



Our Mission: To drive efforts to cure psoriatic disease and improve the lives of those affected.

December 22, 2017

Matt Seidner
Program Manager
Institute for Clinical and Economic Review
2 Liberty Square, 9th Floor
Boston, MA 02109

RE: ICER Psoriasis Condition Update Scoping Document Public Comment

Dear Mr. Seidner,

On behalf of the National Psoriasis Foundation, and the more than 8 million individuals living with psoriatic disease, I write to you today to offer public comment on the Institute for Clinical and Economic Review (ICER) *Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value Condition Update Draft Background and Scope* released on December 4, 2017. The National Psoriasis Foundation appreciates the opportunity to again offer the insights of our patient and provider experts to ICER as you undertake this psoriasis condition update.

Rationale for the ICER psoriasis condition update

The NPF understands from the scoping document and discussions with ICER staff, that the Institute is conducting this first-of-its-kind condition update due to the approval of two new drugs since the psoriasis report was released in December 2016 and the expected 2018 approval of two additional therapies. We also understand that part of the rationale is the emergence of new evidence for “many” of the treatments originally assessed. We look forward to learning more about the new evidence to which ICER is referring, as well as understanding the outlook and timing for future reviews given that the psoriasis pipeline is robust and several other new therapies are anticipated in the coming years. The NPF hopes ICER also intends to look at evidence regarding the degree to which the 2016 report’s policy recommendations – including expanded access to these therapies – have been adopted.

Key Findings of 2016 Review

As is noted in the scoping document, the 2016 assessment concluded all eight of the reviewed therapies to be of good value. The NPF was pleased that based on the evidence reviewed and input offered – including the data and patient perspectives submitted by the National Psoriasis Foundation – ICER and the New England CEPAC concluded that therapy costs were reasonably aligned with the benefits they provided to patients. Additionally, we appreciated that factors considered important by a variety of stakeholders including method of administration, frequency of dosing during maintenance, and rapidity of effect were considered during the review.

Beyond the economic analyses that resulted in incremental cost-effectiveness ratios across all agents that were well-aligned with commonly-accepted thresholds for cost-effectiveness, the report also made a number of policy recommendations. Recommendations included encouraging payers to abolish or limit the use of step

therapy for these treatments; basing co-payment and/or co-insurance for therapies on prices net of discounts and rebates instead of list price; and updating treatment guidelines for patients with moderate-to-severe chronic plaque psoriasis in a form that is easy to understand and easy-to-use by payers, clinicians, and patients. While the NPF appreciates ICER's goal of developing reports that translate evidence into decisions, the timing of this report so soon after the 2016 assessment unfortunately means that the updated guidelines begun by the National Psoriasis Foundation and American Academy of Dermatology in the spring of 2016 are still in development and will not be published until after the conclusion of this condition update. We agree that these will be helpful to payers, providers, and patients alike and look forward to promoting them upon their completion.

The National Psoriasis Foundation also calls ICER's attention to an effort of our medical board mentioned briefly in the 2016 report – a consensus paper published in the Journal of the American Academy of Dermatology (JAAD) in November 2016 on treatment targets that we again encourage ICER to review as part of this condition update.ⁱ This paper sets specific treatment goals that will make achieving clear or almost clear skin the new standard of care for psoriasis. In this treatment strategy, known as “Treat to Target,” a patient and their health care provider set specific targets or goals for improved health outcomes. The goals are meant to reduce the severity of plaque psoriasis so that it covers 1 percent or less of a person's body within three months after starting a treatment.

Scope of the Assessment

The National Psoriasis Foundation appreciates that the proposed scope for the update will generally follow the approach adopted for the prior review. Given the time and resources put in to contributing to the 2016 review by our organization, other stakeholders, patients and providers, it is reasonable for ICER to adopt the same methodology thereby ensuring prior contributions and findings are both relevant to this update and produce comparable results.

Analyses, Populations, and Considerations

As the NPF has reiterated recently during teleconferences with ICER staff and throughout our engagement in the 2016 ICER psoriasis treatment review, psoriasis is a serious chronic disease associated with significant morbidity and increased mortality.^{ii,iii} As is noted in the scoping document, beyond the widespread prevalence of disease, it is also a disease that “significantly decreases health-related quality of life.” As ICER conducts this condition update we are pleased that model inputs will continue to extend beyond disease-specific measures such as the PASI, to include symptom improvement, treatment-related adverse events, health-related quality of life, and systemic manifestations, as well as data for evidence about the comparative effectiveness of targeted immunomodulators in affecting domains such as itch, scaling, pain, quality of life, work productivity, and satisfaction with treatment. We appreciate the steps ICER has taken over the last few years to refine the model in an effort to more accurately capture all the important elements that ought to factor in to these analyses. We continue to encourage you to explore novel approaches to assessing value in such a complex disease state.

As the condition update progresses, the NPF urges ICER to keep individuals living with psoriatic disease at the forefront. Examining sub-populations, for example, in greater detail to ensure the model appropriately reflects the nuances of treating the disease for complex patients. As we discussed during recent teleconferences, and highlighted in the prior assessment, we urge ICER to consider (1) the significant impact that psoriasis has on quality of life - particularly when the disease is present on the face, genitals, hands and feet; (2) the impact of additional comorbid conditions including psoriatic arthritis, cardiovascular disease, diabetes, suicidality, emotional and mental health conditions, among others; (3) limitation using short-term clinical trial outcomes to measure the impact of psoriasis treatments on comorbidity and other long-term costs and measures that do not capture patient satisfaction or dissatisfaction or the realities of managing a chronic disease over a lifetime; and (4) real-life prescribing challenges of this population.

Conclusion

As ICER moves ahead with this condition update, we again acknowledge the benefit of bringing forward sound science and evidence that informs patients and providers about treatment options. We thank ICER for including the perspective of individuals living with psoriatic disease in the 2016 review, and stand ready to meaningfully contribute again to this condition update.

We have a shared goal – to reduce the 55% of patients with moderate to severe psoriasis who are not being treated to the appropriate standards of care. On behalf of National Psoriasis Foundation, thank you for your consideration of these comments which we hope will positively inform this review. We again invite you to call upon us, our Medical Board, and our patient community as you move forward. Please contact Leah Howard, JD, NPF's Chief Operating Officer at lhoward@psoriasis.org with any questions.

Sincerely,



Randy Beranek
President & CEO

Cc: Abby Van Voorhees, M.D., Chair, National Psoriasis Foundation Medical Board
Celia S. Segel, MPP, Program Manager, ICER

ⁱ From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. Armstrong, April W. et al. *Journal of the American Academy of Dermatology* , Volume 76 , Issue 2 , 290 - 298

ⁱⁱ Armstrong AW, Robertson AD, Wu J, Schupp C, Lebwohl MG. Undertreatment, Treatment Trends, and Treatment Dissatisfaction Among Patients With Psoriasis and Psoriatic Arthritis in the United States: Findings From the National Psoriasis Foundation Surveys, 2003-2011. *JAMA Dermatol.* 2013;149(10):1180-1185. doi:10.1001/jamadermatol.2013.5264.

ⁱⁱⁱ Gelfand, Joel M., et al. "The risk of mortality in patients with psoriasis: results from a population-based study." *Archives of Dermatology* 143.12 (2007): 1493-1499.