



**Institute for  
Patient Access**

May 1, 2019

***Submitted electronically to:*** [publiccomments@icer-review.org](mailto: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 on Targeted Immune Modulators for Rheumatoid Arthritis  
(Condition Update)*

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 its upcoming condition update on targeted immune modulators for rheumatoid arthritis.

### **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**

ICER's "Draft Background and Scope" document, dated April 11, 2019, identifies several important considerations, including issues that emerged during ICER's original 2017 evaluation of targeted immune modulators for rheumatoid arthritis. I urge you to take these points into consideration as ICER conducts its updated review.

First, the conclusions from the original study relied upon a homogenous patient population. As IfPA noted in its February 16, 2017 response to the initial "Rheumatoid Arthritis Draft Evidence Report," the homogenous population creates material limitations to the findings' general applicability. The scoping document for the updated analysis states that, in response to the feedback ICER received on the original study, ICER intends to include "key subpopulations" and "data stratifications" into the 2019 analysis. Such considerations are essential; otherwise, the updated findings will suffer from the same limitations as the original study.

Second, the scoping document notes that patient advocacy organizations have emphasized the importance of considering rheumatoid arthritis' impact on caregivers, also a concern raised in IfPA's February 16, 2017 letter. Once again, IfPA encourages ICER to include these considerations in its updated analysis.

Finally, the scoping document highlights the input from stakeholders who noted that "through the use of biologics very few patients progress to disabling joint deformities." IfPA urges ICER to make this important point more than simply a perfunctory statement. The value created by treatment success, in terms of patient outcomes, health care savings, reduced costs on caregivers, and the increased productivity of patients living with RA, all deserve consideration in the analysis.

Several concerns regarding ICER's intended methodology are evidenced in the scoping document as well.

First, the scoping document states that "we expect to integrate these new data in an updated network meta-analysis (NMA) as well as our evaluations of long-term cost-effectiveness and budgetary impact." NMAs are a complex and evolving methodology. Moreover, the well documented limitations of NMAs are particularly relevant to targeted immune modulators and warrant caution in NMAs' use for the updated analysis. NMA analyses assume, for example, that all interventions included in the "network" are equally applicable to all populations and contexts, a condition clearly inapplicable to TIMs. NMA analyses also may introduce study selection bias.

Second, the scoping document argues that "the *economic model found* that all TIMs *provide substantial clinical benefit* in comparison to conventional DMARDs alone" (emphasis added). The statement raises important concerns. Economic models do not determine a medicine's clinical benefits, and we urge ICER to ensure that its analysis does not conflate these considerations when evaluating the clinical benefits TIMs provide patients. As noted earlier in the scoping document, from a clinical perspective TIMs help ensure that "very few patients progress to disabling joint deformities."

Third, while the review will examine at least "one biosimilar, such as Inflectra®" the scoping document continues claiming that "no detailed economic analyses will be performed for the biosimilars." Excluding biosimilars from the economic analysis is a puzzling, if not seriously concerning, oversight. As less expensive versions of the originator biologics, biosimilars bring an important dynamic to the question of cost-effectiveness. Not including these products in the analysis could insert a bias toward higher cost, precipitating findings that could ultimately jeopardize patient access to these medications.

Fourth, the scoping document's plan to "develop a cohort model to assess the cost- effectiveness of each of the TIMs listed earlier relative to conventional DMARDs as well as against alternative TIM agents" is disconcerting. Not only is comparing the relatively inexpensive DMARDs to targeted immune modulators an unreasonable cost comparison, targeted immune modulators are often prescribed after patients have failed on DMARDs. Clinically, the patients who can benefit from DMARDs may differ dramatically from the patients who can benefit from targeted immune

modulators. It is not beneficial to compare the cost effectiveness of these medicines against one another.

Fifth, despite recognizing that there are other important burdens, such as the economic burden from rheumatoid arthritis on caregivers and potential productivity losses, the scoping document states that “the economic evaluation will be from a health care sector perspective, and will thus focus largely on direct medical and pharmacy costs.” Should the report focus only on the direct medical and pharmacy costs, and ignore the many other costs that are noted throughout the scoping document, the potential benefits of targeted immune modulators will be significantly undervalued.

Finally, IfPA has concerns about the inclusion of analyses that identify “lower-value services in the same clinical area that could be reduced or eliminated.” Patients, particularly rheumatoid arthritis patients, are a diverse group. Treatment options that provide high value for some patients are less efficacious for other patients. Even if the value for other services declines for some patients who benefit from targeted immune modulators, this may not be the case for other patients, or for patients who are well treated by DMARDs. Therefore, eliminating or reducing access to other services will likely have a negative impact on patient well-being.

## **Conclusion**

IfPA urges ICER to account for these considerations so that its draft evidence report does not provide an inaccurate picture of the benefits that targeted immune modulators offer patients living with rheumatoid arthritis, particularly those whose conditions would not otherwise be well managed.

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,

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

Brian Kennedy  
Executive Director