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Maryland Prescription Drug Affordability Board
Comments on Skyrizi and Dupixent
September 2026

AARP Maryland, on behalf of its 850,000 members, urges the Maryland Prescription Drug Affordability Board (PDAB) to move rapidly toward a full cost review on Skyrizi and Dupixent. This would lead to important determinations of Upper Payment Limits (UPLs) that would help large numbers of Maryland residents afford these critical but very expensive pharmaceuticals.

Skyrizi is a biologic drug, approved in the U.S. for patients age 6 and above, that now has been prescribed for more than 370,000 U.S. patients to treat chronic inflammation-related issues. Patients typically need to stay on it long-term as continuous maintenance therapy. It is used to treat such significant illnesses as plaque psoriasis, psoriatic arthritis, Crohn's disease and moderate-to-severe ulcerative colitis. The drug is uniquely effective because it selectively targets and blocks interleukin-23, a protein that triggers immune-system-driven inflammation.

But the cost of Skyrizi is prohibitive for many Marylanders. Producer AbbVie's list price recently was $23,838,42, and no relief via generic drugs is in sight since patents on Skyrizi do not expire until at least 2033. While the cost is much lower for patients covered by Medicare Part D and Medicaid, most Maryland patients covered by state and local health insurance programs or by commercial insurance must pay prices that can be unaffordable for a long time.

Insurers react to those sky-high costs by making it harder for patients to qualify for having this medication covered. They usually require prior authorization and/or step therapy before they will cover Skyrizi.

Nor are there good alternatives to Skyrizi. Oral medications Otezla, which requires daily dosing and may cause stomach upset, and Rinvoq, which is suitable only for certain inflammatory conditions, are generally regarded as not as effective. The same situation applies to older biologics Humira and Stellara, which also are very costly.

The situation is similar for Dupixent. It is a complex biologic made from living cells injected subcutaneously every one to four weeks to treat serious inflammatory conditions, such as moderate-to-severe eczema, asthma, and chronic obstructive pulmonary disease (COPD). Produced by a joint venture of Sanofi and Regeneron Pharmaceuticals, it is approved for nine

indications in the U.S. and used by more than 1 million patients worldwide, including many in Maryland. Patients typically stay on the drug for at least six months and often much longer, according to the National Eczema Association.

Dupixent's list price is about $4,193 per carton, which consists of two pens or syringes and lasts only about a month. Even discount card GoodRx charges nearly $2,802 for two prefilled pens. Most adults take one injection every two weeks after the initial loading dose. Alternative and potentially cheaper drugs such as Adbry and Ebglyss are not the same in effect. Moreover, patents on Dupixent do not expire in the U.S. until 2031, and so-called biosimilar drugs might not get to market until a considerable time later. This means there is no price relief for commercial customers on the horizon.

Given that situation, some commercial insurers deny coverage completely, and insurers do not usually cover it for "off-label" purposes, even though there are reports of its effectiveness for them.

With virtually no prospect of the situation changing soon for either Skyrizi or Dupixent, it is important for Maryland's PDAB to take prompt action to assure that government entities in Maryland and the many state residents covered by their plans can afford these critical pharmaceuticals. AARP Maryland therefore urges the PDAB to move quickly to establish UPLs for these drugs and help the many Maryland residents who need them.

abbvie

September 15, 2026

VIA ELECTRONIC MAIL
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

Re: Response to the Board's Request for Public Written Comment for the Cost Review Study Process on SKYRIZI®

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie" or "the Company") appreciates the opportunity to provide comments in response to the request by the Maryland Prescription Drug Affordability Board (the "PDAB" or "Board") for public written comment on the cost-review study process on SKYRIZI® (risankizumab-rzaa) and DUPIXENT® **(**dupilumab**)**, posted on August 31, 2026 (the "Request").

AbbVie is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, and neuroscience. AbbVie is using advanced technologies and data science to gain unprecedented insights that help us to target medicines more precisely, identify opportunities for combinations, and provide patients and their physicians with actionable diagnostic tools. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives.

This letter accompanies and provides additional context for AbbVie's voluntary, confidential response to the Board's Request for Information ("RFI") concerning SKYRIZI, and incorporates by reference the extensive data and analysis AbbVie has submitted already regarding SKYRIZI, as well as AbbVie's repeated and broad objections to the Board's policies and procedures, as well as the Board's lack of adequate transparency.[1]

[1] *See, e.g.*, AbbVie's Comments on SKYRIZI®'s Selection and Referral to the Stakeholder Council (April 23, 2024), at https://pdab.maryland.gov/Documents/comments/4.29.2024%20PDASC%20Comments%20combined.pdf; AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024), at https://pdab.maryland.gov/Documents/comments/AbbVie_MD%20PDAB%20Comment%20Letter_May%209%2024-FINAL.pdf; AbbVie's Comments on the Board's List of SKYRIZI® Therapeutic Alternatives (May 13, 2024), at https://pdab.maryland.gov/Documents/comments/MD%20PDAB%20Therapeutic%20Alternatives%20Comments%20-%20SKYRIZI.pdf; AbbVie's Comments on SKYRIZI®'s Selection for Cost Review (July 22, 2024), at https://pdab.maryland.gov/Documents/comments/Board%20selected%20Drugs%20Comments.pdf; AbbVie's

As a threshold matter, AbbVie believes that the Maryland PDAB statute is flawed public policy that will not improve patient affordability. Moreover, we believe that the Board's implementation of the PDAB statute is unconstitutional. Additionally, as expressed in our prior comment letters, the Board's implementation and administration of the Maryland PDAB statute is inconsistent with Maryland's Administrative Procedure Act ("APA"). For example, the Board's lack of transparency regarding its decision-making is contrary to the public interest and has deprived AbbVie of the ability to effectively participate in the PDAB's drug selection and cost-review study processes. Nonetheless, the Company is engaging substantively and in good faith and taking this opportunity to provide additional comments on the Board's cost-review process.

SKYRIZI Is a Cost-Effective Treatment

Among other life-saving and life-enhancing products, AbbVie manufactures and markets SKYRIZI, a prescription biologic interleukin-23 antagonist indicated for the treatment of: (a) moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy; (b) active psoriatic arthritis in adults; (c) moderately to severely active Crohn's disease in adults; and (d) moderately to severely active ulcerative colitis in adults.[2] Since the U.S. Food and Drug Administration ("FDA") first approved SKYRIZI in 2019, AbbVie has continued to sponsor research on its use to address unmet patient needs, including for rare diseases. SKYRIZI is currently subject to the Board's cost-review study process.

Comments on MD PDAB Draft UPL Action Plan (August 26, 2024), at https://pdab.maryland.gov/Documents/reports/UPL%20Final%20Comment%20Packet%20%281%29.pdf; AbbVie's Written Testimony to MD Legislative Policy Committee (October 18, 2024), at https://mgaleg.maryland.gov/meeting_material/2024/lpc%20-%20133746007389905217%20-%20All%20Meeting%20Materials.pdf; AbbVie's Comments on the Board's Proposed Regulations Issued October 28, 2024 (November 8, 2024), at https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf; AbbVie's Comments on the Board's MD PDAB Proposed Amended Maryland Prescription Drug Affordability Board Cost Review Regulations (December 2, 2024), at https://pdab.maryland.gov/Documents/comments/2024.12.02-%20Regulations%20Comments%20%281%29.pdf; AbbVie's Comments on MD PDAB Proposed Regulations (February 10, 2025), at https://pdab.maryland.gov/media/1204; AbbVie's Comments on the Board's MD PDAB Dossier for FARXIGA® (July 3, 2025), at https://pdab.maryland.gov/Documents/comments/2025/Farxiga%20Dossier%20Comments%207.3.2025.pdf; AbbVie's Comments on the PDAB Preliminary Affordability Determination (August 22, 2025), at https://pdab.maryland.gov/media/1181; AbbVie's Comments on the Dossier - OZEMPIC® (semaglutide) and TRULICITY® (dulaglutide) (September 4, 2025), at https://pdab.maryland.gov/media/1002; AbbVie's Comments on MD Proposed Regulations Issued on March 16, 2026 (March 30, 2026), https://pdab.maryland.gov/media/952; AbbVie's Comments on MD Proposed Regulations Issued on May 1, 2026 (June 1, 2026), https://pdab.maryland.gov/media/1324; AbbVie's Comments on the Board's 340B Program Study and Recommendations for Report Scope (June 15, 2026), https://pdab.maryland.gov/media/1405; and AbbVie's Comments on MD Proposed Regulations Issued May 26, 2026 (June 26, 2026), https://pdab.maryland.gov/media/1417.

[2] SKYRIZI, Full Prescribing Information, https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.

As detailed in AbbVie's prior comment letters, SKYRIZI is an affordable and highly valuable treatment option for people living with debilitating immunology diseases in Maryland, as well as for the broader healthcare system and the state. SKYRIZI delivers rapid, durable, and clinically meaningful improvements for patients living with chronic, progressive, and severe diseases. Across Maryland, patients have experienced life-changing benefits from SKYRIZI, as supported by robust clinical trial data and real-world evidence, underscoring its critical role as a patient-centric, innovative therapy. SKYRIZI is in a class of its own. No other available therapy has proven as efficacious against the most stringent endpoints, with a favorable tolerability profile, across such a breadth of indications.

In addition to being an effective treatment, SKYRIZI is presently accessible and affordable for patients in Maryland. AbbVie has comprehensive programs that enable patients, including those in Maryland, to access our medicines at prices they can afford. AbbVie offers patient support programs that set a new industry standard for patient service by focusing on a high-touch, highly personal, human health care experience delivered through a combination of personal interactions, digital solutions, and sophisticated data management. For example, eligible commercially insured patients may qualify for SKYRIZI Complete, which offers a Savings Card that reduces patient cost-sharing to as little as $0 per dose.[3] AbbVie's understanding is that the PDAB is particularly interested in the cost of SKYRIZI for its state employee insurance plan members, who to our knowledge have coverage under a commercial plan/plans. If not restricted from doing so under your plans, your employees with commercial insurance coverage are eligible to apply for cost-sharing assistance from AbbVie according to program terms and conditions. Specifically, each employee that received such assistance could pay as little as $0 per dose out of pocket. The Board's existing approach to evaluating patient out-of-pocket costs ignores the substantial benefit of these co-pay assistance programs, resulting in an incomplete and misleading picture of affordability. The availability of co-pay assistance is not evidence of unaffordability, as the Board posits; it is a response to insurance benefit designs that manufacturers do not control. The Board's failure to account for real-world patient out-of-pocket costs and manufacturer-supported access programs results in an incomplete and legally insufficient evaluation of affordability under the statute. Further, for Medicaid patients, the other major group of patients under the purview of the Maryland PDAB, the Maryland Medicaid program itself says patients pay no more than $3 per dispense.[4]

While SKYRIZI is accessible and affordable for patients in Maryland today, the Board has failed to address stakeholders' significant concerns regarding the impact that any Board-imposed upper payment limit ("UPL") will have on that patient access. Key stakeholders—and even members of the Board's own Stakeholder Council—have expressed grave doubts regarding the Board's approach, including its disregard for pharmacist and patient concerns (*e.g.*, impact to medication access), and lack of consideration of information critical to evaluating the actual costs

[3] https://www.skyrizi.com/skyrizi-complete/about-skyrizi-complete.

[4] *Maryland Dep't of Health, Pharmacy Provider Claims Processing Manual for Maryland Pharmacy Programs, Maryland Medicaid Pharmacy Program (MMPP) Copays, §9.9, at https://www.mdhrxprograms.com/webportal/#/programInfo/programInfoDetailedPage/4946 (accessed Sept. 15, 2026).*

patients pay for drugs (*e.g.*, Pharmacy Benefit Manager ("PBM") and insurance carrier costs).[5] Commentary by the Board's staff about a stated intention to effectuate any UPL through supplemental rebates[6] from manufacturers—the very PBM-driven rebate arrangements whose opacity the Board has otherwise failed to account for in its affordability analysis—further compounds the uncertainty about the Board's approach and how the imposition of a UPL will address stakeholder concerns. As a result of the imposition of a UPL, AbbVie remains concerned that patients may face restricted access, treatment delays, or outright loss of therapy availability. The Board is not appropriately considering this broader context of patient affordability in Maryland, and in so doing, risks imposing a potential UPL that could significantly harm the strong and affordable access Maryland patients have to SKYRIZI today.

Taken together, the compelling evidence of SKYRIZI's economic and clinical value, as well as patient affordability and access, underscores that it would be inappropriate to select SKYRIZI for cost review, find the product to be "unaffordable," and/or take any other action with respect to the product (including, but not limited to, applying a UPL to the product). We encourage the Board to seek robust input from the patients and healthcare providers who can testify to SKYRIZI's profound impact, underscoring its role as a patient-centric, innovative therapy. When the cost-effectiveness of SKYRIZI is considered through a comprehensive, multifaceted evaluation, it is clear that there are no affordability issues associated with purchases of, and payments made for the product. There certainly are no affordability issues with purchases or payments by Maryland's state and local governments and their respective units — the only patient and payor segments with respect to which the Board currently has authority to consider "affordability."

Request for Transparency and Meaningful Opportunity for Public Comment

AbbVie continues to have concerns about the Board's lack of transparency and failure to ensure input from stakeholders. The administrative record reflects a continuing trend of the Board adopting highly variable and inconsistent timelines across processes, which impedes the ability of stakeholders to meaningfully participate, as required by the Maryland APA. Earlier stages allowed input over longer periods; for example, the response period for the Board's early-stage data requests typically ranged from 30 to 60 days. But more recently, the Board has permitted much shorter comment periods, including the 12 business day comment period for this Request. Under

[5] *See, e.g.*, Kelly Schultz, Commentary, "In Maryland, drug price controls won't help patient affordability," Maryland Matters (October 26, 2024), at https://marylandmatters.org/2024/10/26/in-maryland-drug-price-controls-wont-help-patient-affordability/; see also Community Access National Network, Comment, Re: Comment on Proposed Regulations (November 8, 2024) (noting that the Board's truncated comment timelines and use of emergency rulemaking procedures inhibits patient engagement and "degrade[s] public trust in the institution of the Board and staff"); Coalition of State Rheumatology Organizations, Comment, Re: New Chapter – COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (November 7, 2024) (explaining that the Board's methodology does not account for physician acquisition costs and risks patient access to medications); Healthcare Distribution Alliance, Comment, COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (November 8, 2024) (explaining that the Board's methodology will create hardships for independent pharmacies and the patients they serve).

[6] *See* Maryland Prescription Drug Affordability Stakeholder Council, April 13, 2026 Meeting Materials, "UPL Regulations: Implementation and Monitoring of Upper Payment Limits," at 6, at https://pdab.maryland.gov/media/917.

the federal APA, "a 30-day comment period is generally the shortest time period sufficient for interested persons to meaningfully review a proposed rule and provide informed comment."[7] Similarly, Maryland law requires a state agency proposing a regulation to "permit public comment for at least 30 days."[8] Given the stakes with establishing a UPL—for patients, providers, and manufacturers—these truncated comment periods are wholly inadequate.

Moreover, the Board has frequently established multiple overlapping comment periods, requiring stakeholders to respond to numerous complex documents concurrently. For example, earlier this year, the Board issued several staggered but overlapping regulatory actions and associated comment periods:

- March 16 to 30, 2026: FARXIGA/JARDIANCE UPL regulations (11 business day comment period);
- April 22 to May 1, 2026: OZEMPIC cost review study materials (8 business day comment period);
- May 11 to 13, 2026: Comment period for May 18, 2026 public meeting (agenda materials revised May 11, 2026, leaving two business days to comment);
- May 1 to June 1, 2026: Proposed revisions to COMAR 14.01.04 (with an initial comment period of 6 business days, which the Board subsequently extended to approximately 22 days in response to stakeholder requests which emphasized the breadth and depth of the proposed changes).
- May 27 to June 26, 2026: Proposed revisions to COMAR 14.01.01 (24 business day comment period).

Now, the Board again has opened two staggered but overlapping regulatory actions and associated comment periods—

- August 31 to September 15, 2026: Request for Public Comment for the Cost Review Study Process on DUPIXENT and SKYRIZI (12 business day comment period, with a holiday weekend falling in the middle); and
- September 4 to October 5, 2026: Proposed revisions to COMAR 14.01.01 and 14.01.04 (with a comment period of approximately 21 business days).

These are just examples of the Board's pattern of issuing actions with continuous rolling deadlines, failing to consolidate or coordinate related activities, and seeking public comment on truncated and unpredictable timelines. This pattern requires stakeholders to respond to multiple requests in parallel, impairing their ability to provide input on complex actions that may affect those stakeholders in material ways.

It is important for the Board to seek, consider, and respond to comments from all stakeholders, and AbbVie will continue to engage with the Board in good faith. As AbbVie does so, AbbVie requests that the Board provide a clearer timeline as to how the cost review study

[7] *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1117 (D.C. Cir. 2019).
[8] Md. Code Ann., State Gov't § 10-111(a)(3).

process for SKYRIZI will proceed. AbbVie further requests that the Board ensure that the time for comment at each stage is predictable and adequate, particularly when the Board seeks comment on detailed analyses.

* * * *

As many stakeholders have explained in more than two years since the first six drugs were selected for cost review, evaluating a drug's price in isolation is an overly narrow and misleading approach to affordability, and instead of addressing systemic barriers, the Board risks undermining patient care. We strongly urge the Board to fully assess SKYRIZI's clinical profile and cost-effectiveness as a treatment for Maryland patients, as well as the access Maryland patients have to the product today, and not deem SKYRIZI unaffordable. The evidence clearly demonstrates that SKYRIZI is affordable, delivers holistic value to Maryland's healthcare system, and substantially improves the lives of patients. And it is imperative for the Board to consider the consequences to patient access if a finding of unaffordability is made and a UPL imposed.

AbbVie respectfully requests an opportunity to meet with Board members to further discuss the information we have submitted. We also request the opportunity to meet with the Board before it issues any affordability determination, so that we may understand the factors driving that determination. We look forward to engaging further and sharing how innovations like SKYRIZI are transforming patient outcomes and contributing positively to Maryland's healthcare landscape.

Thank you for the opportunity to provide these comments. Please do not hesitate to contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

Helen Kim Fitzpatrick
Vice President, State Government Affairs
On behalf of AbbVie Inc

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

September 15th, 2026

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

RE: Skyrizi (risankizumab) Affordability Review — Patient Perspective on Therapeutic Alternatives, Value, and Affordability

Dear Members of the Maryland Prescription Drug Affordability Board:

On behalf of the International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient-led organization founded and led by people affected by our diseases - including those treated by Skyrizi (risankizumab) - we appreciate the opportunity to provide comments on behalf of those who rely on this medication to maintain a high quality of life.

Skyrizi is an IL-23 inhibitor used across several immune-mediated diseases, including plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. For patients, the value of a treatment is not simply its price. It is whether that treatment controls their disease, works given their treatment history and other health conditions, can be maintained over time, and allows them to function in their daily lives.

As the Board considers Skyrizi's affordability, we ask that **cost, clinical value, and patient affordability remain distinct questions—and that the solution ultimately selected reflects who the Board intends to help.**

A Broad Cost Comparison Requires Clinical Context

The Board's proposed therapeutic alternative list for Skyrizi includes 22 medications. We understand Maryland intentionally uses a broad definition of “therapeutic alternatives” to compare Skyrizi's cost with other treatments used for the same diseases—not to suggest that all 22 are clinically interchangeable.

That distinction is important because the list includes biologics targeting several different pathways, targeted oral therapies, and even non-biologic treatments such as **methotrexate, cyclosporine, and acitretin**. These non-biologic therapies may be used earlier in the treatment pathway or in addition to a biologic therapy rather than as comparable therapies. Comparing their prices with Skyrizi without accounting for these fundamentally different roles in patient care risks creating a misleading picture of relative cost and value.

Of the 22 therapies, only **two—Tremfya (guselkumab) and Ilumya (tildrakizumab)—share Skyrizi's selective IL-23 p19 target.** Ilumya has much narrower approved use, making **Tremfya the closest comparator**, with the same target and substantial overlap across the

diseases treated. Even Skyrizi and Tremfya are not identical. Dosing, administration, treatment history, individual response, and available evidence may differ. Neither should be presumed better or worse for every patient; they are separate therapies that may be appropriate for different individuals.

Differences across the rest of the list are even greater. Some treat only certain diseases Skyrizi treats. Others work through entirely different immune pathways or have different safety considerations, contraindications, or routes of administration.

This does not mean these medications should be excluded from a cost comparison. It means price alone cannot establish comparative value.

Published head-to-head evidence demonstrates why. In the SEQUENCE trial of patients with moderate-to-severe Crohn's disease who had previously failed or were intolerant to anti-TNF therapy, risankizumab achieved superior endoscopic remission at Week 48 compared with Stelara (ustekinumab)—31.8% versus 16.2%. In the IMMvent trial in moderate-to-severe plaque psoriasis, 72% receiving risankizumab achieved PASI 90 at Week 16 compared with 47% receiving Humira (adalimumab).

These findings do not mean Stelara or Humira are inferior treatments. They demonstrate why medications used for the same disease can provide different value to different patients—and why cost comparisons need clinical context.

Affordability for Whom?

Maryland's statute allows the Board to determine that a drug creates an affordability challenge **for patients *or* the State *or* the healthcare system *or* a combination of these stakeholders. These are not the same affordability problems and, therefore, should not automatically lead to the same solutions.**

For example, a drug may represent significant spending to the healthcare system while remaining affordable to a patient taking it. Conversely, a patient may struggle to afford a medication because of their insurance coverage even when the cost to other stakeholders is lower.

This distinction matters because **Maryland's PDAB was established and has continued to be publicly promoted as an effort to help Marylanders afford their prescription medications**, and Board members have also spoken about helping patients as a priority.

Therefore, if a drug is determined to create affordability challenges for more than one stakeholder, the Board has a responsibility to clearly state whose affordability problem it is prioritizing when selecting a solution.

If patients are a priority, a finding that Skyrizi is affordable or unaffordable to patients is only the beginning. The Board must understand why patients are experiencing it that way before it can determine which solution will actually help them.

Patient Affordability Requires Understanding the "Why"

AiArthritis participates in the Ensuring Access through Collaborative Health (EACH)/Patient Inclusion Council (PIC) coalition, which conducted an 18-month patient-facing study examining the drivers of prescription drug affordability and unaffordability. The research found that **what a patient pays does not tell us *why* they pay it**, and insurance design and coverage practices were major drivers of patient-reported affordability challenges.

One study respondent from Maryland who is taking Skyrizi illustrates this particularly well. The respondent has employer-sponsored insurance, earns $25,000–$49,999 annually, and has always paid just **$0–$10 out of pocket for Skyrizi.** "If it were not for my additional copay program, I would not be able to afford Skyrizi (or any other biologic)."

They previously lost access to biologic treatment when assistance and insurance did not cover enough, going months without medication until their physician provided samples. They have failed multiple biologics over 25 years and described Skyrizi as **"extremely valuable,"** explaining, "Without meds, I would be disabled." They also reported that access to Skyrizi allows them to work and do the things they need to do, while insurance-related interruptions remain a constant concern.

This single experience demonstrates why neither a high nor a low out-of-pocket amount tells the complete affordability story. Skyrizi is *currently* affordable to this patient. Their previous loss of access was also real—but driven by coverage and financial assistance problems. And the medication's value cannot be understood without knowing that multiple previous biologics failed and successful treatment allows this person to continue working.

That is the **"why"** Maryland needs to understand.Patients should have open-ended opportunities to explain what is driving their costs, what changed when affordability changed, what makes their treatment affordable today, and what would happen without that support.

Without this information, the Board may identify that a patient has an affordability problem, but it cannot determine what is causing that problem or which solution will actually resolve it.

Match the Solution to the Problem

This distinction is particularly important because Maryland has authority to consider **non-UPL solutions**. An Upper Payment Limit (UPL) limits what may be paid for a drug by stakeholders that are not patients. It does not directly set an individual patient's out-of-pocket cost. If the

patient-reported affordability problem is driven by insurance design or coverage practices, Maryland's non-UPL authority provides an opportunity to pursue solutions targeted to those actual drivers.

The downstream effects of any solution must also be considered. Changes in payment can change incentives for insurers and PBMs, potentially affecting formulary placement, utilization management, preferred therapies, and coverage. **Even if Skyrizi was to become the preferred medication on an insurance companies formulary, that means all other people with plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis on therapeutic alternatives will likely be asked by their plan to non-medically switch off of their medication to use this drug. The UPL not only does not solve for this, it exacerbates the situation.**

Patients should not have to trade treatment stability for savings elsewhere in the healthcare system. A patient successfully treated with Skyrizi should not risk losing access because another therapy becomes financially preferable to a payer—just as a patient successfully treated with Tremfya, Stelara, Humira, or another appropriate therapy should not be pushed toward Skyrizi for financial reasons.

If patients are among the stakeholders the Board intends to prioritize, we urge the Board to conduct and publicly release **patient-centered scenario mapping before implementing any solution**, clearly showing:

- **What patient affordability problem was identified and what is causing it;**
- **How the proposed solution will address that cause and lower patients' actual out-of-pocket costs;**
- **Whether a non-UPL solution would address the identified problem more directly;**
- **How insurers and PBMs could respond, including potential formulary or utilization-management changes; and**
- **What protections will prevent patients with affordable access and successful disease control from experiencing new cost or access barriers.**

Value Must Be Part of the Equation

Finally, affordability should not be evaluated without recognizing the value of successful treatment. Clinical response can differ among therapies used for the same disease. Treatment stability, healthcare utilization, ability to work, daily functioning, and quality of life also matter.

The Skyrizi respondent in the EACH/PIC study captures this well. **The medication currently costs them almost nothing out of pocket, yet they describe it as “extremely valuable” because it allows them to work and avoid disability after multiple other biologics failed.**

For patients, value ultimately comes down to: **Does this treatment control my disease? Can I stay on it? Can I afford it? And can I continue living my life while taking it?**

Maryland has the authority to distinguish among affordability challenges affecting patients, the State, and the healthcare system, as well as the ability to consider solutions beyond a UPL. We encourage the Board to use that authority deliberately by **identifying who is experiencing the affordability problem, understanding why, and consider the clinical and patient value that could be affected. Then select the solution most likely to address that specific problem without creating a new one for patients.**

Thank you for considering the patient perspective as you continue your review of Skyrizi.

Sincerely,

Tiffany Westrich-Robertson
tiffany@aiarthritis.org
AiArthritis (International Foundation for Autoimmune & Autoinflammatory Arthritis)
CEO
Person living with Axial Spondyloarthritis

References

SEQUENCE Trial
Peyrin-Biroulet L, Chapman JC, Colombel JF, et al. *Risankizumab versus Ustekinumab for Moderate-to-Severe Crohn's Disease.* **New England Journal of Medicine.** 2024. doi:10.1056/NEJMoa2314585.

IMMvent Trial
Reich K, Gooderham M, Thaçi D, et al. *Risankizumab compared with adalimumab in patients with moderate-to-severe plaque psoriasis (IMMvent): a randomised, double-blind, active-comparator-controlled phase 3 trial.* **The Lancet.** 2019;394(10198):576–586. doi:10.1016/S0140-6736(19)30952-3.

Alliance for Patient Access

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

RE: Public Comments on the Cost Review of Dupilumab and Risankizumab and the Establishment of an Upper Payment Limit

Dear Members of the Prescription Drug Affordability Board,

On behalf of the Alliance for Patient Access (AfPA), thank you for the opportunity to submit comments as the Board conducts its cost review of dupilumab and risankizumab, and considers an upper payment limit (UPL) for these medications.

Founded in 2006, the Alliance for Patient Access is a national network of policy-minded healthcare providers who advocate for patient-centered care. AfPA supports health policies that reinforce clinical decision-making, promote personalized care and protect the clinician-patient relationship. Through clinician working groups, advocacy initiatives, stakeholder coalitions and educational efforts, AfPA works to ensure that patients can access the treatments their clinicians determine are most appropriate for their care.

COPD is a leading cause of chronic morbidity and mortality in Maryland, and any policy that affects access to COPD treatment carries significant consequences for the state's patients, families, and health care system. As of 2023, approximately 233,986 Maryland adults have been diagnosed with COPD. It also costs the state an estimated $595 million annually in treatment expenses These figures likely understate the true burden, as half of the national COPD population goes undiagnosed.[1] Additionally, asthma imposes a significant burden on Maryland patients and the health care system. An estimated 6.8% of children in 2021 and 10.8% of adults in 2022 were living with asthma. In 2022 alone, asthma was responsible for 21,852 emergency department visits, as well as 1,866 hospitalizations. These asthma-related health care encounters also carried substantial economic costs, totaling approximately $70 million in 2022, including $48.1 million for emergency department visits and an additional $21.9 million for hospitalizations.[2]

Crohn's disease and ulcerative colitis are forms of inflammatory bowel disease (IBD) that causes inflammation throughout the gastrointestinal tract and can significantly affect a patient's quality of life. While the Maryland Department of Health does not publish state-specific prevalence data for Crohn's disease, national estimates suggest that IBD affects approximately 721 per 100,000 people.

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[1] COPD State Briefs Maryland
[2] Pages - Asthma

U.S. prevalence of inflammatory bowel disease (IBD) is estimated between 2.4 and 3.1 million, with differing burden across groups. Since Crohn's and ulcerative colitis are lifelong conditions characterized by periods of flare-ups and remission, consistent access to treatment, like risankizumab is critical.[3]

We appreciate the Board's efforts to address prescription drug affordability and share the goal of ensuring Maryland patients can access the treatments they need. As the Board considers a UPL for dupilumab and risankizumab, we urge careful consideration of how these policies may affect patient access. Any pricing action should be structured in a way that maintains, rather than inadvertently limits, access for Medicaid beneficiaries and individuals covered by other state health plans.

While UPLs are intended to reduce cost to the state, they can also have unintended consequences within the current coverage system. Changes to a drug's pricing may influence how payers and pharmacy benefit managers (PBMs) design formularies and make coverage decisions. As a result, patients could face higher out-of-pocket costs, more restrictive prior authorization or step-therapy requirements, or the loss of preferred formulary status, making it more difficult to access treatment.

For patients living with serious chronic conditions, uninterrupted access to effective treatment is critical. We urge the Board to consider the effects of formulary restrictions and utilization-management on patient access before finalizing a UPL for dupilumab and risankizumab

Thank you for your attention to this important matter and your commitment to Maryland patients and providers. Should you have any questions or if AfPA can provide additional information, please reach out to Casey McPherson at cmcpherson@allianceforpatientaccess.org.

Sincerely,

Casey McPherson

Executive Director

[3] IBD Facts and Stats | IBD | CDC

Alliance for Patient Access
2020 K St. NW | Suite 505
Washington, DC 20006

Alliance for Patient Access
2020 K St. NW | Suite 505
Washington, DC 20006

Dear Board,

Thank you for the opportunity to submit written comments as part of the Board's cost review study of Skyrizi. The Arthritis Foundation supports efforts to make treatment more affordable for patients, and we appreciate the rigor the Board brings to these reviews. As the Board considers this medication, we ask you to keep patients at the center of the focus. Specifically, please evaluate whether an affordability action would ultimately lower the cost for the patient and not just impact the retail price, but ultimately the price the patient pays with or without insurance coverage and whether affordability actions would protect, rather than narrow, access to that treatment.

Skyrizi is approved for active psoriatic arthritis, and it is typically not a first step. Patients generally reach it only after other therapies have failed to control their disease. Skyrizi is a different mechanism from other biologic classes commonly used in psoriatic arthritis, which means a patient who responds well to this treatment may not respond well to others. These medications are not interchangeable, so the therapy that controls one patient's disease may be the only one that is successful. By the time a patient is stable on Skyrizi, it is often not one option among many, it is the only one that works.

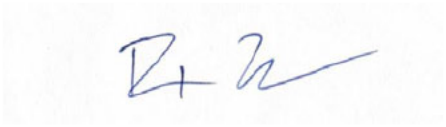
Given these real life patient experiences, we urge the Board to weigh the downstream effects of any affordability determination. Our concern is not the Board's goal but its resulting consequences: if a determination by this Board results in formulary restrictions, or non-medical switching, patients stable on Skyrizi can be forced off an effective therapy. For a patient who has already exhausted other options, an interruption is not a minor inconvenience; it can mean a disease flare, lost function, and months to regain control, if control returns at all. We ask the Board to ensure its work does not become a new access barrier for the patients who depend on this medication.

We also encourage the Board to consider what its findings will mean at the pharmacy counter. Measures aimed at savings for the system, such as a cap on what the state pays, do not, by themselves, change what a patient owes. A system-level saving can leave a patient's cost at the counter untouched, while possibly limiting access to the medication. For an affordability action to matter to patients, the savings must reach them directly.

We respectfully ask the Board to: (1) guard against any determination that results in new access barriers for patients already stabilized on therapy, and (2) treat a reduction in real patient point-of-sale cost, not system-level savings alone, as a primary measure of whether an action has succeeded

Thank you to the Board for your commitment to improving the lives of patients in Maryland.

Sincerely,



Robert Nolan
State Affairs Coordinator
Arthritis Foundation

Dear Members of the Maryland Prescription Drug Affordability Board,

My name is Lovette Brown, and I am writing as a Maryland patient who knows personally what it feels like to have access to medication become a struggle.

I do not currently take Skyrizi or Dupixent, but I wanted to comment because I understand what it is like to need a medication and have insurance and cost stand between you and the treatment you and your doctor have discussed.

I have struggled with obesity and eventually had gastric sleeve surgery as part of my journey to improve my health. Even after surgery, obesity care does not just stop. It is something I continue to manage, and medication has been part of those conversations with my healthcare providers.

I have been denied access to GLP-1 medications through my VA healthcare coverage. I have had to deal with requirements, coverage issues, and trying to figure out what options were available to me. At one point, I even paid for additional insurance through my job because I was trying to have another option for getting the obesity treatment I needed.

That experience changed the way I look at medication access.

When you are the patient, you are not thinking about a medication as a number on a spreadsheet. You are thinking about whether you can get it, whether your insurance will cover it, what hoops you will have to jump through, and whether you will have to start all over again if something changes.

I absolutely understand wanting medications to be more affordable. Patients need that. But I also know from my own experience that a medication being considered affordable does not mean very much if I cannot actually access it.

My concern is making sure that whatever decisions are made do not create another hurdle for patients. I have already experienced what it is like to have a treatment option discussed with my healthcare provider and then find out that getting access to it is another battle entirely. I would not want another patient to go through that because of a decision that was originally intended to help them.

My patient advocacy work has made this even more important to me. I speak about obesity, access to care, and what it is actually like to navigate the healthcare system as a patient. I bring my own experiences into that work because patients need to be part of conversations where decisions about our care are being made.

I am not asking the Board to ignore the cost of medications. I am asking you to remember the patient on the other side of the decision.

Please make sure that making medication more affordable does not come at the expense of a patient’s ability to actually get the medication their healthcare provider believes is right for them.

Thank you for allowing me to share my experience.

Sincerely,

Lovette Brown

Dear Members of the Maryland Prescription Drug Affordability Board,

I am writing as a Maryland resident and patient living with Crohn's disease to express my support for efforts to protect affordable access to necessary medications.

While I am not currently taking either medication under review, I am in the process of navigating treatment options and determining what may be appropriate for me in the future. Living with a chronic illness can make this process incredibly stressful, particularly when also trying to plan for a family, maintain employment, manage responsibilities at home, and navigate the financial realities of ongoing care.

For patients with chronic conditions and limited treatment options, consistency and affordability are especially important. Decisions about medication should be based on what best supports a patient's health and quality of life, not solely on whether that treatment is financially accessible.

I encourage the Board to consider the real-world impact that medication affordability and access can have on patients and families, including those who may need these treatments in the future.

Thank you for considering the patient perspective in this important process.

Sincerely,

Morgan Brown

CSRO
Coalition of State Rheumatology Organizations

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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

September 15, 2026

Mr. Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Mr. York:

On August 26, 2024, I wrote a letter to the Maryland Prescription Drug Affordability Board (PDAB), attached, on behalf of the Color of Gastrointestinal Illness (COGI) to comment on the Board's ongoing cost review activities, highlighting my personal experience with Skyrizi. As I understand, the Board is now accepting comments on both Skyrizi and Dupixant, having decided to advance their consideration for Upper Payment Limits. COGI represents black, indigenous and other people of color (BIPOC) who are affected by inflammatory bowel disease (IBD), digestive disorders, gastrointestinal cancer and associated chronic illnesses, many of whom have experience with these medicines.

I would urge you to consider the experiences of other similar state boards and the unintended consequences highlighted by experts in the disability community. As Tony Coelho, the original author and sponsor of the Americans with Disabilities Act (ADA) stated, "While PDABs exist to reduce system costs, they're doing so at the expense of patients and people with disabilities." I am particularly sensitive to the "one-size-fits-all" problem whereby critical input about how treatments benefit individual patients and improve their quality of life is lost in the measurement of cost effectiveness that drives PDAB decision-making. My community has different needs based on age, income, location, and disability. As Tony Coelho stated in Health Affairs, "No person is average, and standardized measures will always fall short of what patients need and deserve."[1]

The patient and disability communities are united in their concern that the PDAB serves as a healthcare financing mechanism that may exacerbate disparities. Therefore, I urge the PDAB to reconsider advancing an upper payment limit, which has implications for access to care, and instead develop policies that truly conserve human life while reducing unnecessary hardship and ensuring equitable access to effective treatments.

Sincerely,

Melodie Narain-Blackwell
President, Color of Gastrointestinal Illnesses

[1] https://www.healthaffairs.org/sponsored-content/national-minority-quality-forum/state-prescription-drug-affordability-boards-when-cost-takes-precedence-over-patient-health

August 26, 2024

Mr. Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Mr. York:

I am writing on behalf of the Color of Gastrointestinal Illness (COGI) to comment on the Board's ongoing cost review activities, particularly as it pertains to Skyrizi. COGI represents black, indigenous and other people of color (BIPOC) who are affected by inflammatory bowel disease (IBD), digestive disorders, gastrointestinal cancer and associated chronic illnesses.

Skyrizi is a highly effective and needed treatment for many in our community. One of COGI's key missions is breaking down the barriers preventing people of color from achieving optimal health outcomes. We have serious concerns that the work the PDAB is doing will have the unintended consequence of putting up more barriers for our patients to access Skyrizi and other needed treatments.

Due to the historic perception that people of color are not impacted by gastrointestinal diseases, it often takes far too long for patients in our community to get an accurate diagnosis. Given this delay, it is essential that once we are diagnosed, we are able to quickly and efficiently access the medications we need – additional delays only enhance the disparities in care that patients of color already face. For many patients, Skyrizi is needed to manage conditions like Crohn's disease and others may a different drug. It is imperative to protect patients from unintended consequences for accessing Skyrizi or for encouraging step therapy and prior authorization policies that create barriers to other drugs that treat Crohn's disease or ulcerative colitis.

Therefore, we have real concerns that the PDAB's actions related to Skyrizi may lead to the drug being unavailable to patients in Maryland and/or may lead to more aggressive utilization management being employed by insurers on competitor products that some of our patients also need. This outcome would be a significant step back in the push for health equity. We urge the PDAB to carefully consider this reality as it moves forward with cost reviews and proposed upper payment limits.

We support the intent to help patients access the care they need – which is only possible if the Board meaningfully engages and listen to patients. We have been consistently concerned that the Board's processes for cost reviews are not centered on the patients and people with disabilities impacted by its decisions. As a small patient advocacy organization, we do not know how our engagement makes a difference or how the information we provide to the Board may be used in its decisions. With a process that values our input, COGI stands ready to help the Board conduct its work in a patient-centered manner.

We are pleased to be working with the Ensuring Access through Collaborative Health (EACH) Coalition on a new survey for patients that elicits information about their challenges accessing affordable medications. When that survey becomes available, we look forward to sharing it with patients in an effort to get reliable information to the Board about the real-world experiences of patients.

Thank you for your consideration of our comments.

Sincerely,

Melodie C. Narain-Blackwell

Melodie C. Narain-Blackwell
President & CEO
Color of Gastrointestinal Illnesses (COGI)

September 11, 2026

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

Subject: Skyrizi comments

Dear Members of the Maryland Prescription Drug Affordability Board:

I am a gastroenterologist practicing in Chevy Chase Maryland, where I care for patients with Crohn's disease and ulcerative colitis. I appreciate the Board's efforts to address the affordability of prescription drugs and welcome the opportunity to comment on Skyrizi.

Inflammatory bowel disease is complex, and patients do not respond uniformly to available treatments. Selecting an appropriate therapy requires consideration of the patient's disease severity, prior treatment history, response to therapy, other medical conditions, and individual needs. These decisions should remain grounded in clinical evidence and shared decision-making between the patient and treating physician.

For a patient whose disease is responding to Skyrizi, continued access can be important to maintaining disease control. A coverage change, nonmedical switch, or additional step-therapy or prior-authorization requirement interrupts treatment and places the patient at risk of renewed symptoms or other adverse consequences. While we have a number of approved therapies for Inflammatory Bowel Disease the efficacy ceiling is 60% response. Changing therapy despite healing has potential serious consequences. Previous comments submitted to the Board by other stakeholders raised similar concerns that patients with Crohn's disease may respond differently to available therapies and that cost-review policies should not create additional access barriers.

I respectfully ask the Board to ensure that any action involving Skyrizi:

- improves patients' ability to afford the treatment;
- preserves access for patients when Skyrizi is clinically appropriate;
- protects patients who are stable on treatment from non-medical switching or interruptions in care; and
- does not encourage additional prior-authorization, step-therapy, or formulary barriers.

Affordability and access must be addressed together. I urge the Board to adopt a patient-centered approach that reduces financial burdens without limiting the ability of

Maryland patients and their physicians to select and continue the most appropriate treatment.

Thank you for considering my comments.

Sincerely,

Erica R. Cohen, MD

Director of IBD Chronic Care Program and Research

Capital Digestive Care

733 Third Avenue
Suite 510
New York, NY 10017

212-685-3440
info@crohnscolitisfoundation.org
www.crohnscolitisfoundation.org

CROHN'S &COLITIS FOUNDATION

September 15, 2026

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

RE: Therapeutic Alternatives – Skyrizi (risankizumab-rzaa)

Sent Via Email: comments.pdab@maryland.gov

Dear Prescription Drug Affordability Board Members and Staff:

The Crohn's & Colitis Foundation submits these comments in response to Maryland's Prescription Drug Affordability Board's (MD-PDAB) request for comments on therapeutic alternatives – Skyrizi (risankizumab-rzaa).

The Crohn's & Colitis Foundation is a non-profit, volunteer-fueled organization dedicated to curing Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel disease (IBD), and to improving the quality of life of the children and adults affected by these diseases. Over more than 50 years, the Foundation has invested more than $500 million in IBD research and, through more than 30 chapters nationwide, provides education and support directly to patients and caregivers, including through our IBD Help Center. Advocacy on behalf of patients, caregivers, and healthcare providers – including advocacy for improved access to care – is a core part of our mission.

IBD is a chronic, lifelong condition with no cure, affecting an estimated 1 in 100 Americans, including more than 40,000 residents of Maryland. It is marked by unpredictable flares of abdominal pain, persistent diarrhea, rectal bleeding, and fatigue, and it carries a well-documented burden of extraintestinal complications, mental health impact, and reduced quality of life. Left uncontrolled, IBD drives costly emergency care, hospitalization, and surgery – outcomes that biologic therapy is specifically intended to prevent.

We recognize and support Maryland's goal of addressing the rising cost of prescription drugs, and we appreciate Board's willingness to solicit patient and stakeholder input. However, we are concerned that the therapeutic alternatives proposed for Skyrizi, and the prospect of an upper payment limit or other affordability action tied to this review, could create unintended consequences for the Marylanders who depend on it.

1. IBD is clinically heterogeneous. Treatment decisions are best made between the patient and their healthcare provider.

Crohn's disease and ulcerative colitis vary widely in location, severity, and disease behavior from one patient to the next, and patients often cycle through multiple therapies before finding one that achieves and sustains remission. Shared decision-making between patient and provider that is grounded in clinical response, side-effect profile, dosing burden, and patient preference, has been shown to improve adherence, trust, and outcomes. Any Board action that

narrows the therapies available to Maryland patients on state-based plans risks disrupting that process for patients currently stable on Skyrizi.

2. The proposed therapeutic alternatives are not interchangeable with Skyrizi.

Skyrizi (risankizumab-rzaa) an interleukin-23 (IL-23) inhibitor is currently one of a few IL-23-specific biologics approved by the FDA for both moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis. Other biologics and small-molecule therapies used in IBD differ in mechanism of action, route and frequency of administration, response and remission rates, and safety considerations, including boxed warnings carried by some oral therapies in this space. A patient who has failed or cannot tolerate those alternatives – or whose disease responds specifically to IL-23 inhibition – may have no comparable substitute.

3. Skyrizi does not yet have a biosimilar on the market.

Unlike some biologics used in immune-mediated disease that now face biosimilar competition, Skyrizi is still protected by exclusivity, with biosimilar entry not expected until after 2028. Deeming Skyrizi unaffordable today would not, in the near term, give patients a lower-cost version of the same molecule to switch to. In practice, it could instead push stable patients toward non-medical switching (changing a patient's medication for reasons unrelated to clinical response, side effects, or nonadherence) to a clinically distinct alternative. Published literature associates non-medical switching with reduced adherence and worse disease control, and our own community consistently reports that losing access to a working therapy is often followed by a disease flare.

4. Restricting access to an FDA-approved IBD therapy runs counter to the access-to-care principles for which the Foundation and the broader IBD community have long advocated.

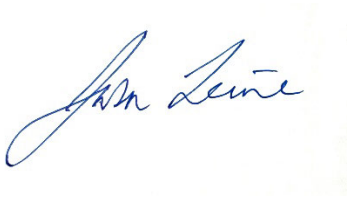
IBD patients have a fundamental right to access appropriate, effective medication, and that the choice of therapy should be a shared decision between patient and provider, with all FDA-approved treatments accessible according to medical guidance. The Crohn's & Colitis Foundation's advocacy for step therapy reform reflects this: national survey data shows more than 40 percent of Crohn's disease and ulcerative colitis patients have already had to try and fail on an insurer-preferred medication before receiving the treatment their own provider selected. Further, these delays have been linked to worse outcomes, including expensive bowel-damaging surgery. An affordability determination that narrows access to Skyrizi risks compounding those existing utilization-management barriers rather than relieving them.

5. We are concerned that patients will lose access to the treatment that is currently working for them.

For a Marylander with IBD who has achieved remission on Skyrizi, an affordability action that limits coverage or reimbursement could mean returning to active disease, additional specialist visits, escalated monitoring, or even hospitalization or surgery. We ask that the Board weigh these downstream clinical and cost consequences, not only the list price of the drug, in its determination.

As you continue your deliberations, please consider the Crohn's & Colitis Foundation a resource on the patient experience of IBD and on efforts to improve care while addressing cost, coverage, and access.

Sincerely,



Jason Levine
Vice President, Advocacy
Crohn's & Colitis Foundation

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Skyrizi Comments

Cross, Raymond [redacted] Tue, Sep 8, 2026 at 4:43 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

To Whom It May Concern:

I write as a provider with over 20 years of experience caring for patients with inflammatory bowel disease, which includes Crohn's disease and ulcerative colitis, regarding my clinical experience with Skyrizi. As you know, Skyrizi is an IL-23 inhibitor, and Skyrizi was the first drug in this class approved for treatment of patients with moderate to severe Crohn's disease. It has been an absolutely essential treatment in clinical practice for a number of reasons. First, it was the first agent to show persistent efficacy in patients that had been exposed to anti-TNF therapy previously. Second, in a landmark clinical trial, it demonstrated clinically meaningful and statistically significant superiority over another effective treatment for Crohn's disease (Stelara). This is an important point as biosimilars of Stelara are available, which are less expensive but not as effective. Third, Skyrizi has since been approved for ulcerative colitis and is very effective first line treatment and can also be used for salvage therapy when other treatments have failed.

In general, this class of medication is highly desired by patients given their general effectiveness, superior safety compared to anti-TNF agents, simplicity (no need for concurrent immune suppressants and/or therapeutic drug monitoring), and convenience of every 8 weeks maintenance dosing. Importantly, Skyrizi has no black box warnings in the label which is comforting for patients that are reticent to start an advanced therapy.

In summary, Skyrizi has been a transformational medication for treatment of Crohn's and colitis in Maryland, nationwide, and internationally.

Please let me know if you have questions or concerns.

[redacted]

[redacted]

September 14, 2026

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

RE: Ensuring Patient Access to Dermatological Care

Dear Members of the Board:

On behalf of the Derma Care Access Network (DCAN) and the Coalition of Skin Diseases (CSD), thank you for the opportunity to provide written comment as the Maryland Prescription Drug Affordability Review Board considers Skyrizi (risankizumab-rzaa) and Dupixent (dupilumab) in its affordability review process.

DCAN is a national coalition of more than two dozen advocacy organizations representing patients, health care providers and other skin health stakeholders working to raise awareness of, and inform policies impacting, patient-centered care. Our organization encourages informed policymaking about the benefits of access to approved therapies and appropriate clinical care for individuals living with skin diseases.

CSD advocates on behalf of the 84 million Americans living with a skin disease. As the largest consortium of skin disease patient advocacy organizations in the United States, the efforts of CSD aim to ensure that all Americans living with dermatological diseases and skin traumas receive the care they need to live healthy and productive lives. By working independently, in coalition, and alongside advocacy organizations committed to patients living with dermatological conditions, CSD endeavors to be at the forefront of progress toward a day where all individuals affected by skin disease have access to life-preserving/changing treatments and high-quality care

DCAN and CSD recognize the importance of addressing prescription drug affordability and reducing financial barriers to care. At the same time, we encourage the Board to carefully consider the potential impact that any affordability-related policy, including the establishment of an Upper Payment Limit (UPL), could have on patient access to medically necessary treatments. Patients who rely on Skyrizi and Dupixent often have chronic, complex conditions that can significantly affect their physical health, emotional well-being, and quality of life. For many patients in Maryland, these therapies represent the treatment option that has enabled them to successfully manage their symptoms and maintain daily functioning.

Skyrizi is approved by the FDA to treat plaque psoriasis, one of the most common forms of psoriasis affecting over 80 percent of individuals living with psoriasis.[1] Psoriasis plaques can appear anywhere on the body and have significant impacts on patients' quality of life. A chronic immune-mediated disease, plaque psoriasis is associated with anxiety, social isolation and heightened levels of psychosocial distress that can negatively impact patient adherence to treatment.[2]

Dupixent is approved by the FDA to treat atopic dermatitis (eczema), bullous pemphigoid and chronic spontaneous urticaria (CSU).[3] Atopic dermatitis is a chronic, inflammatory skin condition that can cause intense itching, dry and irritated skin, and recurring flares that can significantly affect patients' quality of life. Beyond its physical symptoms, atopic dermatitis is associated with sleep disturbances, anxiety, depression and social isolation.[4] Bullous pemphigoid is a chronic autoimmune blistering disorder characterized by symptoms including blisters, itching, rash and pain, and can significantly affect patients' quality of life and daily activities.[5] CSU is characterized by recurring hives and swelling that can persist for months or years, often interfering with sleep, work and everyday activities.[6]

DCAN and CSD are particularly concerned about the Board's selection of two treatments with dermatological indications, and the Marylanders already prescribed these medications that may face access barriers following UPL implementation. Dermatological conditions are more than skin-deep; given their chronic inflammatory nature, psoriasis, CSU, atopic dermatitis, and bullous pemphigoid can be associated with a range of comorbidities and systemic health impacts. Depending on the condition, patients may experience complications or comorbidities including psoriatic arthritis, metabolic and cardiovascular conditions, anxiety, depression, and other immune-mediated or inflammatory diseases.[7] As such, it is critical that any future policy actions intended to limit drug costs do not result in delayed access for patients and harm health outcomes in the long-term.

As the Board evaluates these medications, we urge you to consider the importance of patient-centered treatment decisions. Dermatologic and immune-mediated conditions

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[1] Wilson, et al. (2009). Incidence and clinical predictors of psoriatic arthritis in patients with psoriasis: A population-based study. *Arthritis Care & Research, 61*(2), 143-288. https://doi.org/10.1002%2Fart.24172
[2] Meneguin, et al. (2020). Quality of life of patients living with psoriasis: A qualitative study. *BMC Dermatology, 20*(22). https://link.springer.com/content/pdf/10.1186/s12895-020-00116-9.pdf
[3] U.S. Food and Drug Administration. (2025). Bimzelx (bimekizumab-bkzx) prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761055s070lbl.pdf
[4] Eckert, et al. (2017). Impact of atopic dermatitis on health-related quality of life and productivity in adults in the United States: An analysis using the National Health and Wellness Survey. Journal of the American Academy of Dermatology, 77(2), 274-279.e3. https://doi.org/10.1016/j.jaad.2017.04.019
[5] Ho, et al. (2025). Patient experiences of bullous pemphigoid: Symptoms and health-related quality of life impacts. Dermatology and Therapy, 15(7), 1813-1831. https://doi.org/10.1007/s13555-025-01424-z
[6] Maurer, et al. (2017). The burden of chronic spontaneous urticaria is substantial: Real-world evidence from ASSURE-CSU. Allergy, 72(12), 2005-2016. https://doi.org/10.1111/all.13209
[7] Molla, A. (2026). Comorbidities in skin diseases. *Frontiers in Medicine*. https://www.frontiersin.org/research-topics/79703/comorbidities-in-skin-diseases

affect all patients differently, and treatment responses can vary significantly from person to person. For this reason, health care delivery decisions should remain in the hands of patients and their health care providers, who are best positioned to determine the most appropriate course of treatment based on each patient's unique clinical circumstances. Policies that unintentionally limit access to particular therapies may disrupt successful treatment plans and create new challenges for patients already managing burdensome chronic conditions.

DCAN and CSD also encourage the Board to consider the patient perspective when examining affordability. Research has shown that patients often define affordability more broadly than a medication's price alone, incorporating factors such as insurance benefit design, financial assistance and additional economic burdens associated with chronic illness into assessments of whether treatment is truly affordable and accessible.[8] As a result, affordability evaluations should incorporate patient experiences alongside financial and utilization data to provide a more complete understanding of the real-world impact of policy decisions.

DCAN and CSD respectfully urge the Board to carefully weigh the potential unintended consequences that UPL implementation may have on patient access to Skyrizi and Dupixent. Efforts to improve affordability should support, rather than restrict, access to FDA-approved treatment options that patients and providers depend on to effectively manage chronic skin conditions.

Thank you for your consideration of these comments and for your commitment to improving health outcomes for Marylanders. DCAN respectfully asks that the Board keep in mind the access implications associated with any future actions affecting these therapies and resulting patient outcomes.

Sincerely,

Adina Lasser
Executive Director
Derma Care Access Network
alasser@dermacareaccess.org

Hannah Krauss
Advocacy and Policy Director
Derma Care Access Network
hkrauss@dermacareaccess.org

[8] EACH/PIC Coalition. (n.d.). *Patient experience survey: Prescription drug affordability and unaffordability*. https://eachpic.org/wp-content/uploads/2025/08/FINAL-PIC-Patient-Experience-Survey-Prescription-Drug-Affordability-and-Unaffordability-1.pdf

Natalie Mamerow
Executive Director
Coalition of Skin Diseases
natalie@coalitionofskindiseases.org

Dear Members of the Prescription Drug Affordability Board,

I am writing about a prescription drug you are currently considering for an upper payment limit, because it is one I take. As I mentioned when I testified in front of the board this plan does not put patients at the forefront and has not been able to show how patients will save money. The cartoon character that displayed a patient going to the counter and saving was not real. What it didn't show was a patient going to the pharmacy and not being able to get their medicine because a pharmacy stopped carrying it.

Getting to this medication was not simple. It came after time, trial, and, frankly, some treatments that did not help me. I am not in financial hardship with this drug. What I am afraid of is being sent back to the beginning, trying alternatives, waiting to see what works, living in the uncertainty of a new medication I didn't need to take because the one I'm currently taking is no longer accessible. I finally found something that works. That matters more than I can fully put into words. It's hard enough as a patient to feel like you have no control over your body because of an illness you didn't ask for, but to have a board that has no idea what they will do if I lose access to my medication being the ones making rules for it is scary.

I support patients everyday that are living with illnesses that have them fighting for their lives. They also battle referrals, prior authorizations and the many hurdles that insurance companies make them fight through to get what they need. Please don't add losing access to the medication they need to the fight.

Sincerely,

Dominique Daniels

EACH PIC COALITION

September 15, 2026

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

RE: Comments on Skyrizi Cost Review

Dear Members and Staff of the Maryland Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

As the board begins its cost review of Skyrizi, we urge it to focus first on whether Maryland patients are experiencing affordability or access challenges, identify the specific factors driving those challenges, and ensure that any resulting policy recommendations are tailored to address them. A finding that a drug imposes costs on the health care system is not, on its own, evidence that the drug is unaffordable for patients or that an upper payment limit (UPL) will improve patient affordability.

Centering the Process on Patient Burdens and Affordability

We urge the board to focus on identifying and addressing patient concerns with prescription drugs. Our Patient Experience Survey found that 41% of respondents had paid multiple out-of-pocket amounts for the same drug over time, and more than half of those respondents reported that the same medication had been affordable at one point and unaffordable at another. Ninety percent of respondents who explained why their costs changed attributed those shifts to insurance-related factors. These findings demonstrate why a cost review must look beyond a drug's price and determine what is actually driving affordability challenges for patients.

In evaluating patient affordability, the board should distinguish between affordability challenges driven by direct cost-sharing and access challenges driven by coverage denials, deductibles, utilization management, formulary restrictions, or limitations on financial assistance. Those experiences may all be reported as “unaffordability,” but they point to different underlying problems and require different policy responses.

Maryland's framework allows the board to evaluate both UPL and non-UPL policy interventions as part of its affordability work. The board should use the Skyrizi review not simply to determine whether an affordability challenge exists, but to identify its source and evaluate which available policy response is best suited to address it.

Therapeutic Class Framework and Patient Value Assessments

Therapeutic alternatives should not be treated as evidence that patients can readily substitute one therapy for another. Setting prices based on class-wide comparisons may unintentionally encourage insurers and PBMs to treat distinct therapies as substitutes, when the lived experience of patients shows they are not.

Our survey revealed that among respondents who had tried multiple treatments, more than 80% described their current medication as valuable, often because other treatments had failed or stopped working, caused different side effects, were more difficult to administer, or were less appropriate given other health conditions. Even patients taking the same medication reported very different experiences, underscoring that treatment value cannot be generalized.

These differences matter when evaluating therapeutic alternatives. When patients experienced non-medical switching, they reported disease recurrence, side effects, worsened outcomes, and other disruptions to care.

These experiences reinforce that the availability of drugs within the same therapeutic class does not mean those treatments are interchangeable for an individual patient. Reviews that flatten those differences risk reinforcing coverage policies that overlook patient value and could unintentionally disrupt access to the therapies that work best for them.

Evaluate Potential Access Consequences Before Recommending Policy Interventions

Any policy intervention resulting from the Skyrizi review should be evaluated not only for its intended effect on costs, but also for its potential impact on patient access and continuity of care. Changes in payer incentives can affect formulary placement, utilization management, coverage criteria, and treatment availability. For patients who have already found a therapy that effectively manages their condition, even an unintended change in access can have significant consequences.

While UPLs are intended to address affordability, they also create new financial incentives for payers that could affect formulary placement, utilization management, or coverage of selected medications. The board should carefully evaluate these potential consequences before recommending a UPL, particularly when the affordability challenges identified through its review may be better addressed through other policy interventions.

We encourage the board to take the necessary time and care to ensure this process supports, not disrupts, continuity of care. Patients must not face unintended consequences from policy decisions that limit treatment options or impose additional burdens.

Conclusion

As the board undertakes its review of Skyrizi, we respectfully encourage it to distinguish patient affordability from broader health system costs, identify the specific drivers behind any patient-reported affordability or access challenges, and evaluate policy responses based on their ability to address the identified problem without disrupting access to effective treatment.

Sincerely,

Tiffany Westrich-Robertson
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Ensuring Access through Collaborative Health (EACH) Coalition Lead

EACH PIC COALITION

Vanessa Lathan
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Patient Inclusion Council (PIC) Coalition Lead

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September 14, 2026

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

Re: Public Comment Regarding Skyrizi (risankizumab)

Dear Members of the Maryland Prescription Drug Affordability Board:

The Global Healthy Living Foundation (GHLF) appreciates the opportunity to provide comments as the Maryland Prescription Drug Affordability Board conducts its cost review of Skyrizi (risankizumab).

GHLF is a national nonprofit organization dedicated to improving the lives of people living with chronic disease through patient education, research, advocacy, and support. Through our patient communities, including CreakyJoints and the 50-State Network, we regularly hear from people living with inflammatory and autoimmune conditions who have experienced the difficult process of finding a treatment that effectively controls their disease.

We support Maryland's goal of making prescription medications affordable and accessible. At the same time, we urge the Board to ensure that its review of Skyrizi fully accounts for the realities patients face when selecting and maintaining treatment.

Skyrizi is approved to treat multiple chronic inflammatory diseases, including plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Patients living with these conditions often experience very different disease courses and treatment histories. A therapy that works well for one patient may not work for another, and many patients reach an effective treatment only after trying other therapies.

For that reason, an affordability assessment should consider more than the price of an individual drug or comparisons among products within a therapeutic category. The Board should also consider:

- the importance of maintaining treatment stability for patients whose disease is well controlled;
- patients' previous treatment failures, adverse effects, and individual clinical circumstances;
- the potential health consequences of treatment delays or nonmedical switching;
- differences among therapies that may affect whether a particular treatment is appropriate for an individual patient; and
- the broader costs associated with inadequately controlled disease, including physician visits, hospitalizations, procedures, disability, and lost productivity.

We also encourage the Board to distinguish between reducing costs within the health care system and reducing the financial burden experienced directly by patients. Policies intended to address overall prescription drug spending should ultimately translate into meaningful improvements in affordability and access for patients and should not unintentionally create new barriers to obtaining medically appropriate treatment.

The Board has specifically requested patient experience as part of this review. We strongly support that effort. Patient perspectives should play a meaningful role in determining whether a medication creates an affordability challenge and in evaluating any policy response that may follow. In particular, the Board should seek input from patients with direct experience using Skyrizi and from people who have navigated multiple therapies before achieving disease control.

GHLF respectfully urges the Board to approach its review of Skyrizi with the recognition that affordability and access are closely connected. Efforts to lower health care costs should protect patients from excessive financial burden while preserving the ability of patients and their clinicians to select and maintain the treatment that best meets the patient's individual medical needs.

Thank you for considering the perspective of patients living with chronic inflammatory disease. GHLF welcomes the opportunity to continue engaging with the Board as its review proceeds.

Sincerely,

Steven R. Newmark
Chief Legal & Policy Officer
Global Healthy Living Foundation

September 15, 2026

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

TO: Members of the Maryland Prescription Drug Affordability Board

Having viewed the current Cost Review Study Process, I submit these written comments on Dupixent (dupilumab) and Skyrizi (risagkizumab) on behalf of the Let My Doctors Decide Action Network and our deep concerns regarding the potential implementation of Upper Payment Limits (UPLs) for these two medications. As a board-certified pediatrician and pediatric rheumatologist with decades of experience caring for patients with chronic and disabling conditions, I have a firsthand understanding of what is at stake when access to successful therapies is disrupted. I fear if the Board decides to institute UPLs for these medications, many patients will have their diseases flare.

I applaud the Board for creating pathways for public engagement and for taking seriously the challenge of prescription drug affordability. That goal is one every clinician and patient shares. However, the current process, which, at this stage, has made available only the NDC numbers under review without accompanying dossiers does not yet allow for the kind of comprehensive, evidence-based input that a consequential affordability determination demands. I urge the Board to ensure that any Dupixent and/or Skyrizi determination reflects the entire clinical and economic picture, not just pharmaceutical line-item prices.

Maryland has already approved UPLs for Jardiance and Ozempic, benchmarked to the Medicare Maximum Fair Price, with implementation beginning January 1, 2027. Dupixent and Skyrizi are now in the same pipeline. But these are fundamentally different medications. Dupixent and Skyrizi are biologics indicated for chronic immune inflammatory conditions where therapeutic control and stability is not a convenience, it is the treatment's clinical target. Each patient responds differently to so-called "therapeutic alternatives." Your own public documents describe Dupixent as having unique FDA indications as compared to your comparison medications. And your only public comment about Skyrizi is that it "… is a heavily advertised product. The amount of money spent on direct to consumer advertising is worth considering." We think the

effects of any medication on the conditions it treats deserves more consideration. Switching therapies carries significant potential clinical risks, including loss of disease control, disease flares, permanent damage and in pediatric patients, irreversible developmental consequences. These consequences are even more difficult when there are no medical indications for switching from a successful therapy. Your affordability determinations must include consideration and understanding of the consequences of your decisions..

Everyone shares your goal to lower prescription drug costs, but the current process that only focuses on the drug list prices and not the patient total cost risks limiting access to essential medications while creating longer term negative health outcomes and higher overall health care costs. Since the Board is unable to address the roles of all participants within the drug pricing and supply ecosystem, I fear your many efforts will be for naught.

All clinicians and patients are eager to collaborate with the Board to ensure affordability decisions reflect real-world patient needs utilizing a more thoughtful, holistic, patient-centered approach. As it stands, however, the Board's actions could restrict access to effective cost-saving medications for those Maryland residents who need them the most.

We encourage the Board to address its multiple deficiencies and restrictions by asking the legislature to consider expanding your ability to develop methods of lowering actual drug and health costs, not just the list prices of drugs purchased by the State and Marylanders.

Thank you for your attention to this critical issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, MACR
Board Member, Let My Doctors Decide Action Network

Dear Members of the Maryland Prescription Drug Affordability Board:

I am writing as a Maryland caregiver for someone living with Crohn's. I have watched firsthand what it took to get to a treatment that actually works for her

Before Skyrizi, we went through medication after medication, each one with a different side effect or simply didn't work. Together, we sat through flare-ups, missed workdays, and appointments where we kept hoping the next option would be the one. When we finally found a treatment that gave my daughter a normal life back, it changed our whole family.

That is why an upper payment limit on Skyrizi concerns me. If it pushes our insurer to stop covering it because they change their formulary once a UPL goes into effect, or makes it unprofitable for our pharmacy to keep it in stock, we could be forced back into that search, this time for reasons that have nothing to do with their health. A "therapeutic alternative" chosen because of a price cap is not the same as a treatment chosen by a doctor who knows our history.

Healthcare decisions like this one are deeply personal, and they do not happen in isolation from the people who love and care for the patient. I would ask the Board to consider what a policy like this means for families like mine, who fought hard to get here, before unwinding it over cost alone.

Sincerely,

Lisa Griffin

MARYLAND HEALTH BENEFIT EXCHANGE

750 E. Pratt St., 6th floor
Baltimore, MD 21202
marylandhbe.com

September 1, 2026

Re: MHBE - DOSSIER COMMENT – SKYRIZI (risankizumab)

The Maryland Health Benefit Exchange (MHBE) respectfully submits this comment letter for – Dossiers for prescription drug product Skyrizi (risankizumab).

MHBE recognizes the importance of state-wide efforts to address high costs of prescription drug products and health care costs generally. We know that prescription drugs, in particular brand name drugs, are a significant driver of premium costs in the individual market and state costs via the state reinsurance program. A report from the Maryland Health Care Commission determined that **prescription drugs accounted for almost a third (30%) of total per capita spending** for privately insured markets in Maryland in 2020.[1] In an MHBE analysis of 2022 Maryland individual market claims, **brand name drugs accounted for** 21% ($343M) of all claims costs by all enrollees and **27% ($279M) of all claims costs by enrollees in the state reinsurance program (SRP)**.

In the 2022 MHBE analysis, Skyrizi accounted for a significant portion of total drug claims costs in the individual market - **117 enrollees received at least one prescription of various formulations of Skyrizi** [2], accounting for **1.74% ($5.97M)** alone of brand name prescription drug claims costs in the individual market. Further, Skyrizi accounted for a significant portion of individual market drug claims costs by enrollees in the SRP as well. Just **109 enrollees who received at least one prescription of various formulations of Skyrizi** accounted for **2.1% ($5.85M)** alone of brand name prescription drug claims costs by SRP enrollees.

Lower prices for higher-cost prescription drugs could reduce commercial insurers' per capita spending, putting downward pressure on average monthly premiums, along with out-of-pocket drug costs for consumers. Recent polling by the Kaiser Family Foundation found that more than a quarter of adults taking prescription drugs report difficulty affording their medication, including 40% of those with annual household incomes below $40,000.[3]

Lowering certain prescription drug costs would also potentially decrease costs associated with the reinsurance program, which works to mitigate the impact of high-cost enrollees on premium rate increases in the individual market. Specifically, lower prescription drug costs could reduce the number of individuals whose annual costs exceed the threshold at which reinsurance payments made by the State to an individual's insurer kicks in ($24,000 for plan year 2026),[4] and, for those individuals who reach the threshold, reduce the claims costs that the reinsurance program reimburses.

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[1] Maryland Health Care Commission: Spending and Use Among Maryland's Privately Insured Report, 2020 (2022).
[2] SKYRIZI 150 MG/ML SYRINGE, 150 MG/ML PEN
[3] Kaiser Family Foundation: Public Opinion on Prescription Drugs and Their Prices (August 2023).
[4] Maryland Health Benefit Exchange: 2026 Reinsurance Parameters (August 18, 2025 MHBE Board Meeting).

MARYLAND HEALTH BENEFIT EXCHANGE

750 E. Pratt St., 6th floor
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For further discussions or questions, please contact Ken Buerger, Director of Policy and Plan Management at ken.buerger@maryland.gov.

Sincerely,

Johanna Fabian-Marks
Executive Director

NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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www.infusioncenter.org ▪ info@infusioncenter.org

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

September 8, 2026

Re: Skyrizi (risankizumab) Cost Review Study

Dear Members of the Prescription Drug Affordability Board:

On behalf of the infusion providers we represent in Maryland, the National Infusion Center Association (NICA) appreciates the opportunity to provide comments as the Maryland Prescription Drug Affordability Board evaluates Skyrizi (risankizumab) through its cost review study process.

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of infused and injectable medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in high-quality, non-hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting.

As the Board evaluates Skyrizi, we urge you to carefully consider how potential affordability policies could affect patients receiving the provider-administered formulation of this therapy and the community-based providers responsible for delivering their care.

Community infusion providers commonly operate under a buy-and-bill model, meaning they purchase medications in advance, maintain the necessary inventory, administer treatment, and then seek reimbursement from the patient's health plan. Drug reimbursement is therefore closely tied to a provider's ability to acquire and continue offering a medication.

This distinction is particularly important when considering policies such as an Upper Payment Limit (UPL). A limit on what a health plan reimburses for Skyrizi would not necessarily reduce the amount an infusion provider must pay to acquire the drug. If reimbursement falls below or too close to acquisition and operating costs, community infusion centers may be unable to sustainably provide the treatment.

The consequences ultimately extend to patients. Reduced access to Skyrizi in community-based settings could result in patients having to:

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The Nation's Advocacy Voice for In-Office Infusion

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- Travel farther to receive treatment;
- Transition to a different site of care;
- Experience disruptions or delays in ongoing therapy; or
- Receive care in a higher-cost setting.

For patients managing complex and chronic conditions, continuity of treatment and access to the appropriate site of care are important considerations alongside affordability.

We therefore encourage the Board, as it evaluates Skyrizi, to distinguish between reducing costs within the healthcare system and reducing the reimbursement needed for providers to acquire and administer treatment. Any policy resulting from the cost review should account for provider acquisition costs and avoid creating reimbursement shortfalls that could unintentionally limit patient access.

NICA appreciates the Board's efforts to address prescription drug affordability and its consideration of the perspectives of clinicians and providers directly involved in delivering these therapies. We share the goal of making treatment more affordable for patients and encourage the Board to pursue approaches that achieve that goal without jeopardizing access to community-based infusion care.

Thank you for your consideration. Please do not hesitate to contact us if NICA can provide additional information regarding the administration of Skyrizi or the potential impact of affordability policies on community-based infusion providers.

Sincerely,

Brian Nyquist, MPH
President and CEO
National Infusion Center Association

September 15, 2026

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

Submitted via comments.pdab@maryland.gov

RE: Public Comment on the Cost Review Study Process for Skyrizi (risankizumab), BLA761105 (COMAR 14.01.04.05C(2))

Dear Members of the Maryland Prescription Drug Affordability Board:

Patients Rising is a national nonprofit that represents patients living with chronic and life-threatening conditions, including many Marylanders who manage moderate-to-severe plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. We appreciate the Board's specific invitation for patient perspectives during the cost review study of Skyrizi, and we offer these comments as the people whose out-of-pocket costs the statute names, and whose experience of getting on, paying for, and staying on a therapy is what this study is ultimately meant to describe.

We share the Board's goal. Patients should not be priced out of medicines that work. Our aim in this letter is to help the Board build a dossier that measures affordability the way patients actually experience it, and to flag where the study's design will determine whether any eventual policy reaches the patient or stops somewhere upstream.

I. The statute asks two different questions, and the dossier should answer both separately.

Maryland law directs the Board to determine whether a drug "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients." Those are different questions with potentially different answers. A drug can represent meaningful spending for a large purchaser while the individual patient's out-of-pocket exposure is driven by how a plan has structured its benefit, and, for this drug in particular, by whether a given dose is billed under the pharmacy benefit or the medical benefit. We ask the Board to keep the two inquiries distinct in the dossier and in any preliminary determination, and to show where any patient-level cost actually originates, because the remedy for a coinsurance or site-of-care problem is not the same as the remedy for a list-price problem.

II. What patients actually pay is a benefit-design number, not a list-price number.

COMAR 14.01.04.05C(1) authorizes the Board to review average patient copay and other cost-sharing data, patient assistance programs, and the impact of cost on access for priority populations. We urge the Board to make these the center of the patient-facing half of the study. Three composite scenarios show why this drug in particular deserves that treatment.

A patient with Crohn's disease moving from induction to maintenance. Consider a 34-year-old nurse in Howard County with moderate-to-severe Crohn's disease who has lost 20 pounds, cannot work a full shift without planning around a bathroom, and has already failed an older biologic class. Her gastroenterologist starts her on this therapy. The induction doses are given by intravenous infusion, which her plan covers under the medical benefit at a hospital outpatient infusion center. She is billed a facility fee plus 20 percent coinsurance on the drug, and each of the three induction visits produces a bill in the high hundreds of dollars before she meets her out-of-pocket maximum. Maintenance is then a self-administered subcutaneous dose every eight weeks, which her plan covers under the pharmacy benefit at a specialty-tier copay that manufacturer assistance covers almost entirely. Same molecule, same patient, two completely different affordability experiences within the first four months, determined not by the drug's price but by which benefit it flowed through and where the infusion happened. A cost review that reports one average out-of-pocket figure for this drug will hide the thing that actually matters to her.

A patient with psoriatic arthritis stepped through therapies that did not work. Consider a 52-year-old electrician in Frederick with psoriatic arthritis whose joint damage is progressing on x-ray. His rheumatologist recommends this therapy, which targets the pathway she believes is driving his disease. The plan requires him to first try and fail a therapy from an older biologic class. He does, over five months, during which his hands worsen enough that he cannot grip his tools and moves to light duty at reduced pay. When the requested therapy is finally approved, his disease stabilizes. Then, at plan renewal, the formulary changes and he is asked to switch to a different product for non-medical reasons, and his physician spends weeks on an exception request to keep him on the therapy that is working. His story contains no moment where the list price of the drug was the problem. His costs were lost wages, a delayed approval, and the risk of losing a therapy that was working. The Board's study should count those costs, and it should recognize that they are governed by utilization management decisions a payment limit cannot reach.

A state employee with plaque psoriasis on the State plan. Consider a 40-year-old state agency employee in Annapolis with moderate-to-severe plaque psoriasis covering her scalp, trunk, and hands, who has tried topical therapy, phototherapy, and an oral systemic agent without adequate control. On this therapy, dosed every 12 weeks after loading doses, her skin is largely clear and she has stopped avoiding meetings and public events. We include her because the State Employee and Retiree Health and Welfare Benefits Program is the purchaser most directly within the Board's reach, and because her case illustrates what a well-designed benefit looks like: a flat specialty copay rather than percentage coinsurance, no annual re-authorization for a stable patient, and manufacturer assistance that counts toward her out-of-pocket maximum. If the Board finds that the State plan faces an affordability challenge on this drug, we ask that

the dossier also document whether the plan's own benefit design already protects patients like her, so that any policy that follows does not solve the plan's problem by shifting cost or friction onto patients who are currently doing well.

III. Therapeutic alternatives are only alternatives if a patient can actually use them.

The regulation directs the Board to consider the pricing and out-of-pocket costs of therapeutic alternatives, and this drug sits in a therapeutic area with several biologic classes. We ask the Board to apply that factor with clinical honesty. Patients typically arrive at this therapy after failing or losing response to something else, and the biologics in these conditions are not interchangeable: they target different pathways, and a patient who has failed one class has, by definition, already tried the alternative the average would point to. The dossier should evaluate alternatives at the level of the individual patient's treatment history, and it should examine the cost-sharing and utilization management attached to those alternatives, not only their list prices, because the practical question for a patient is what it costs to get and stay on a therapy that works.

IV. Any downstream policy needs a mechanism to reach the patient.

We recognize that this comment period concerns the cost review study, not the policy phase that may follow. But the study is what will justify that phase, so we raise the point now. An upper payment limit operates on the amount a purchaser pays. It does not set the tier a plan places a drug on, the coinsurance percentage a plan charges, the size of a deductible, whether a dose is routed through the medical or pharmacy benefit, or the prior authorization, step therapy, and formulary changes a plan imposes. In every composite above, those are the levers that determined what the patient paid and whether the patient stayed on therapy. A price is not a cost. If the Board's study concludes that patients face high out-of-pocket costs, we ask that the dossier model, plan type by plan type and benefit by benefit, what patients would actually pay under any policy the Board might consider, and that it identify what additional mechanism would be needed for savings to reach the patient.

Because this drug's induction doses for inflammatory bowel disease are infused, we also ask the Board to examine specifically whether a payment limit could affect the willingness of infusion centers, physician offices, and specialty pharmacies to acquire and administer the drug in Maryland, since a provider that cannot recover its acquisition cost will stop offering the therapy, and the patient will be the one who travels farther or waits longer. The same access factor should address the continuity of manufacturer assistance programs that many patients currently rely on.

V. Specific requests to the Board.

First, publish the dossier for this drug and provide a defined public comment window on it before any preliminary affordability determination. The dossier is not yet public, so today's comments necessarily address the study's design rather than its findings, and patients deserve the chance to respond to the evidence itself.

Second, report patient out-of-pocket data disaggregated by plan type, medical versus pharmacy benefit, site of care, formulary tier, copay versus coinsurance structure, deductible phase, and the treatment of manufacturer assistance, so that the source of any high out-of-pocket cost is visible.

Third, examine net price, rebates, and price concessions alongside wholesale acquisition cost, and describe where those concessions go.

Fourth, account for the costs the therapy displaces, including hospitalization, surgery, emergency care, and lost work, and for the cost of delays imposed by step therapy, prior authorization, and non-medical switching.

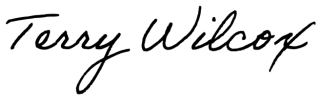
Fifth, apply the therapeutic alternatives factor at the level of the individual patient's treatment history, not the population average.

Sixth, model patient-level cost-sharing under any policy the Board may consider, state clearly which patients such a policy could and could not reach, and assess risks to infusion and dispensing access and to assistance program continuity.

Seventh, continue the practice of inviting patient and clinician testimony, and consider publishing a plain-language summary of each dossier so that the patients whose costs are at issue can follow the Board's work.

Patients Rising is grateful for the Board's attention to the patient experience, and we would welcome the opportunity to help connect the Board with Maryland patients and clinicians as this study proceeds. Please contact me at terry@patientsrising.org with any questions.

Respectfully,



Terry Wilcox
Co-Founder and CEO
Patients Rising

Value of Care Coalition

September 15, 2026

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

RE: SKYRIZI COST REVIEW

Dear Members of the Board,

As a broad coalition of advocacy organizations representing patients, caregivers and health care providers, we write concerning the value of Skyrizi (risankizumab-rzaa), chosen by the Prescription Drug Affordability Board for cost review and consideration of affordability. The Coalition has previously submitted comments expressing concern that methods available to the Board to lower health care spending, the setting of upper payment limits in particular, may restrict patients' access to needed treatments. As the Board considers affordability, we urge it to keep patients and their ability to access needed treatments at the center of its review. Affordability matters to patients, but efforts to lower costs should not make an effective treatment harder to obtain or continue.

The Value of Care Coalition believes that value is best determined by those who know: providers who prescribe medicines, and patients who rely on the medicine to keep their medical conditions stable. Just as the term “affordability” has many different definitions and could be determined by a multitude of criteria, so does “value.” Cost and value are not the same thing, but cost, nor affordability, cannot be fully considered without accounting for value.

Skyrizi is a biologic approved to treat moderate to severe plaque psoriasis, active psoriatic arthritis, moderate to severe Crohn's disease, and moderate to severe ulcerative colitis, with approval extended in June 2026 to children as young as six for the psoriasis and psoriatic arthritis indications.[1] These four conditions are not unrelated diagnoses that happen to respond to the same drug. Plaque psoriasis, psoriatic arthritis, and inflammatory bowel disease sit along a shared spectrum of immune-driven inflammation, and clinicians who treat these patients see the overlap routinely: a psoriasis patient who develops persistent joint pain, or a patient with longstanding bowel disease who later develops the same skin changes on exam. Prescribers weigh this

[1]AbbVie, SKYRIZI (risankizumab-rzaa) Now FDA Approved for Pediatric Use in Psoriatic Disease, June 26, 2026, https://news.abbvie.com/2026-06-26-SKYRIZI-R-risankizumab-rzaa-Now-FDA-Approved-for-Pediatric-Use-in-Psoriatic-Disease

connection directly when choosing a treatment, because a drug built around one narrow target may leave a second, related diagnosis unaddressed.

An estimated one in three people with plaque psoriasis will go on to develop psoriatic arthritis.[2] Psoriasis patients as a group face a meaningfully higher risk of inflammatory bowel disease than the general population, and that risk rises sharply with psoriasis severity, and rises further still for patients who already have psoriatic arthritis.[3] For these patients, the clinically relevant question is often not which single condition to treat, but how to manage two or three related, overlapping diseases in the joints, skin, and bowel without stacking separate drug regimens, each with its own selection process, monitoring requirements, and cost, on top of one another. A therapy that can address more than one of these diagnoses with a single, well-studied mechanism has value that a condition-by-condition accounting will not capture.

Because Skyrizi's value rests on treating multiple overlapping conditions in the same patient, any therapeutic alternatives list the Board considers should meet the same criteria. A treatment approved for one of these conditions is not automatically an appropriate substitute for a patient managing two or three of them at once. Alternatives can differ in the age groups they are approved for, how they are administered, the specific test results or disease markers a patient must have before they qualify, and the safety monitoring involved. A list built on a single shared indication alone risks treating options as interchangeable when they are not interchangeable for a given patient's combination of diagnoses, age, and medical history.

The consequences of these diseases are tangible in patients' daily lives. Plaque psoriasis causes scaly, itchy, and often painful patches of skin that, left uncontrolled, can lead to infection and, in more serious cases, life-threatening complications.[4] Psoriatic arthritis can be deforming and disabling, carrying an increased risk of early heart disease, and can leave a patient unable to work, care for their family, or take part in their community.[5] Crohn's disease and ulcerative colitis bring persistent diarrhea, abdominal pain, bleeding, weight loss, and fatigue, and unmanaged disease raises the risk of gastrointestinal cancer and can require surgical removal of portions of the digestive tract.[6]

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[2]National Psoriasis Foundation, About Psoriasis, https://www.psoriasis.org/about-psoriasis/

[3]Nationwide cohort study cited in “Psoriasis Severity Tied to Increased Risk of Inflammatory Bowel Disease,” American Journal of Managed Care, https://www.ajmc.com/view/psoriasis-severity-tied-to-increased-risk-of-inflammatory-bowel-disease

[4]National Psoriasis Foundation, Plaque Psoriasis, https://www.psoriasis.org/plaque/

[5] National Psoriasis Foundation, Why Treat Psoriatic Arthritis?, https://www.psoriasis.org/why-treat-psoriatic-arthritis/

[6]CDC, What is inflammatory bowel disease?, https://www.cdc.gov/ibd/what-is-IBD.htm

The burden of these diseases is not limited to the joints, skin, and bowel. An estimated one in five people with psoriasis experience depression, and a similar share experience anxiety.[7] Inflammatory bowel disease carries an even heavier mental health burden, with pooled estimates finding anxiety symptoms in roughly 32 percent of patients and depression symptoms in roughly 25 percent.[8] Patients carrying more than one of these diagnoses, as many do, can face this burden from more than one direction at once. Bringing the physical disease under control is itself one of the most direct ways to ease that burden. Patients who see their skin clear, their joint pain ease, or their digestive symptoms resolve consistently report meaningful improvement in mood and anxiety alongside the physical relief.[9]

For a patient managing more than one of these conditions at once, a single effective therapy is not a convenience. It is the difference between one course of treatment and several, between a disease that is manageable and one that is not, and between a mental health burden carried alone and one eased as the physical disease comes under control.

It may be difficult to quantify precisely what preserved mobility, an intact digestive tract, or clear skin is worth, but these benefits cannot be ignored when considering the affordability of this treatment. A policy that lowers cost at the expense of access does not create value. It shifts the burden onto the patients and families living with these diseases, perhaps increasing future health care spending.

The Value of Care Coalition asks that as the Board evaluates the affordability of Skyrizi, it considers the value this treatment provides to the clinicians who prescribe it and the patients in Maryland who depend on it.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition

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[7] "Significant Amount of Patients With Psoriasis Experience Depression, Anxiety," American Journal of Managed Care, https://www.ajmc.com/view/significant-amount-of-patients-with-psoriasis-experience-depression-anxiety

[8] Anxiety and depression in inflammatory bowel disease: a systematic review and meta-analysis of prevalence, incident risk, and disease subtype differences, The Egyptian Journal of Internal Medicine, cited via PMC, https://pmc.ncbi.nlm.nih.gov/articles/PMC12758077/

[9] Biologic Therapies Decrease Disease Severity and Improve Depression and Anxiety Symptoms in Psoriasis Patients, cited via PMC, https://pmc.ncbi.nlm.nih.gov/articles/PMC10220716/