



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

July 8, 2016

Bill Dreitlein, Pharm.D., BCPS
Director of Pharmaceutical Policy
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

RE: **ICER Psoriasis Scoping Document Public Comment**

Dear Dr. Dreitlein,

I write to you today on behalf of the 7.5 million Americans living with psoriatic disease to offer public comment on the Institute for Clinical and Economic Review (ICER) *Treatment Options for Plaque Psoriasis: Effectiveness, Value, and Value-Based Price Benchmarks Draft Background and Scope* released on June 24, 2016. We thank you for the calls you held with us in May and June and for the many emails we have exchanged since this review began. We appreciate your willingness to engage the NPF in this value discussion, and hope to have continued dialogue with you as the review progresses.

Psoriasis is a serious chronic disease associated with significant morbidity and increased mortality.^{i,ii} While the scoping document captured some of the challenges and frustrations of this disease, among the items missing were: (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) 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 with current treatment options; and (4) real-life prescribing challenges of this population. We explore those items below further.

Yes, psoriasis presents a substantial public health burden. But it all comes back to the individual patient. 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."^{iii,iv} 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. As previously shared, psoriasis is a relentless and unpredictable disease, individual and diverse, presenting differently from one person to the next. We noted that ICER briefly commented on the multiple forms of psoriasis and connection to psoriatic arthritis. We are concerned how the framework will account for the real-world concurrent nature of these diseases and overlap among populations. Each of these diseases is significant and must be properly addressed.

We have shared 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 are glad that you viewed the March 17,

2016 Food and Drug Administration (FDA) Patient Focused Drug Development (PFDD) meeting which included patient insights on many of these items. The scoping document notes that on the opposite end, dissatisfaction with treatments may be due to a number of issues. Listed in the document are just some of the challenges and frustrations patients experience. Not included are issues such as the need for persistence in administering medications, the lag time before new medications may be effective, lapses in efficacy over time, lower real life response compared to clinical trials, monitoring burdens, and a lack of information regarding how the therapy may address comorbid conditions. As these issues are coupled with those mentioned in the report, we hope it is recognized that patients are both frustrated by – and value – many different elements in treating their disease. What is paramount to one patient may not be a significant issue to another. Additionally, in instances where patients receive an ineffective or inadequate treatment, plaque psoriasis can lead to more life-threatening forms of the disease, chiefly pustular and erythrodermic psoriasis.

As ICER moves forward with your review, we strongly encourage you to continue engaging with individual patients and keep them at the center of your model. It is critical for ICER to ensure any review and recommendations do not further challenge patients in realizing improved health outcomes. 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. Many individuals living with psoriasis already struggle with restrictive or limiting health insurance coverage and utilization management practices that limit access to therapies. We therefore encourage you to be aware of the potentially negative impact any ICER recommendations may impose on our community.

There is significant value in treating, but those benefits are often difficult to monetize.

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. 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 scoping document, 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 exactly what question(s) will be answered, though, 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 are captured for limited periods of time. 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.^{v,vi}

Getting outcomes right and utilizing available data and evidence from patients and clinicians.

The scoping document states that ICER will "engage with patient groups and clinical experts to ascertain which outcomes are of greatest importance to patients and determine whether patient-reported outcomes or other evidence sources can be found to supplement the available clinical data." The NPF is eager to hear more about

this process and understand how this survey and landscape analysis will pull in the multiple treatment benefits that should be considered beyond impact on skin lesions, including itch, pain, psycho-social implications, and impact on comorbid conditions among others.

Assuming the model aims to consider each of these relevant benefits, the absence of a trusted, validated, and uniformly utilized outcomes measure that includes patient preferences and incorporates all these end points is likely to challenge this review. As the NPF has previously noted, many outcomes measures fail to properly capture the most bothersome symptoms of the disease. We are also confused as to the categorization in the scoping document analytic framework of investigator assessed disease outcomes (Psoriasis Area Severity Index (PASI) and Psoriasis Global Assessment (PGA) as "surrogate outcomes". These are certainly different outcomes from patient reported outcomes that focus on health related quality of life and functional outcomes, however, we would disagree that these are 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.

Other contextual issues that are important to consider

As ICER refines the scope of review and moves ahead with your process, we again urge you to remain mindful, as patient perspectives illustrate, of how challenging it is to live with these chronic diseases. We've encouraged ICER in each of our conversations to consider the systemic implications of psoriatic disease on overall health and quality of life. We also remind you that these are lifelong conditions with no cure. An individual diagnosed as a 20 year old is likely to face four or more decades of disease management challenges. Cost benefit analyses that do not properly account for the lifetime nature of these diseases, or that fail to address that many of these therapies have been on the market for more than a decade are inadequate.

Conclusion

As ICER moves ahead with this review, we acknowledge the benefit of bringing forward sound science and evidence that informs patients and providers about treatment options. 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 reviewed here - 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 Leah Howard, JD, VP of Government Relations at lhoward@psoriasis.org with any questions.

Sincerely,



Randy Beranek
President & CEO

Cc: Abby Van Voorhees, M.D., Chair, National Psoriasis Foundation Medical Board

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- 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 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.
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