

September 12, 2016

Steven D. Pearson, MD, MSc

President

Institute for Clinical and Economic Review

Two Liberty Square, Ninth Floor

Boston, MA 02109

*Submitted via email:*  publiccomments@icer-review.org

RE: **Response to ICER** **National Call for Proposed Improvements to its Value Assessment Framework**

Dear Dr. Pearson,

I write to you today on behalf of the more than 8 million Americans living with psoriatic disease to offer public comment on the Institute for Clinical and Economic Review (ICER) *National Call for Proposed Improvements to its Value Assessment Framework* released on July 14, 2016. We thank you for the opportunity to provide input on the 2017 update of the methods used by ICER to develop evidence reports on new therapies and health care interventions. We are pleased that you have invited all interested parties to react to the current ICER value framework. As patients are the ultimate beneficiaries of the therapies and interventions reviewed by ICER, the National Psoriasis Foundation feels strongly that the perspectives of individual patients, patient representatives and those that care for patients should be of central concern to you as you move forward with this update.

This spring ICER began a review of psoriatic disease therapies. This review – now focused only on psoriasis therapies only – will culminate in the New England CEPAC convening on November 18, 2016 to deliberate and vote on evidence presented in ICER's report on treatments for psoriasis. As we are only “half-way” through the review process, our comments are reflective of our experience to date. We urge you to give considerable reflection to the input of other patient advocacy organizations and the National Health Council (NHC), which may be more comprehensive in scope.

***Methods to integrate patient and clinicians perspectives on the value of interventions***

When the NPF reached out to ICER earlier this year in advance of the psoriatic disease treatment review, one of the key points we wanted to convey was that psoriasis is a relentless and unpredictable disease, individual and diverse, presenting differently from one person to the next. Answering the simple question of “what is important to patients” is, therefore, quite challenging. Patients have told the NPF they place value on a number of items including the expected efficacy of the treatment, the ability to access all psoriatic disease treatments, the safety of the treatment, the burden of utilizing this particular treatment, the impact that the therapy may (or may not) have on related or concurrent health conditions (including physical, mental and emotional health), and cost – among others.

In raising these items with ICER, we noted that these perspectives are so varied and patient preferences so diverse that the Food and Drug Administration (FDA) chose to spend an entire day hearing from the psoriasis community as part of FDA Patient Focused Drug Development (PFDD) initiative. It has been fortunate for our community that we had the benefit of pointing ICER toward the March 17, 2016 psoriasis PFDD meeting webcast <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm> as a way to give the institute an opportunity to hear directly from more than 100 patients about symptom challenges and treatment preferences. Time and again during this day-long meeting, patient participants shared their frustrations and the challenges of managing the wily symptoms of psoriasis and the unpredictable nature of the body’s response to treatments. The second panel of this meeting, in fact, focused specifically on discussing patient perspectives on treatments. While some of the perspectives offered that day are captured in scientific literature, many of the unique – and very personal and sensitive – reflections of patients are often not known or understood by clinicians and researchers.

Assuming the model aims to consider each of the relevant benefits of interest to patients, the absence of a trusted, validated, and uniformly utilized outcomes measure for psoriasis that includes patient preferences and incorporates all these end points is a concern of the NPF with regard to the review underway. As ICER proceeds with this review and others in the chronic disease space, any reliance on outcomes measures that fail to properly capture the most bothersome symptoms of the disease (as in the case of psoriasis) is a concern. We raised this in a comment on the draft scoping document this summer. We disagree with the use of outcomes such as Psoriasis Area Severity Index (PASI) and Psoriasis Global Assessment (PGA) as "surrogate outcomes” en route to "key measures of clinical benefit." Focusing on PASI and PGA is but the tip of the iceberg and will limit one’s ability to measure the total benefit of treating and will also fail to account for the transformational nature of biologic therapies.

Any discussion – or review – of treatments should also bear in mind that treatments that work for one person may not for others. Many patients cycle through accepted treatment options unsuccessfully, or temporarily successfully, and are ultimately left at the end of the treatment road with no alternatives. As we noted on several occasions during our discussions with ICER staff, this frustration is often one of compounded by insurance policies and practices that erect barriers for patients in urgent need of treatment.

The NPF has long recognized the importance of systematically gathering patient perspectives on all these issues and involving patients directly in research and clinical efforts including the development and validation of outcome measures and the identification of research priorities. Even for an organization such as the NPF which has devoted significant time and resources to doing this well, we note how challenging it is to engage patients and encourage them to share their perspectives in a way that can inform future efforts. This should be of particular concern for ICER which has neither a natural link to patients nor direct relationships with the experts who serve communities such as ours on a day-to-day basis. Analyses that fail to take real-life patient preferences, needs, and socio-economic challenges (among other considerations) into account will produce a value-discussion in a vacuum with little relevance or usefulness to patients, providers, and payers.

***Cost effectiveness ratios, appropriate thresholds, budget impacts and best practices***

As we shared earlier this year, an NPF survey of more than 400 patients done in 2012 found that two-thirds of these respondents were angry, frustrated, and/or helpless. While these numbers are stunning, the stories shared by patients are even more powerful than the statistics and expose the multiple challenges faced by patients on a daily basis. Talk to almost any patient with moderate to severe psoriasis – about 30 percent of whom often have both psoriasis and psoriatic arthritis, thus contributing to the intensity and cost of treatment – and they will tell you about the life changing experience it was for them when they (finally) got on a treatment that worked or the devastation they felt when a therapy lost efficacy, or they lost access to a therapy that was working for them. As it is, NPF annual surveys find that many patients are unable to obtain their first-choice prescription because the insurer would not cover it (21%), the co-pay was too much (18%), or they could not find a provider (8%)— (a problem often associated with costs and/or narrow networks). Talk to a patient who has been unable or ashamed to be intimate with a spouse, or who has suffered social stigma, endured bullying, shunning, embarrassment, and maybe have even contemplated suicide due to their disease – it will not take long to hear that patients know the personal benefit of treating their psoriasis as clinically recommended.

Yet inherent challenges with identifying and assigning value to the benefits at both an individual level and societal level are large. According to the psoriasis scoping document released this summer, the aim of the report is to evaluate both the comparative clinical effectiveness and value of targeted immunomodulators for adults with moderate-to-severe plaque psoriasis. It is unclear, though, exactly what question(s) will be answered as part of this review. Regardless of the academic value of conducting such an evaluation, the real world challenge of attempting this sort of cost-benefit analysis on the psoriatic disease community where benefits of treating psoriasis are so difficult to monetize is concerning. Important cost questions to address include the need to up-dose, the use of combination therapy, costs associated with lab monitoring, impact on comorbid conditions – most of which are not captured in the literature or captured only for limited periods of time. Cost benefit analyses that are based on short term outcomes from trials (which fail to assess long term health consequences) do not properly account for the lifetime nature of these diseases. Finally, estimates of the cost of psoriasis frequently underestimate the impact of the disease because they fail to factor in costs associated with lost or reduced productivity or the financial impact associated with a lower quality of life.[[1]](#endnote-1),[[2]](#endnote-2)

***Conclusion***

As ICER moves ahead with reviews such as the one for psoriasis therapies, we acknowledge the benefit of bringing forward sound science and evidence that informs patients and providers about treatment options. We encourage the Institute to consider the concerns raised by the NPF, and other patient representatives as it completes the 2017 methods updating.

No relationship in the health care landscape should be more sacred than that of the patient and provider. It is critical that patients and physicians have access to all of the therapies approved by the FDA - both new and those that have been on the market for more than a decade - along with those that come to market in the future. Only when physicians are able to access all the tools in their treatment toolbox, will they be able to provide individual patients with the care most appropriate for them and their disease.

Any framework that fails to meaningfully include patients, and ultimately disrupts the sanctity of this relationship through policy recommendations that limit access to treatments, will only serve to grow 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 me with any questions.

Sincerely,



Leah Howard, JD

Vice President, Government Relations and Advocacy

1. Vanderpuye-Orgle J, Zhao Y, Lu J, Shrestha A, Sexton A, Seabury S, Lebwohl M. Evaluating the economic burden of psoriasis in the United States. J Am Acad Dermatol. 2015 Jun;72(6):961-7.e5. doi: 10.1016/j.jaad.2015.02.1099. Epub 2015 Apr 14. Review. PubMed PMID: 25882886. [↑](#endnote-ref-1)
2. Brezinski EA, Dhillon JS, Armstrong AW. Economic Burden of Psoriasis in the United States: A Systematic Review. JAMA Dermatol. 2015 Jun;151(6):651-8. doi: 10.1001/jamadermatol.2014.3593. Review. PubMed PMID: 25565304. [↑](#endnote-ref-2)