CSRO
Coalition of State Rheumatology Organizations

BOARD OF DIRECTORS

Aaron Broadwell, MD
President

Gary Feldman, MD
Immediate Past President

Madelaine Feldman, MD
VP, Advocacy & Government Affairs

Michael Saitta, MD, MBA
Treasurer

Firas Kassab, MD
Secretary

Erin Arnold, MD
Director

Leyka Barbosa, MD
Director

Kostas Botsoglou, MD
Director

Mark Box, MD
Director

Michael Brooks, MD
Director

Amish Dave, MD, MPH
Director

Harry Gewanter, MD, MACR
Director

Adrienne Hollander, MD
Director

Robert Levin, MD
Director

Amar Majjhoo, MD
Director

Gregory Niemer, MD
Director

Joshua Stolow, MD
Director

EXECUTIVE OFFICE

Leslie Del Ponte
Executive Director

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414.918.9825
Email: info@csro.info
Website: www.csro.info

September 15, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive
Suite 112-114
Bowie, MD 20715

Re: Maryland PDAB – Prescription Drug Affordability Board Review: Skyrizi

Members of the Maryland Prescription Drug Affordability Board:

The Coalition of State Rheumatology Organizations (CSRO) appreciates the opportunity to comment on the Prescription Drug Affordability Board (PDAB)'s cost review study process of **Skyrizi (risankizumab-rzaa).** 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.

Rheumatologic disease is 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.

Skyrizi is a biologic therapy that plays a critical role in the treatment of several inflammatory autoimmune conditions, including plaque psoriasis, psoriatic arthritis, Crohn's disease, and Ulcerative Colitis. This prescription drug works by blocking the p19 subunit of interleukin-23 (IL-23), a protein that drives chronic inflammation—helping to control disease progression, prevent joint damage, and improve patient function and quality of life. For many patients, Skyrizi has made the difference between long-term disability and independence.

As the Board conducts a cost review study of **Skyrizi (risankizumab-rzaa)** for an Upper Payment Limit (UPL), we hope it will keep in mind the importance of protecting patient access to therapies that are essential to effective disease management in rheumatology. We respectfully offer the following comments and recommendations for your consideration.

Insufficient Insight into What Patients Actually Pay

PDAB drug-selection criteria often rely heavily on list price, such as wholesale acquisition cost (WAC) and payer spending rather than on the patient's actual out-of-pocket exposure. Yet a patient's pharmacy counter cost is determined by benefit design: deductible status, coinsurance, formulary tier, prior authorization, accumulator programs, rebates, and, often most importantly, **eligibility for manufacturer copay assistance.**

Boards may review a drug as "unaffordable" without sufficiently establishing whether the affordability problem stems from the drug's price, the insurance benefit design, or failures to pass rebates and discounts through to patients. A drug with a high WAC may

be affordable to patients because of insurance coverage or because of manufacturer copay assistance. Conversely, a lower-priced drug can remain unaffordable if it sits on a high-cost tier or is subject to a high percentage co-insurance. A Health Affairs analysis notes that PDAB eligibility criteria primarily focus on list prices and inflation, not patient copayments, and that state frameworks do not consistently establish whether high out-of-pocket costs arise from benefit design versus the drug's price.[1] The practical concern is that PDAB policy can target the wrong problem: reducing payer reimbursement while leaving the patient's cost-sharing obligation unchanged.

Therapeutic Alternatives Are Not Appropriate Substitutions

In evaluating Skyrizi, CSRO urges the Board to recognize that not all therapeutic alternatives are therapeutically equivalent. This is particularly important for specialized therapies—such as a targeted "P-dab" drug—where the proposed alternative may be a treatment option in the same disease area but not a true therapeutic equivalent for the patient who is stable on, dependent on, or uniquely responsive to that treatment.

A board's conclusion that a drug has a "therapeutic alternative" should not be treated as proof that the alternative is clinically interchangeable for the individual patient. A medicine may have the same broad indication or be in the same therapeutic class while differing materially in FDA-approved population, mechanism, dosing route, adverse-effect profile, contraindications, durability of response, administration burden, or effectiveness after prior treatment failure. Therefore, we strongly recommend that the Board recognize that only therapeutic equivalents to Skyrizi, are clinically appropriate to consider for substitutions.

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 who 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, co-morbid conditions, and side-effect balancing drug interactions.

Skyrizi blocks the p19 subunit of interleukin-23 (IL-23) and has a mutated Fc region with negligible CD64 binding. Older IL-23 inhibitors (ustekinumab) block the p40 subunit shared with IL-12. It also shows an efficacy leap over older p40 inhibitors. Because p40 inhibitors also block IL-12, they broadly shut down a separate, helpful arm of the immune system. By leaving IL-12 completely untouched, Skyrizi preserves the body's natural defense pathways against serious infections, creating a far safer profile than early-generation biologics. This would leave patients who respond to IL-23 inhibitors with a "therapeutic alternative" that leaves them open to more serious side effects such as infections.

These distinctions are clinically meaningful for patients with overlapping disease manifestations, pediatric-onset disease, adherence or self-injection barriers, or prior treatment history. IL-23 pathway agents differ in labeled indications, route options, age groups studied, mechanism of action, warnings, and contraindications. For that reason, even an alternative IL-23 inhibitor may not be an appropriate substitute for every patient stabilized on Skyrizi, much less a medication with an entirely different mechanism of action.

[1] Health Affairs Forefront, *Unanswered Questions And Unintended Consequences Of State Prescription Drug Affordability Boards* (June 2024). https://www.healthaffairs.org/content/forefront/unanswered-questions-and-unintended-consequences-state-prescription-drug-affordability

No Assurance That a Lower Payment Limit Preserves or Improves Patient Access

CSRO strongly encourages the Board to study the real-world impact of establishing a UPL for Skyrizi (risankizumab-rzaa) as it conducts its cost review study process. In particular, we urge the Board to monitor whether these medications remain accessible to patients following implementation. A UPL regulates the maximum reimbursement amount paid by purchasers or payers; it does not directly regulate the patient's copay, coinsurance, deductible, formulary placement, or coverage rules. Therefore, savings do not automatically flow to the patient. More importantly, if the reimbursement ceiling is below what manufacturers, wholesalers, pharmacies, providers, or supply-chain participants can accept, the policy can create access risks. Plans may respond with narrower formularies, stricter utilization management, higher tiers, or expanded prior authorization and step-therapy requirements. Pharmacies may be unable to stock or dispense affected drugs if reimbursement does not cover acquisition and dispensing costs. Manufacturers may limit distribution, alter contracting, or decline participation in the affected market. Providers and patients may face delays, travel burdens, treatment disruption, or fewer treatment options, despite a nominally lower price.

There is no inherent pass-through mechanism from a UPL to patient out-of-pocket relief. Identifying average out-of-pocket costs and consumer access as factors for review, is not the same as guaranteeing lower patient cost sharing or uninterrupted access. Research and stakeholder analyses have also found broad concern that UPLs could prompt coverage changes, tiering changes, higher cost sharing, pharmacy supply problems, and impaired access.

For Part B drugs, if reimbursement falls below acquisition, physicians may stop stocking the drug and refer patients to hospitals. Unfortunately, many hospitals are higher-cost-of-care sites, or they may refuse to infuse that medication, leaving patients with higher costs and/or loss of access to the treatment entirely. Essentially, the UPL may lower reimbursement without ensuring that providers can continue offering the medication.

Additionally, there appears to be no guardrails requiring that after a UPL is implemented, the drug remains on formulary, prior authorization does not increase, step therapy does not expand, coinsurance does not increase, and provider access is maintained. It assumes that reducing reimbursement will improve affordability. It does not demonstrate that patients will pay less, nor does it require that patient access be preserved. Without both affordability and availability, lowering a payment limit alone does not improve access.

On behalf of practicing rheumatologists throughout Maryland, 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