

August 1, 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: Open Call: ICER Inclusion of Psoriatic Arthritis in Rheumatoid Arthritis Treatment Review

Dear Dr. Dreitlein,

I write to you today on behalf of the 7.5 million Americans living with psoriasis – up to 30% of whom may develop psoriatic arthritis – and the thousands of Americans living with psoriatic arthritis alone, to offer public comment to the Institute for Clinical and Economic Review (ICER) on the potential for a combined review of rheumatoid arthritis and psoriatic arthritis treatments. We thank you for the call you held with National Psoriasis Foundation medical experts and staff on July 27th to discuss the possible inclusion of psoriatic arthritis in this review. As we shared during this dialogue and earlier discussions prior to the release of the plaque psoriasis scoping document, both psoriasis and psoriatic arthritis are serious chronic diseases with significant morbidity and impact on mortality. Given the unique and heterogeneous nature of each disease, we encourage ICER to conduct any treatment reviews of these diseases independently of other conditions.

***Rheumatoid arthritis and psoriatic arthritis are unique conditions warranting individual reviews.***

As National Psoriasis Foundation medical experts shared during our discussion last week, despite some commonalities between rheumatoid arthritis (RA) and psoriatic arthritis (PsA) – such as in the use of ACR 20, an older outcomes measure – the individual nature of these diseases, different implications of comorbid health conditions, and variable effectiveness of medications between RA and PsA warrant individual reviews. We appreciated the opportunity to detail some of these differences using the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and European League Against Rheumatism (EULAR) guidelines for PsA during our recent discussion. 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 – ICER should separate out the diseases to ensure that any reviews appropriately account for patient preferences and individual disease considerations.

***Disease specific instruments and clinical trial challenges***

Last month we shared with ICER staff that in many ways there is no better time in history to be diagnosed with psoriasis than today. From the number of new treatments on the market and those in the pipeline, to mounting scientific advances, there is much hope for individuals living with psoriasis. It is equally the case that the landscape of psoriatic arthritis is changing rapidly. And while these changes are exciting for patients and give us hope about the opportunities to improve health outcomes for individuals living with the disease today, there remain significant clinical changes when making treatment decisions for the psoriatic arthritis community.

As the Public Health Agenda for Psoriasis and Psoriatic Arthritis published by the Centers for Disease Control and Prevention in 2013 articulates, “both psoriasis and psoriatic arthritis present a substantial public health burden; however, additional, population-based research is required in all six of the priority areas (burden, case

definitions, comorbidities, disparities, natural history, and severity).” In addition to these knowledge gaps, outcome measures are also lagging behind the rate of treatment progress and there is a challenge deploying all outcome measures because of patient burden during office visits.

Within clinical trials, there are additional challenges. Oligo and monoarticular (<5 joints) disease are not well captured because which joints are effected may be more significant. For example, the presence of disease in both knees is likely to have a more significant impact on a patient than many other joints. Spine disease is also spotty in clinical trial data – in part because a patient reported outcome is used when an MRI is needed. To get around spine challenges, rheumatologists often use ankylosing spondylitis data as a surrogate to inform management of psoriatic arthritis with spine involvement. While imaging can be informative, enthesitis – irritability of soft tissues - exams do not correlate well with imaging. Dactylitis, inflammation of an entire digit, is also not well measured. As we discussed during the planning for the psoriasis review, even when the skin disease is decently measured by PASI and PSI, psychometric measures do not correlate well in cases of minor involvement.

***Moving beyond trials: The challenges of treating a heterogeneous patient population***

While the number of advanced treatments brought to market for psoriatic arthritis in the last decade have significantly impacted the ability of individuals living with psoriatic arthritis to manage their disease, multiple challenges remain in uniformly administering these therapies. Today, trial and error guides much of PsA treatment decision-making. This is partly due to a lack of treatment guidelines for psoriatic arthritis – which is why the National Psoriasis Foundation and American College of Rheumatology have joined together to develop PsA guidelines (<http://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Psoriatic-Arthritis>) which anticipate publication in 2018. Yet the progression of the disease itself, and lack of clinical trial data previously discussed, also present challenges. While RA has a very uniform disease progression, psoriatic arthritis (like Lupus) has a heterogeneous disease progression. This variability in disease progression coupled with a lack of clinical trial data presents challenges to physicians seeking to replace experientially based treatment decisions with evidence-based ones.

***Conclusion***

As ICER moves ahead with this arthritis review, we urge you to recognize the individual and unique challenges of managing rheumatoid arthritis and psoriatic arthritis and conduct any reviews of these diseases independently. 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: Philip J Mease, MD, Chief of Rheumatology Research, Swedish Hospital Medical Center, Clinical Professor of Medicine, University of Washington

Elaine Husni, MD, Vice Chair of Rheumatology, Director of Arthritis and Musculoskeletal Center, Staff Physician in the Orthopedic and Rheumatologic Institute at Cleveland Clinic, Assistant Professor at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University

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