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

May 25, 2018

Steven D. Pearson, MD, MSc
President
Institute for Clinical and Economic Review
2 Liberty Square, 9th Floor
Boston, MA 02109

RE: **ICER Psoriasis Condition Update Draft Evidence Report**

Dear Dr. Pearson,

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 Evidence Report* released on April 27, 2018. We offer the following comments as part of the National Psoriasis Foundation's commitment to ensuring the perspective of individuals living with psoriatic disease are properly considered and reflected in discussions regarding the value of therapies. Included in our comments is also a discussion of soon to be released coverage trend data gathered earlier this year to understand – among other access issues – the impact of the 2016 ICER review on access to the systemic psoriasis therapies. We urge ICER to consider this information and future access conditions as part of these value assessments.

Background on Psoriasis, Patient Insights and Continued Challenges in this Review

Measures

The NPF has reiterated consistently in teleconferences, comment letters, and public dialogues (including the November 2016 ICER public meeting on this topic) the serious nature of psoriasis and the associated significant morbidity and increased mortality.[i,ii] Significant attention has also been dedicated in NPF comments to the widespread prevalence of disease, and way in which it "significantly decreases health-related quality of life." While the NPF appreciates that ICER has given greater attention to these issues in this condition update evidence report as compared to the 2016 review, on behalf of the patient community we continue to stress the challenge of measuring a chronic disease such as psoriasis with the measures (QALY, PASI, BSA, etc) and tools available today.

We have previously commented on the limitation of each of the aforementioned measures. ICER itself noted PASI limitations (p. 64) in this report. During a payer and pharmacy benefit manager roundtable hosted by the NPF in April 2018, these limitations were a large focus of discussion. Roundtable participants – payer and pharmacy benefit manager representatives – raised several concerns around Psoriasis Area and Severity Index (PASI) 75 scale, including its lack of application in clinical practice outside of academic settings, challenges in understanding the potential clinical improvement associated with a medication and an increasing lack of relevance given newer therapies able to obtain higher levels of clearance. Participants even questioned the applicability for formulary decisions of an ICER assessment with a focus on PASI 75 if a PASI 90 is

achievable. Separately, NPF medical experts have also questioned the appropriateness of including Otezla in this review, as they did in 2016, given the nature of the cost-effectiveness model and that it is the only non-biologic in the review.

Subpopulations & Additional Considerations
We were pleased to see greater discussion given in this report to the disconnect between individual patient frustrations and the focus of various outcome measures. As ICER noted, the March 2016 FDA Patient Focused Drug Development (PFDD) meeting provided great insight into the significant quality of life impacts of this disease and the challenges in trying to manage each of the symptoms – including itch and pain – that often accompany moderate to severe disease. We were pleased that the model inputs in the condition update continued 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 noted the addition of 'satisfaction with treatment' was new to this 2018 condition update among the domains considered.

Nonetheless, while we were pleased to see these additions, section ***3.4 Summary and Comment*** and ***Table 3.9. ICER Evidence Ratings for Available Head-to-Head Comparisons*** **(**included therein) do not include measures that speak to those patient perspectives. Limited mention is also given in ***5. Additional Considerations*** to several issues discussed during the 2016 review including patient perspectives on the route of administration of certain therapies (e.g. favoring oral therapies or preference for self-administered versus infused therapies) and frequency of administration. It is unclear to us how ICER has factored these patient preferences in to the cost-effectiveness model.

In earlier comments, the NPF urged ICER to keep individuals living with psoriatic disease at the forefront and specifically encouraged the importance of examining sub-populations in greater detail to ensure the model appropriately reflects the nuances of treating the disease for complex patients. ICER did include a limited number of items related to subgroups of individuals living with psoriasis (Asian population, patients with previous biologic therapy exposure and patients with psoriatic arthritis), and as well as disparities experienced by racial and ethnic minorities (including delayed diagnosis, more severe disease, more common misdiagnosis, and more frequent non-treatment, reduced representation in clinical trials, and lower use of biologics in Medicare compared to white patients). However, there are many more subpopulations of individuals living with psoriasis that may have been examined. Given the unique nature of the individual subpopulations of individuals living with psoriasis, and the noted lack of robust data about treatment patterns and discontinuation rates, the NPF continues to encourage ICER and those informed by this condition update to avoid treating the community as a homogenous population for which a single standard first or second line treatment decision model can be easily imposed.

Policy Considerations
The 2016 economic analyses resulted in incremental cost-effectiveness ratios across all agents that were well-aligned with commonly-accepted thresholds for cost-effectiveness. This finding of "good value" for all reviewed treatments was accompanied by 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.

In spring 2018, the National Psoriasis Foundation in collaboration with the State Access to Innovative Medicines (SAIM) coalition commissioned a study by Avalere Health to examine patient access to a select

group of therapies across public and private healthcare plans. The NPF was eager to see whether the 2016 ICER assessment that found all of the eight reviewed therapies to be "of good value" had a positive impact on patient access to these therapies. Avalere analyzed a total of 15 therapies used to treat plaque psoriasis, Crohn's disease, arthritis, and ulcerative colitis – including all ten of the on the market treatments included in this condition update – Humira, Enbrel, Remicade, Cimzia, Stelara, Tremfya, Cosentyx, Taltz, Siliq, and Otezla. The analysis examined coverage trends including changes to formularies, tier placement, cost sharing, step therapy and other utilization management tools over a three year period (2015-2017). The plans included in the review were representative of all major health insurance markets—employer, ACA exchange, Medicare, and Medicaid.

The study findings raise concern for the NPF about the impact of the 2016 assessment.[iii] Among the key findings:

- Over the three years included in the study, the percentage of drugs covered by health insurers dropped in all health insurance markets.
- Newer biologic drugs are commonly placed on the highest drug tier, where cost sharing with the member is the least generous. The migration of covered biologics to the specialty tier was evident across three the years of the study.
- Health insurers are also increasingly relying on utilization management tools, e.g., step therapy and prior authorization, to limit access to covered drugs. This is true across all insurance markets, but particularly true in the employer market where only 18 percent of health plans relied on both step therapy and prior authorization in 2015, but 60 percent did in 2017.
- Partly as a result of formulary tier placement, cost sharing responsibilities on plan members can be very high. Among 2017 silver plans on the health insurance exchanges, 50 percent of biologic drugs are either uncovered or subject to very high coinsurance payments (40 percent or greater).

It is unfortunate that it appears the "access problem" may have gotten worse for individuals living with psoriasis. In many ways, there is no better time to be diagnosed with psoriasis than today given the many safe and effective therapies available. Our hope would be that individuals living with psoriasis be able to work with their provider choose the most appropriate treatment for them given their individual disease. As ICER completes this review, the NPF encourages consideration be given to recommendations that may positively improve patient access to therapies. One example may be that shared recently by Express Scripts during a panel talk on "Defining Value" hosted by The Atlantic on *The State of Care: Patient Access & Affordability*. These remarks touched new contracting procedures at Express Scripts that have created easy access for patients and given physician access to all the reviewed psoriasis therapies "in the toolbox."[iv]

Cost Saving Measures

New to this update, ICER has requested information on wasteful or lower-value services in the same clinical area that may be reduced or eliminated to create budget headroom. Such recommendations are hard to identify in a chronic disease such as psoriasis. As is noted in the draft report, to date no suggestions have been received or professional society recommendations been identified. While this information is worth capturing, the NPF would reiterate the individual, personal benefits of treating moderate to severe psoriasis appropriately that – while hard to quantify – deliver significant long term individual and societal benefits. For an individual living with moderate to severe psoriasis who is under treating their disease with a topical cream, for example, to begin treating up to the standard of care would not save the system resources from a wasteful standpoint but would likely result in significant quality of life improvements and thereby likely reduce some of the indirect costs of psoriasis such as worker absenteeism or presentism.

Future Considerations: Updated Guidelines

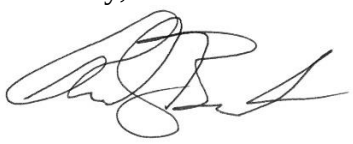
The NPF appreciates ICER's goal of developing reports that translate evidence into decisions. Nonetheless, the timing of this update is disappointing in that it, too, will fail to include updated guidelines currently in development by the National Psoriasis Foundation and American Academy of Dermatology. As you may know, the development of guidelines is a rigorous process following an established methodology and administrative regulations. We believe that, once released, these guidelines will be highly informative to payers, providers, and patients alike. Were they available for this review, they would likely have also brought additional considerations forward for this update. It is unfortunate that timing of this update occurred so soon after the initial review such that these guidelines are not yet complete. (The NPF would additionally recommend that the use of the word "guidelines" on page 19 of the report in the discussion of the NPF Medical Board JAAD paper on treatment targets would be more accurate as "recommendations").

Conclusion

Throughout the 2016 and 2018 ICER reviews, the NPF has acknowledged 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 again believe the assessment is improved by our meaningful contributions to this condition update.

As we have previously stated, we believe 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. And to achieve that goal, we are going to need to engage every stakeholder who has an interest in the psoriatic disease community from value modelers, to payers, to pharmacy benefit managers, to physicians, to patients themselves in this dialogue. 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

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[i] 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.

[ii] 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.

[iii] Study documents are expected to be released online the first week of June. Note: The findings presented above are not weighted by the enrollment of the plans in the analysis. The findings pertaining to coverage are based on a percentage of available drugs, and are not adjusted to reflect new drugs coming into the market. This creates a possibility that the same number of covered drugs might result in a lower percentage of covered drugs. The findings do not consider coverage permitted through off-formulary exceptions processes and appeals as this is not easily accessible data.

[iv] https://youtu.be/-jY_16eOGJI?t=1h28m10s