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President

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Oregon Prescription Drug Affordability Board
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Request for Information: Individuals with scientific or medical training per OAR-925-200-0020

Firas Kassab, MD
Secretary

Members of the Oregon Prescription Drug Affordability Board:

Erin Arnold, MD
Director

Leyka Barbosa, MD
Director

The Coalition of State Rheumatology Organizations (CSRO) appreciates the opportunity to provide feedback on the Request for Information (RFI) that will be used for future drugs selected by the PDAB for affordability reviews. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Kostas Botsoglou, MD
Director

Mark Box, MD
Director

Michael Brooks, MD
Director

Rheumatologic diseases, such as rheumatoid arthritis, psoriatic arthritis and lupus, are systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

Amish Dave, MD, MPH
Director

Harry Gewanter, MD, MACR
Director

CSRO has been an active participant in the PDAB's public hearings and comment periods, offering feedback on the impact of the PDAB's policies on patient access and provider reimbursement. We recommend the following improvements to the RFI so that the information offered to the Board offers helpful insights as decisions impacting patient access to medications are made.

Adrienne Hollander, MD
Director

Robert Levin, MD
Director

Q5. What is the administrative burden of the drug (prior authorization, step therapy, for example)?

Amar Majjhoo, MD
Director

We appreciate the Board's attention to the prevalence of utilization management protocols that often delay or prevent patient access to essential medications. As we know, patients will be unable to afford most medications without health insurance coverage. Thus, medication coverage and inclusion on the plan's prescription drug formulary is the essential first step in ensuring patient affordability.

Gregory Niemer, MD
Director

Joshua Stalow, MD
Director

EXECUTIVE OFFICE

Leslie Del Ponte
Executive Director

However, this question fails to recognize that the utilization management protocols, including prior authorization and step therapy, will be different for every health plan and is completely dependent on the individual health plan's prescription drug formulary. Even within a single plan, patients who are prescribed the same medication for different conditions will experience different protocol under the same health plan. Instead, to recognize the prevalence of utilization management across all health plans, we recommend the RFI ask:

In the past year, has this drug been subject to utilization management protocols by private health insurance, group health insurance, Medicaid, CHIP or the Marketplace/Exchange health plan?

We believe the responses will be illuminating for both the PDAB and other state bodies.

Q6. Are there therapeutic alternatives for this drug? (OAR-925-200-0020 2.k.B.ii)

Q7. Benefits of the prescription drug compared to therapeutic alternatives.

While we recognize that the statute incorporates “therapeutic alternatives” as criteria for drug affordability reviews, we would be remiss if we did not continue to highlight that not all therapeutic alternatives are therapeutically equivalent, having drastically different clinical outcomes for patients. When healthcare providers evaluate medication substitutions, they typically consider therapeutic equivalents – not alternatives.

Deeming medications “therapeutic alternatives” is a one-size fits all approach that disrupts the physician’s ability to exercise their medical expertise in concert with their patient. Patients that suffer from complex chronic conditions, such as rheumatoid arthritis and other rheumatologic diseases, require continuity of care to successfully manage their condition. Patients may spend months or years of trial and error, working with their physician to find a treatment regimen that properly manages their condition. The resulting course of treatment must carefully balance each patient’s unique medical history and co-morbidities, as well as balance the side-effects of other drug interactions.

Slight deviations in treatment and variations between drugs, even those in the same therapeutic class, can cause serious adverse events. Aside from the needless suffering endured by the patient as they work with their physician to find the right course of treatment, any disease progression caused by a delay in appropriate treatment can be irreversible, life threatening, and cause the patient’s original treatment to lose effectiveness. Therefore, we strongly recommend that the Board recognize these clinical practice standards and update the question within the RFI to ask:

Are there therapeutic equivalents, as recognized by the U.S. Food & Drug Administration, for this drug?

Benefits of the prescription drug compared to therapeutic equivalents.

Furthermore, we encourage the Board to adopt **additional questions** on the RFI to highlight the expertise of scientific or medically trained individuals, such as:

- *If the patient was prescribed an alternate drug in this class, how could that impact the patient’s condition?*
- *How could delayed access to this medication impact the patient’s condition?*
- *Do your patients typically utilize patient assistance programs or other medication assistance to access this drug?*
 - *If covered under insurance, have patients typically experienced difficulty affording this medication after the use of patient assistance programs or other medication assistance programs?*
- *For provider administered medications,*
 - *Do you currently source this product from a national distributor or out of state?*
 - *Do you currently bill an add-on payment to cover acquisition costs on top of the drug list price?*
 - *Would you be able to continue administering this medication without an add-on payment?*

We believe these additional questions will provide helpful insights that are critical for the Board's understanding within the affordability review process, as well as the true impact of implementing future upper payment limits on these medications. We encourage the Board to allow responses to the RFI to be accepted beyond the small space allotted on this form so that the PDAB can gain a full understanding of the questions at hand.

We thank you for your consideration and are happy to further detail our comments to the Board upon request.

Respectfully,



Aaron Broadwell, MD, FACR
President
Board of Directors



Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors