budget impact numbers do not accurately reflect rising health care costs in the United States.*

   ICER bases its threshold for "net health care cost growth" on the growth in U.S. GDP + 1 percent. However, overall health care expenditures have been growing faster than this pace; over the past 10 years, for example, the average annual growth in total healthcare expenditures has been 1.5 percentage points faster than the average annual growth in GDP.

   By assuming that pharmaceutical spending will grow more slowly than health care expenditures, ICER estimates a cost threshold that is over $140 million smaller and a 13.5 percent lower budgetary threshold.

   While a reduction in the growth rate in national health expenditures may be desired, ICER's assumption arbitrarily restricts the growth in the pharmaceutical segment of the health care industry. The cost benchmark should be adjusted to reflect actual growth in U.S. health care expenditures.

4. *ICER's measures of quality do not fully encompass RA patients' experiences.*

   While quality-adjusted life year methodology is often controversial, the controversy is heightened with diseases such as rheumatoid arthritis that involve pain and other subjective measures of well-being. QALY cannot adequately reflect all of the factors that impact RA patients and their quality of life.

   Moreover, due to the limitations of using a simulation methodology, the ICER model relies upon only the Health Assessment Questionnaire to define quality. This single tool precludes the use of other assessment measures, such as x-rays or other imaging technologies, to diagnose erosive damage to the joints. It therefore presents an incomplete depiction of patients' health quality.

Conclusions

I urge you to consider the input provided here as ICER prepares a final report on rheumatoid arthritis treatments. If IfPA can provide further detail or aid the Institute for Clinical and Economic Review in incorporating any of the above recommendations into its final draft, please contact us at 202-499-4114.

Sincerely,

Brian Kennedy
Executive Director