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.

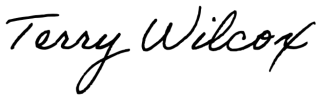
Fifth, apply the therapeutic alternatives factor at the level of the individual patient's treatment history, not the population average.

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,



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