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 Dupixent (dupilumab), BLA761055 (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 atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, and other type 2 inflammatory conditions. We appreciate the Board's specific invitation for patient perspectives during the cost review study of Dupixent, and we offer these comments in that spirit: as the people whose out-of-pocket costs the statute names, and whose day-to-day experience of paying for and staying on a therapy is the thing 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 at the pharmacy counter 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 not the same question, and they can have different answers. A drug can represent meaningful spending for a large purchaser while the individual patient's out-of-pocket exposure is driven almost entirely by how a plan has structured its benefit: which tier the drug sits on, whether cost-sharing is a flat copay or a percentage coinsurance, how large the deductible is, and whether manufacturer assistance counts toward it.

We ask the Board to keep these two inquiries distinct in the dossier and in any preliminary determination. If the finding is that the drug is a budgetary challenge for the State plan, the Board should

say so plainly. If the finding is that patients face high out-of-pocket costs, the dossier should show where those costs come from, because the remedy for a coinsurance 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, rather than treating them as supporting detail to a wholesale acquisition cost analysis. Three composite scenarios show why.

A young adult with severe atopic dermatitis on a high-deductible employer plan. Consider a 26-year-old in Baltimore County whose eczema has been severe since childhood: cracked, bleeding skin on the hands and face, recurrent skin infections, and sleep so disrupted that holding a full-time job was a struggle before treatment. After two years of topical steroids, phototherapy, and an oral immunosuppressant that caused side effects, this patient started a self-injected biologic and, for the first time as an adult, slept through the night. The problem is January. The plan places the drug on a specialty tier with 30 percent coinsurance after a $3,500 deductible, and the plan's accumulator program means the manufacturer's copay assistance no longer counts toward that deductible. Each new plan year, this patient faces a choice between a four-figure bill in the first quarter or a gap in treatment while the paperwork for an assistance program restarts. Notice what would and would not change if the list price of the drug were lower: the deductible would still be $3,500, the coinsurance would still be 30 percent, and the accumulator would still be in place. The patient's January would look much the same.

A working parent with uncontrolled asthma. Consider a 44-year-old school bus driver on the Eastern Shore with moderate-to-severe eosinophilic asthma who has been to the emergency department three times in a year despite maximal inhaled therapy. Her pulmonologist recommends an add-on biologic. The plan requires that she first fail step therapy with a different biologic class, which takes four months to document, during which she has another exacerbation and misses two weeks of work. When the therapy is finally approved, it is covered on the pharmacy benefit at a flat specialty copay she can manage, and her ER visits stop. Her affordability story was never really about the price of the medicine. It was about the cost of the delay, the lost wages, and the emergency care that the State's health care system paid for while she waited. A cost review that counts only the drug's spend, and not the spend it displaces, will get the arithmetic wrong for patients.

An older adult with COPD on Medicare with a supplemental plan. Consider a 71-year-old retiree in Prince George's County with COPD and an eosinophilic phenotype, recently prescribed a biologic as add-on maintenance therapy. Under Medicare's out-of-pocket cap, her exposure is bounded, but she reaches that cap within a few months and then pays nothing for the rest of the year. Her real barrier is a prior authorization that has to be renewed, and her lung function has to be re-documented each time. We include her because she represents a large share of the patients who use this therapy, and because a state upper payment limit would not touch her coverage at all. The Board should be clear in the dossier about which patients any eventual policy could reach and which it could not.

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. We ask the Board to apply that factor with clinical honesty. For many of the conditions this drug treats, the "alternatives" are the therapies patients have already failed or could not tolerate: systemic steroids with serious long-term risks, broad immunosuppressants with monitoring requirements, or a different biologic that targets a different pathway and does not work for everyone. A lower-cost option that a patient's own history has already ruled out is not an alternative for that patient, and the dossier should not average across patients as though it were. We also ask the Board to look at the cost-sharing and utilization management attached to the alternatives, not only their list prices, since 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, and cannot, set the tier a plan places a drug on, the coinsurance percentage a plan charges, the size of a deductible, or the prior authorization and step therapy a plan imposes. For the patients above, those are the levers that determine what the patient pays and whether the patient stays 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 also model, plan type by plan type, 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 counter.

We also ask the Board to examine, as part of the access factor in COMAR 14.01.04.05C(1), whether a payment limit could affect the willingness of specialty pharmacies and providers to stock and dispense the drug in Maryland, and whether it could affect the continuity of manufacturer assistance programs that many patients currently depend on to cover cost-sharing. Patients have watched other states' boards struggle with these questions, and Maryland has the opportunity to answer them in the study rather than after the fact.

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, 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 emergency care, hospitalization, systemic steroid complications, and lost work, and for the cost of delays imposed by utilization management.

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 dispensing access and 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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