



October 20, 2016

Submitted electronically to: publiccomments@icer-review.org

Steven D. Pearson, MD, MSc
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Feedback on ICER's Psoriasis 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 on the comparative clinical effectiveness and value of targeted immunomodulators for adults with moderate-to-severe plaque psoriasis.

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 nearly 700 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, plaque psoriasis is a common disease that can impact patients' quality of life and daily functioning. With no cure available, patients have historically managed the condition with therapies such as methotrexate. Newer targeted and biologic therapies, however, can improve the duration and level of symptom relief that patients can achieve.

In the interest of patients' ability to access these treatments, IfPA is pleased that ICER's analyses show all targeted agents to be cost-effective and to carry a budget impact below ICER's limit.

IfPA does have concerns, however, that ICER's conclusions diverge from the results of its analyses. Specifically, IfPA finds it problematic that ICER concludes:

1. *"Targeted agents other than infliximab do not represent good economic value unless drug rebates and work productivity impacts are assessed, in which case they are moderately cost effective."* ("Summary and Comments," page 66)

When compared to initial non-targeted therapy, the cost-effectiveness ratios of all agents fall under (or very close, in the case of etanercept) the threshold used by ICER. Therefore, it is unclear why ICER concludes that only infliximab represents "good economic value."

In this analysis of targeted therapy for psoriasis, cost-effectiveness ratios do not provide a basis for discriminating among treatments.

2. *"...differentiating which targeted agent should be used first-line is highly dependent on the rate of second-line targeted drug use" and "If second-line targeted drug use is high, our findings suggest the main means of discriminations among agents should be price."* ("Summary and Comments," page 66)

No credible results are presented to support these findings. Moreover, it is difficult to understand how the possible results of unknown future decisions (such as the choice of second-line therapy) should affect current decisions (in this case, the first-line choice). It is even more perplexing that the impact would be to change the criterion for the first decision.

In addition, IfPA observes from this draft report that safety profiles and routes of administration for the treatments, aspects that can significantly impact patients' quality of life, were not incorporated in the model. As described on page 56, "Utilities," the safety profiles of the treatments were not incorporated in the model because of "similar adverse event profiles between drugs and the absence of their utility evaluation in other cost-effectiveness analyses in psoriasis." Mode of administration was not modeled.

ICER consulted patient advocacy groups, and they voiced challenges with current therapies – specifically poor tolerability and inconvenience – particularly with applying topical agents and with multiple injections. These are important aspects that should have been incorporated in the model, as they do affect patients' quality of life. ICER cites the PSOLAR observational study comparing the rates of infections among patients treated with targeted therapies. The findings of this study were "notable differences among treatments," which contradicts ICER's statement of "similar adverse event profiles."

The impact of the differences in the route of administration, an aspect judged to be relevant by the patients and an important differentiator among the treatments should have

been analyzed as well. Missing aspects such as route of administration and safety may have substantial influence on the results and are inadequately considered in this draft.

Conclusions

I urge you to consider the input provided here as ICER prepares a final report. If we may provide further detail or aid the Institute for Clinical and Economic Review in incorporating any of the above recommendations, please contact us at 202-499-4114.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian Kennedy". The signature is fluid and cursive, with the first name "Brian" and last name "Kennedy" clearly distinguishable.

Brian Kennedy
Executive Director