October 18, 2019

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

RE: ICER Proposed Updates to 2020 Value Assessment Framework Methods and Procedures

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 comments on the Institute for Clinical and Economic Review (ICER) 2020 Value Assessment Framework Methods and Procedures Proposed Updates released on August 21, 2019. The National Psoriasis Foundation has had the unique experience of participating in both a value assessment on systemic psoriasis therapies in 2016, and a condition update in 2018. Throughout both reviews, our goal was to ensure that the perspective of individuals living with psoriatic disease were properly considered and reflected in discussions regarding the value of therapies. We thank ICER for accepting our feedback on these experiences, and have noted a number of improvements since 2016. We offer the following comments now as part of our continued commitment to elevating the experience of individuals living with chronic diseases in value assessments. We appreciate ICER’s consideration of these comments as you refine and finalize the 2020 value assessment framework.

The Use of Real World Evidence

The National Psoriasis Foundation is pleased that ICER has listened to patient advocacy organizations and is reaffirming its commitment to using existing real-world evidence (RWE) and exploring new collaborative relationships with organizations to generate RWE that can complement published data sources. As the National Psoriasis Foundation has noted in the 2018 condition update, there are often disconnects between individual patient frustrations and the focus of various outcome measures. As ICER noted during the prior psoriasis reviews, 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 immunomodulatory 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. This sort of expansion of evidence is critical to ensuring that the data reviewed by ICER during value assessments accurately reflects the challenges of living with chronic disease. We encourage ICER to continue to move in this direction and remain open to supplementing published data sources with additional real world evidence.
The Use of Multiple Cost-effectiveness Outcome Measures
The NPF has reiterated consistently in teleconferences, comment letters, and public dialogues the serious nature of psoriasis and the associated significant morbidity and increased mortality.\textsuperscript{1,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.” As we have noted in previous comment letters, while the NPF appreciates that ICER has given greater attention to these issues (including in the 2018 condition update), 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. The NPF appreciates that ICER is striving to ensure that the information considered does not discriminate against any patient group.

Creating a New Process for Re-evaluating Evidence
As ICER considers the process for reassessing whether new evidence has emerged that should be included in an update to the report, the NPF would urge ICER to be cognizant of the many resources that stakeholders must expend to participate in any condition update. As we noted in our 2018 review, participating in a condition update soon after an initial value assessment is a major undertaking for a patient advocacy organization. Ensuring that an update is not burdensome on the patient community must be considered as part of the decision to update.

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 both reviews, and considering the input of the patient community in updates to the value assessment framework.

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.

Sincerely,

Leah M. Howard, J.D.
Chief Operating Officer
