



Q&A with Leah Howard, Vice President of Government Relations and Advocacy for the National Psoriasis Foundation regarding ICER's assessment of psoriasis treatments (October 27, 2016)

What prompted ICER to target psoriatic disease as a focus for its research and how did NPF become involved in the discussion?

ICER reviews cover drugs, devices, procedures, and delivery system innovations. In November 2015, ICER [announced](#) the Institute's topic list for 2016. According to this press release, the list of drugs chosen for review is "based on ICER's discussion with multiple payers and other stakeholders to prioritize the most important new drugs in the pipeline with expected FDA approval between late 2015 and mid-2016."

When the National Psoriasis Foundation learned of this review, we reached out immediately to ICER's President, Dr. Steve Pearson to express our desire to contribute to the process. Though much literature exists on psoriasis and psoriatic arthritis, there is much about the disease that is **not** captured in scientific literature including the challenges of living with and managing the disease over a lifetime. NPF wanted to make sure that these important points were not missing from the ICER review. Through numerous conversations over many months, we sought to share the expertise of our patients, clinicians and researchers on the real-world challenges and realities of treating psoriasis and psoriatic arthritis. NPF organized a team of patients, clinicians, researchers, and policy and economic experts. Together, these individuals have illuminated key issues including: (1) the significant impact that psoriasis has on quality of life - particularly when the disease is present on the face and genitals (along with presentation on the hands and feet as mentioned); (2) the impact of additional comorbid conditions including psoriatic arthritis, cardiovascular disease, diabetes, suicidality, emotional and mental health conditions, among others; (3) limitations of 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 with current treatment options; and (4) real-life prescribing challenges of this population.

Why do value frameworks matter to patients?

Too many individuals – 55% of people with moderate-to-severe psoriasis and 41% of those living with psoriatic arthritis – are not being treated to levels appropriate for their disease. The mission of the National Psoriasis Foundation is to drive efforts toward a cure and dramatically improve the lives of individuals living with psoriasis and psoriatic arthritis. But when so many patients are under-treating, this brings about a real challenge. That's why the NPF is working hard under an aggressive five year strategic plan to identify the barriers that keep individuals from treating their disease appropriately. We understand that there are multiple reasons for these high under-treatment numbers, among them insurance and cost barriers. Given that insurers and the federal government are increasingly looking to ICER and other value

framework modelers to advise them on coverage decisions, it is critical that patients and patient organizations have a seat at the table during these assessments.

In the opinion of the NPF medical and scientific experts, did the ICER report offer an accurate assessment of psoriasis and its treatments?

NPF respects the work ICER has done, but at present we have a number of concerns with the draft report. These include the way in which psoriasis was portrayed, how perspectives of patients were factored into the assessment, and the lack of real world treatment administration considerations. NPF experts found that the report lacked an acknowledgement of the heterogeneity of psoriatic disease – different locations, different systemic symptoms, different severity, and different response to different treatments – along with differing patient preferences. As our experts - and individuals living with psoriasis themselves – know, psoriasis is a serious systemic disease. Though the report noted that psoriasis significantly decreases health-related quality of life, this discussion failed to include information about the impact of disease management on psoriasis long-term, its impact on related health conditions or comorbidities, and significant benefits of treating to long term quality of life. Similarly, the discussion of the therapies under review was also lacking in that it was too broad and general in some areas and ignored key factors, such as extreme variability in establishing costs, in others. Ultimately, we have several concerns, which we have shared, and we hope the final version reflects this feedback.

Was there anything the report failed to address or take into consideration?

The NPF is concerned about a number of gaping omissions, assumptions, and value conclusions that we believe challenge the report findings. In brief, we summarize those failures as follows:

1. ***Characterizing psoriasis and patient perspectives without accounting for the heterogeneity of psoriasis***
 - a. The immune-mediated and systemic nature of psoriasis is not addressed in full, and the serious nature of comorbid health conditions were minimized.
 - b. Discussion fails to include information about the impact of disease management on related health conditions or comorbidities as well as quality of life; and ignores data showing early mortality.
 - c. The location of disease (face, genitals, soles/palms) is not addressed or considered in detail.
 - d. Little recognition of heterogeneity of psoriatic disease – different locations, different systemic symptoms, different severity, and different response to different treatments – along with differing patient preferences.
2. ***Omissions, treatments assumptions, and lack of real world administration considerations***
 - a. Adverse events discussion too broad, lacking context, and overly specific with some interventions
 - b. Rigid approach to dosing and frequency of administration that is not reflective of real world practice
 - c. Minimal mention of biosimilars despite approval of three biosimilar therapies for psoriasis
3. ***ICER cost model lacks transparency and acknowledgement of variability between payers and over time***
 - a. Lack of a comprehensive description of the costs ICER used in the model

- b. All measures of drug costs do not move in tandem for all drugs in a class, price relativities change
 - c. Assuming one set rebate percentage, consistent across all therapies, fails to acknowledge the real and variable world of drug price rebates.
 - d. Pharmacy and medical benefits are paid differently. The report does not recognize this, particularly in the context of the product it deems to be most cost-effective.
4. **Report findings and concerning one-size-fits-all recommendations**
- a. Numerous omissions and assumptions underlie the findings, and unclear or incomplete information on the course of therapy, sequencing, dosing, discontinuation rates challenge basic framework was used.
 - b. One-size-fits-all determination does not account for the challenging nature of managing psoriatic disease
 - c. Infliximab up dosing, frequency of administration, and adverse events are not appropriately addressed.
 - d. Findings are inconsistent with other studies that infliximab is similar or higher in cost to the TNF-blockers.

Why is it important for value framework groups to incorporate the unique needs of the patient into their research?

As the NPF shared in one of our letters to ICER, “it is one thing when the Centers for Disease Control and Prevention (CDC) states psoriasis (and psoriatic arthritis, which affects up to 30% of psoriasis patients) present a “substantial public health burden.”^{i,ii} It is another, though, when you engage an individual living with the disease directly and are able to hear just how significant the disease impact is day to day, year after year.” We know from our 50 years of talking to and supporting individuals living with psoriatic disease that patients place value on numerous items including a treatment's expected efficacy, the ability to access all approved treatments, treatment safety, utilization burden of each treatment, potential impact on related or comorbid health conditions, and cost – among others. We also know that what frustrates one patient may not be significant to another and that what one patient desires in a treatment might not be of interest to the next person. Given that the outcomes measures used to assess the performance of psoriasis therapies did not incorporate patient perspectives in their development, it is critical that patient perspective be considered to shape the outcome in the final report.

How might the results of the report impact treatment accessibility?

Thanks to the number of effective therapies on the market, there has never been a better time in human history to be diagnosed with psoriasis than today. Yet, as noted earlier, too few individuals are reporting their disease to be well-managed, in part because of challenges accessing affordable treatments. Given these challenges, it is very important for providers and patients to know about new candidate therapies in the pipeline and new agents coming to market. And it is critical that once these therapies are approved, patients have affordable access to them. Perhaps our most significant concern with the ICER report is that if not modified to reflect the true benefits of these treatments, payers may use the findings to enact even greater limits or restrictions on patient access. This threatens to setback millions of Americans already struggling to manager their disease.

We have shared with ICER that any 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. Throughout the process we have reminded the Institute that individuals living with psoriasis already struggle with restrictive or limiting health insurance coverage and utilization management practices that limit access to therapies. We have therefore encouraged ICER to be aware of the potentially negative impact any ICER recommendations may impose on our community.

Will there be a similar report conducted on psoriatic arthritis? If so, what's the status of NPF's involvement?

Earlier this summer, ICER considered a combined rheumatoid arthritis (RA) and psoriatic arthritis (PsA) review. The NPF raised a number of concerns with this combined approach including the individual nature of these diseases, different implications of comorbid health conditions, and variable effectiveness of medications between RA and PsA. While both diseases are degenerative inflammatory conditions causing chronic and life-long challenges, given the way they impact individual patients differently, variances in treatment, and differences in disease progression – we encouraged ICER to separate out the diseases to ensure that any reviews appropriately account for patient preferences and individual disease considerations. ICER agreed and is moving forward with a rheumatoid arthritis currently. We understand that a psoriatic arthritis therapy review may commence in 2017, and we will look forward to being similarly engaged in the process.

How can patients and providers get involved in discussions with ICER?

While the current review is nearing its conclusion, patients must remain vigilant about ICER going forward. NPF relies upon our patients to develop the evidence needed to put forward arguments to shape outcomes of projects like this. We encourage our patients to participate fully in NPF surveys and other opportunities to share your data, particularly data on cost and access challenges. We also want patients to pay close attention to the final outcome. If the final report is not modified, patients should express their concerns to ICER and others.

For more information on ICER and our work with value frameworks, visit www.psoriasis.org/valueframeworks. To discuss the ICER review with NPF staff, please contact Leah Howard, VP of Government Relations and Advocacy at lhoward@psoriasis.org. If you are a patient or a caregiver looking for information about psoriatic disease treatment options, contact our Patient Navigation Center at www.psoriasis.org/navigationcenter.

ⁱ Helmick CG, Sacks JJ, Gelfand JM, et al. Psoriasis and Psoriatic Arthritis: A Public Health Agenda. *American journal of preventive medicine*. 2013;44(4):424-426. doi:10.1016/j.amepre.2013.01.004.

ⁱⁱ Mease, Philip J., et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics." *Journal of the American Academy of Dermatology* 69.5 (2013): 729-735.