AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

October 20, 2016

Steven Pearson, MD
Institute for Clinical and Economic Review
2 Liberty Square, Ninth Floor
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Dear Dr. Pearson:

The Alliance for the Adoption of Innovations in Medicine (Aimed Alliance) is a tax-exempt, not-for-profit organization that improves health care in the United States by expanding access to evidence-based treatments and technologies. On behalf of Aimed Alliance, I respectfully submit the following comment in response to the Draft Evidence Report, entitled "Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis" ("Draft Report") published by the Institute for Clinical and Economic Review ("ICER").

Psoriasis is a significant public health problem that affects approximately 7.5 million adults in the United States.[1] It is a chronic inflammatory disease of the immune system that mostly affects the skin and joints.[2] Plaque psoriasis is the most common type of psoriasis, affecting up to 80 percent of individuals with psoriasis.[3] Psoriasis can dramatically impact individuals' quality of life and self-esteem, and can result in depression, social isolation, and work-related problems.[4] Individuals with psoriasis must have access to effective treatment options. Yet, we fear that the Draft Report will limit those options.

QALYs are Discriminatory

The use of quality-adjusted life-years ("QALYs") is inconsistent with American values and public policy. Recognizing that value-based frameworks can result in an inappropriate rationing of care, Congress added language to the Patient Protection and Affordable Care Act that prohibited the Patient-Centered Outcomes Research Institute ("PCORI") from using QALYs as a threshold for determining coverage, reimbursement, or incentives in the Medicare program. The ban reflected a long-standing concern in the U.S. that the approach would lead to discrimination on the basis of age and health status, unfairly favoring younger and healthier populations.

QALYs put a price tag on the value of a human life that merely reflects the individual's diagnosis and deems those with chronic, debilitating, and rare conditions, such as psoriasis, as

[1] Charles G. Helmick, *Prevalence of Psoriasis Among Adults in the U.S.*, 47(1) Am J. Prev. Med. 27 (2014); *Psoriasis Treatments and Drugs*, Mayo Clinic, http://www.mayoclinic.org/diseases-conditions/psoriasis/basics/treatment/con-20030838 (last visited Oct. 20, 2016).
[2] *Psoriasis*, American Academy of Dermatology, https://www.aad.org/media/stats/conditions/psoriasis (Oct. 20, 2016).
[3] Ann Pietrangelo, *Psoriasis by the Numbers: Facts, Statistics, and You*, Health Nice (June 9, 2016), http://www.healthline.com/health/psoriasis/facts-statistics-infographic#Introduction1.
[4] Loretta Fala, *Otezla (Apremilast), an Oral PDE-4 Inhibitor, Receives FDA Approval for the Treatment of Patients with Active Psoriatic Arthritis and Plaque Psoriasis*, 8 Am Health Drug Benefit 105 (2015).

being worth less than the rest of the population. They treat individuals' lives and health as a commodity and ignore the patients' and practitioners' individualized concept of the value of treatment. Therefore, the QALY should not be used to set a threshold for a large population of individuals with one-of-a-kind life narratives across a complicated health care system.

Prioritizing Access to Options

To ensure patients receive adequate care, quality and choice of treatment options should not, by default, be sacrificed for cost-saving measures. The United States Court of Appeals for the Ninth Circuit has stated that "[f]aced with such a conflict between financial concerns and human suffering . . . the balance of hardships tips decidedly in [the patients'] favor."[5] Yet, the Draft Report concludes that targeted agents other than infliximab do not represent good economic value unless drug rebates and work productivity impacts are assessed, in which case they are moderately cost effective. It also concludes that "if second-line targeted drug use is high, . . . the main means of discrimination among agents should be price."

These conclusions ignore several benefits that immunomodulators provide in improving the quality of life of patients and controlling their symptoms. They also ignore that individual patient response, relevant comorbidities, and patient preference must also be considered when determining a treatment's value.[6]

As ICER acknowledges, individuals with psoriasis have unique responses to different psoriasis medications. Individuals with psoriasis may build up a resistance to various medication over time.[7] Their medication may become ineffective, and therefore, they must have access to all treatments available to them. Therefore, the value of each of these drugs must be made at the patient level, on a case-by-case basis given that each individual responds to these treatments differently.

Patient and Practitioner Perspectives

Patients must have a meaningful role in the discussion of value. They are directly impacted by a report that seeks to define the effectiveness and value of their treatment options. Therefore, accounting for how patients define the value of their treatment options should be critical to ICER's analysis.

Although ICER consulted with patients and patient groups on the topic of moderate-to-severe plaque psoriasis, it does not appear that ICER incorporated patient feedback. For example, the Draft Report states that patient groups discussed benefits that were not captured in clinical trials, such as reductions in distress and anxiety. Psoriasis tends to affect overall emotional wellbeing in 88 percent of patients, and interferes with the enjoyment of life in 82 percent.[8] It can result in

[5] Lopez v. Heckler, 713 F.2d 1432, 1437 (9th Cir. 1983).
[6] A. Schieder, et al., *Comorbidities Significantly Impact Patients' Preferences for Psoriasis Treatments*, 67 J. Am Acad. Dermatol. 363 (2012).
[7] *Psoriasis Treatments and Drugs*, Mayo Clinic, http://www.mayoclinic.org/diseases-conditions/psoriasis/basics/treatment/con-20030838 (last visited Oct. 20, 2016).
[8] April W. Armstrong, et al., *Quality of Life and Work Productivity Impairment among Psoriasis Patients: Findings from the National Psoriasis Foundation Survey Data 2003-2011*, 7(12) PLos One 2012.

anger, frustration, helplessness, embarrassment, and self-consciousness in a large majority of patients. While ICER did take into consideration the significant impact psoriasis has on work productivity, it appears that ICER did not take emotional and psychological impacts into consideration in its value assessment.

Additionally, the opinions of health care practitioners are vital in understanding the value of treatment options. Over the course of professional practice, health care practitioners obtain clinical experience with medications and identify emerging clinical trends and best practices. They can employ their practical knowledge to determine which medications are best suited to each patient's individual needs. However, it does not appear that ICER consulted with any dermatologists, internal medicine physicians, rheumatologists, or other physicians who commonly treat moderate-to-severe plaque psoriasis.

Nonmedical Switching

As ICER acknowledges, insurers and pharmacy benefit managers often employ burdensome benefit utilization management tools, such as step therapy and prior authorization to limit access to immunomodulators. Another commonly employed policy to reduce access to immunomodulators is nonmedical switching. Nonmedical switching occurs when an insurer requires a stable patient to switch from his or her current, effective medication to a cheaper, alternative drug.[9] The change occurs as the result of the insurer dropping a medication from the formulary altogether, moving a drug to a higher cost tier, or increasing the out-of-pocket costs owed after the plan year has begun. Nonmedical switching is done without consideration of the medical repercussions or reasoning behind the prescriber's selection of the original medication, and often without the prescriber's knowledge.[10]

This practice is particularly problematic for immunomodulators because, as previously discussed, patients can build up an immunity or tolerance to their medication. Therefore, if a stable patient is switched to a different treatment in an effort to save money, and that cheaper treatment is less effective, it is possible that switching back to their original medication will no longer be effective. Therefore, we caution against using assessments based on cost-savings alone, especially for stable patients.

Conclusion

Thank you for your consideration regarding the Draft Report, and we are available for discussion to address our shared goals of access to high quality health care at a price that accurately reflects public and personal benefits in the Final Report.

Respectfully submitted.

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[9] *Keeping Stable Patients on Their Medications*, Coal. of State Rheumatology Organizations, http://www.csro.info/Switching (last visited Jan. 14, 2016).
[10] *Id.*