Q&A on ICER FINAL REPORT

Q&A with Leah Howard, Vice President of Government Relations and Advocacy for the National Psoriasis Foundation (NPF), following the Institute for Clinical and Economic Review's (ICER) release of the Final Evidence Report and Meeting Summary on psoriasis treatments (Dec. 5, 2016).

Before we discuss the Final Report's findings, can you remind us of the scope of the ICER review?
ICER's review of psoriasis treatments focused on adults with moderate-to-severe chronic plaque psoriasis. Subgroups – patients who have and have not been previously treated with targeted immunomodulators, and those with/without psoriatic arthritis) – were also evaluated where data was available. The review focused on eight therapies (one is still awaiting final approval by the FDA). Brief mention is also given to biosimilars approved in 2016.

Anti-TNF agents:	Adalimumab (Humira®, AbbVie), Etanercept (Enbrel®, Amgen, Inc.), Infliximab (Remicade®, Janssen). (Brief mention also given to biosimilars Adalimumab-atto (Amjevita®, Amgen, Inc.) and Etanercept-szzs (Erelzi®, Sandoz Inc.). Another biosimilar, Infliximab-dyyb (Inflectra®, Pfizer), is not included in the report.
Anti IL-17A agents:	Secukinumab (Cosentyx®, Novartis), Ixekizumab (Taltz®, Eli Lilly and Co.) Brodalumab (Valeant Pharmaceuticals and AstraZeneca)
Anti IL-12/13 agent:	Ustekinumab (Stelara®, Janssen)
Anti-PDE4 agent:	Apremilast (Otezla®, Celgene)

Can you summarize the Final Evidence Report findings released on Dec. 2, 2016?
Following is the summary of the final review findings, which I can speak to a bit further later in this discussion.

Final Review Findings

Quoted directly from pages 82-83 of final report.

1. All the targeted drugs had reasonably good value for money compared to non-targeted therapy, using our estimated, discounted drug costs. The value of targeted agents is driven primarily by their meaningful impact on patient quality of life, and secondarily by offsetting other costs of care such as clinic visits and use of non-targeted therapies. While there are multiple sources of uncertainty, primarily caused by data limitations, this finding is robust using our base-case drug prices.

2. Despite the somewhat similar cost-effectiveness ratios vs. non-targeted therapy, there were important differences in the total amount of patient benefit (measured as QALYs) that could be gained for each drug. Drugs with high first-line efficacy and low discontinuation rates provide the greatest patient benefit, despite the availability of second-line therapy for those who failed first-line treatment. There are several reasons for this. First, not all patients who fail first-line therapy will continue to second-line therapy, and potential patient benefit is lost. Second, initiating second-line therapy incurs the added drug cost of another initiation period. Finally, although there is a paucity of data, it appears that second-line therapy may be slightly less effective than first-line treatment with the same drug.

3. The newer IL-17A targeted agents provide good economic value in relation to etanercept. The lower initial effectiveness of etanercept, high long-term discontinuation rates, and the need for more expensive second-line therapy decrease its overall value despite lower initial drug cost.

Summary

Our analyses suggest that if health care payers are able to achieve significant drug rebates, the most effective (and most expensive) targeted drugs provide the greatest benefit to psoriasis patients at a reasonable economic value.

The Final Report findings are a major shift from the findings of the draft report issued in late September. The draft report concluded that only one treatment, infliximab, appears to be the most cost-effective targeted agent for psoriasis treatment and that targeted agents other than infliximab do not represent good economic value. Given the comment letter submitted by NPF to ICER on Oct. 20, 2016, detailing a number of concerns with the draft, please speak to NPF's reaction to the findings in the Final Report.

NPF was very pleased to see such a substantial evolution in the findings to one that now accurately reflects the value all eight of the therapies represent to our patient community. As noted, the NPF had a number of concerns with the draft report, including how psoriasis was portrayed, how perspectives of patients were factored into the assessment, and the lack of real world treatment and economic considerations. Additionally, NPF experts raised a number of questions regarding ICER's cost model and the data inputs used to reach the draft findings. The NPF detailed each of these concerns in a five-page comment letter submitted on Oct. 20. We appreciated that ICER listened to these concerns and adjusted the final version of the report to reflect this feedback and to ultimately reach a new conclusion that appropriately reflects the value delivered by all eight of the therapies reviewed. More information on the changes by ICER to the final report based on 15 comments received on the draft may be found here in a summary of public comments received and ICER responses.

In an Oct. 31st Q&A, you explained that NPF has invested countless hours and many resources into participating in this ICER review. This was done (a) to ensure that the review accurately represented the disease and patient challenges managing psoriasis symptom, and (b) knowing the impact value frameworks have on the ability of patients and clinicians to access therapies. Since that Q&A, the NPF participated in ICER's Nov. 18 meeting of the New England Comparative Effectiveness Public Advisory Council (New England CEPAC). It was at this meeting that the New England CEPAC deliberated and voted on evidence presented in ICER's report on treatments for psoriasis. How did the Foundation highlight challenges faced by patients in managing their disease during this day-long discussion?

NPF approached the Nov. 18 meeting just as we have every comment letter, teleconference and email exchange during this psoriasis review. We sought to use every opportunity during the meeting to bring forward those challenges of psoriatic disease *not* captured in scientific literature, including the frustrations of living with and managing the disease over a lifetime. NPF experts and staff who participated in the meeting also drew out the nuances of psoriatic disease management that are well known to clinicians but may not have been clear to panel members who are experts in other disease states.

Specifically, NPF's Vice President of Research, Dr. Michael Siegel, offered a public comment on behalf of the Foundation focused on the heterogeneity, complexity, and uncertainty facing the 8.3 million Americans living with this disease. In his comments, Dr. Siegel said:

> "Psoriasis has a heterogeneous genetic foundation, complex immunological pathogenesis, and uncertain environmental triggers. Symptoms are heterogeneous, there is complexity in disease progression, and uncertainty around the development of comorbidities. Finally, there is heterogeneity of treatment efficacy, complexity determining appropriate treatment, and uncertainty around access. These issues are compounded by the fact that psoriasis is a chronic disease, affecting patients throughout life. Given these challenges, NPF is committed to the preservation of patient-provider dialog driving all treatment decisions. We believe that broad treatment access is central to the individual patient's success. Much uncertainty exists for patients living with psoriasis. What we know is that most patients say psoriasis is a problem in everyday life, are dissatisfied with treatment, and are not treating to the level dictated by their disease severity. We urge ICER to consider these challenges and ensure recommendations do not disrupt the sanctity of the patient-provider relationship."

We were pleased that ICER also acknowledged the value of having NPF's perspective on the policy roundtable, and I was glad to serve in this capacity. I joined NPF's Medical Board Chair Dr. Abby Van Voorhees, NPF Medical Board Member Dr. Joseph Merola, MMSC, patient Chris Pettit, Paul Jeffrey, Pharm.D. of Massachusetts Medicaid, and Thomas Kowalski, R.Ph. of Blue Cross Blue Shield of Massachusetts on the panel. Policy roundtable participations were available to answer questions during the panel's deliberation and voting. During this Q&A and the policy conversation that followed, I spoke to the anger, frustration and helplessness often expressed by individuals living with psoriasis – and their families. It was critical that patients and NPF (as the patient organization for the psoriasis community) have a seat at the table during this policy conversation.

In conclusion, we are pleased that ICER provided a genuine opportunity for dialog and engagement that clearly influenced the findings. We believe our contributions during the meeting and throughout the year-long process positively informed the dialog and recommendations that followed.

What were the policy recommendations that came out of this discussion?
Following are the top-line policy recommendations included in the final report.

Top Line Policy Implications

Pages 91-97 of final report.

Specialty Societies and Patient Advocacy Groups

- Update outdated 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.

Purchasers and Insurers

- Consider limiting or abolishing "step therapy" approaches to coverage.
- If step therapy will be used: (a) Allow individuals switching insurers to bypass step therapy if they are already on an effective treatment. (b) Remove requirements for patients to have higher out-of-pocket expenses for "later step" treatments.
- As alternative mechanisms to manage costs, consider developing indication-specific formulary designs and outcome-based payment contracts.
- Co-payment and/or co-insurance for therapies should be based on prices net of discounts and rebates instead of list price.

Manufacturers

- Foster transparency in the rationale for price increases.
- Release treatment-specific quality-of-life data.

Researchers and Manufacturers

- Conduct research that directly compares real-world treatment options and sequential treatment effectiveness for both naive and treatment-experienced patients.
- Generate additional information on the treatment durability of IL-17A agents.

Patient Advocacy Groups, Clinicians, and Researchers

- Patients and patient organizations should take a leadership role in the design of clinical trials and all stakeholders should advocate for rigorous study in diverse populations evaluating real-world comparative treatments.
- Lead research efforts to evaluate heritability of psoriasis and the impact of managing plaque psoriasis on caregivers and families.

The policy recommendations include limiting or abolishing step therapy! They also include some interesting points around indication-based pricing and cost-sharing. For patients and providers frustrated by step therapy, this policy recommendation confirms the challenges of navigating care. What will NPF be doing to share the Final Report findings and policy recommendations with policymakers and insurers? Are there ways for patients and providers to get involved?

The findings of the report that all eight therapies are of good value, and that step therapy is inappropriate for our community and should be limited or abolished, is indeed an amazing validation of the perspectives of patients, NPF and experts who care for our community. While we are pleased with many of these recommendations, as you noted, the step therapy recommendation and the corresponding point around protecting patients from high out-of-pocket certainly rise to the top.

Over the next several months, NPF will be reaching out directly to share the report and policy recommendations with policymakers and insurers. We want to make sure they see these recommendations so that ultimately they will impact formulary and other access decisions. NPF remains very interested in working with payers on these reforms, including exploration of indication-based pricing models that may yield more favorable access to a drug for a patient with psoriasis than for another condition if the evidence indicates superior effectiveness and value. We also look forward to continuing to embrace the recommendations directed at the patient community and to continuing to engage with clinical leaders and societies to ensure that clinical guidance is updated, evidence-based and widely disseminated.

If you would like to join us in advocating for our step therapy legislation, please reach out to the advocacy department at advocacy@psoriasis.org. To discuss the ICER review with NPF staff, please contact Leah Howard, Vice President 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.