Exhibit 6B-

Written Comments

(Request September 15, 2026)

AARP Maryland

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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.

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent comments

Melissa Abrams <[redacted]> Mon, Sep 14, 2026 at 7:37 PM
To: comments.pdab@maryland.gov
Cc: Melissa Abrams <[redacted]>

To whom it may concern,
I am a pediatric dermatologist, practicing for 16 years. I see numerous new and established patients with a diagnosis of atopic dermatitis on a daily basis. As such, I have been fortunate enough to watch the landscape of our treatment options grow dramatically.
The most dramatic change to this landscape has been Dupixent.
If one understands the pathophysiology of the disease state it is clear that conventional therapy-moisturizers and topicals only treat current inflammation (rash) it does not prevent the rash from recurring. And that-waxing/waning/recurrence despite treatment is extremely frustrating-as patients always fear but expect the onset of another flare.
Not only do these flares cause intense itch and discomfort leading to poor quality sleep in terms of getting adequate deep/Rem sleep (restorative sleep necessary for growth) but psychosocially these pts wear specific clothing to cover their rash (long sleeves and pants despite temperatures in the 90's). They refuse to participate in sports, dance or other activities because the sweat aggravates their condition. They miss out on social events because they are embarrassed of their appearance and constant need to scratch.
They and their parents worry about long term use of topical steroids (I have seen young girls with striae from overuse of potent steroid.

Dupixent (which is able to attempt to stop the inflammation from occurring) has been a game changer for these patients and families. Their rash and itch improve, kids who scratched all night with.blood on the sheets are able to sleep thru the night. One mom came into our office in tears after her daughter started Dupixent with a photo of her 14yr old daughter in shorts. She noted that prior to Dupixent her daughter had never worn shorts. Day after day patients and parents thank me for the dramatic improvement in their skin and therefore life-both the patient and their family. I remind them it is not me-it is science and the development of drugs such as Dupixent-
And all of this without immunosuppression, black box warnings, need for lab evaluation, etc.
please put yourself in the shoes of these patients and these families when considering coverage for Dupixent. It would be cruel and unfair to prolong the suffering of those with atopic dermatitis when we now have a treatment that can stop the flares.

Please do not hesitate to contact me with any additional questions or concerns.

Respectfully,
Melissa Abrams, MD

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
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September 10, 2026

By Electronic Submission

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112
Bowie, Maryland 20715
comments.pdab@maryland.gov

Re: Dupixent Comments

Dear Members of the Maryland Prescription Drug Affordability Board:

On behalf of the American College of Allergy, Asthma & Immunology (ACAAI) and the Maryland Asthma and Allergy Society (MAAS), we appreciate the opportunity to comment on the Board's cost review of Dupixent (dupilumab). ACAAI represents more than 6,500 allergists-immunologists and other health care professionals nationwide, with more than 100 allergy professionals in Maryland who care directly for patients with asthma, allergic conditions, and immunologic diseases.

We recognize the importance of making prescription drugs affordable. At the same time, we urge the Board to ensure that any action involving Dupixent preserves timely and clinically appropriate access for patients whose health and quality of life depend upon it. A policy that lowers a payment benchmark but makes a life-changing medication more difficult to obtain would not serve Maryland patients.

Dupixent has transformed the treatment of several serious chronic inflammatory diseases commonly managed by allergists, including atopic dermatitis, moderate-to-severe asthma, and chronic rhinosinusitis with nasal polyps. These conditions can profoundly affect nearly every aspect of a patient's life.

Severe atopic dermatitis can cause relentless itching, skin pain, infection, sleep disruption, anxiety, and difficulty functioning at school or work. Uncontrolled asthma can result in frightening exacerbations, emergency department visits, hospitalizations, missed work and school, and repeated exposure to systemic corticosteroids. Chronic rhinosinusitis with nasal polyps can impair breathing, sleep, and the senses of smell and taste, and may lead to repeated courses of corticosteroids or sinus surgery.

For appropriately selected patients, Dupixent can change that trajectory. It can substantially improve skin disease and itching, reduce asthma exacerbations and dependence on oral corticosteroids, improve lung function, and reduce nasal polyp burden and related symptoms. In clinical practice, these benefits can mean that a child sleeps through the night, an adult returns to work, a patient with asthma avoids an emergency department visit, or a patient with nasal polyps regains the ability to breathe and smell. These outcomes represent meaningful clinical and human value that cannot be captured adequately by examining the acquisition price of the medication alone.

Dupixent also has a unique mechanism of action. It binds to the interleukin-4 receptor alpha subunit and inhibits signaling from both interleukin-4 and interleukin-13, two central drivers of type 2 inflammation. Because the same inflammatory pathway may contribute to atopic dermatitis, asthma, and chronic rhinosinusitis with nasal polyps, one medication may control multiple coexisting diseases in the same patient. This can reduce the need for separate medications, repeated systemic corticosteroid treatment, procedures, hospital care, and other medical services. The Board's assessment should therefore consider the full value of treatment across all of a patient's affected conditions and over an appropriate period of time.

Biologic medications are not interchangeable therapies. Different biologics target different molecules, have different approved indications, and may produce very different responses in individual patients. A patient who responds well to Dupixent cannot be presumed to obtain the same benefit from a biologic directed against IgE, interleukin-5, TSLP, interleukin-13 alone, or another inflammatory target. Selection of a biologic requires individualized clinical judgment based on disease phenotype, biomarkers, comorbid conditions, previous treatment response, safety considerations, and the patient's circumstances and preferences.

Biologics also differ fundamentally from conventional small-molecule drugs and their generic versions. A small-molecule generic contains the same active ingredient as its reference drug and can generally be chemically reproduced. Biologics are much larger and more complex products manufactured in living systems and cannot be replicated identically. A biosimilar is therefore not a generic biologic and should not be treated as one.

Although federal law permits the FDA to apply the administrative designation "interchangeable" to certain biosimilars, that designation should not be interpreted as proof that substitution is clinically appropriate for every patient. It does not account for an individual patient's disease control, treatment history, comorbidities, previous adverse effects, concerns about immunogenicity, or the consequences of destabilizing successful therapy. Nor does it make one biologic interchangeable with another biologic that has a different molecular target. Decisions to initiate or switch biologic therapy should remain with the treating physician and patient, not a payer, pharmacy, purchasing authority, or affordability board.

We are particularly concerned that the Board could treat Dupixent as interchangeable with other biologics, or eventually with a biosimilar, based primarily on price. Nonmedical switching of a patient who is stable on Dupixent can introduce avoidable clinical risk and undermine continuity of care. Any cost-containment policy should explicitly protect the physician's authority to prescribe the biologic judged most appropriate and to prevent substitution when continued treatment is medically necessary.

The Board also should consider the costs that successful biologic treatment can prevent. These may include emergency department visits, hospitalizations, systemic corticosteroid complications, repeated sinus surgeries, treatment of skin infections, additional medications, missed work and school, and caregiver burden. Restricting access to an effective treatment may reduce spending on the medication while increasing costs elsewhere in the health care system.

We respectfully urge the Board to:

1. Consider Dupixent's benefits across all of its approved indications and the value of treating multiple coexisting type 2 inflammatory diseases with one medication.
2. Evaluate total health care utilization and long-term clinical outcomes rather than focusing primarily on the medication's acquisition cost.
3. Recognize that biologics with different molecular targets are not therapeutically interchangeable and that biosimilars are not generic drugs.
4. Preserve the ability of physicians and patients to select and continue the biologic most appropriate for the individual patient.
5. Avoid policies that result in additional prior-authorization requirements, mandatory step therapy, nonmedical switching, or treatment interruptions.
6. Include substantial input from practicing specialists and patients before making an affordability determination or establishing an upper payment limit.

Affordability and access should be complementary goals. We urge the Board to approach its review of Dupixent in a manner that protects individualized treatment decisions and ensures that Maryland patients who need this therapy can begin and continue it without unnecessary delay or disruption.

Thank you for considering the perspective of allergists and the patients we serve.

Sincerely,

Cherie Y. Zachary, MD, FACAAI
President
American College of Allergy, Asthma & Immunology

Jonathan Matz, MD, FACAAI
President
Maryland Asthma and Allergy Society

Rachel Schreiber, MD, FAAAAI, FACAAI
Member
ACAAI House of Delegates Representative from Maryland

Asthma and Allergy Foundation of America

September 15, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive
Suite 112-114
Bowie, MD 20715
Submitted to: comments.pdab@maryland.gov

RE: Consideration of Dupixent

Dear Members of the Board:

I am writing on behalf of the Asthma and Allergy Foundation of America (AAFA), the leading patient organization advocating for people with asthma and allergies and the oldest asthma and allergy patient group in the world. AAFA's mission is to save lives and reduce the burden of disease for people with asthma and allergies through support, advocacy, education and research.

Dupixent is one of the drugs currently open for comment for the PDAB cost review study process. We understand that PDAB assesses drugs to identify those that pose a high cost burden for health systems and patients in Maryland. AAFA applauds the goal of making Dupixent and other prescription drugs affordable and accessible for the citizens of Maryland. I am writing to share information about the importance of affordable access to Dupixent for our patient community.

Background: Asthma and Allergies

Asthma is a chronic lung disease that causes airway inflammation and hinders breathing. Asthma is one of the most prevalent diseases in the United States, affecting nearly 28 million Americans and killing between 9 and 11 individuals every day.[1] It is also very expensive, exacting a toll of more than $118 billion on the U.S. economy each year.[2]

[1] National Center for Health Statistics. 2024 NHIS Adult Summary Health Statistics. Data accessed August 3, 2026. Available from https://data.cdc.gov/d/25m4-6qqq.

[2] Nurmagambetov, T., Kuwahara, R., & Garbe, P. (2018). The Economic Burden of Asthma in the United States, 2008–2013. Annals of the American Thoracic Society, 15(3), 348–356. https://doi.org/10.1513/annalsats.201703- 259oc

Proper care and disease management, including medication, can allow people with asthma to live healthy lives.

In Maryland, 10.1% of adults reported ever having been diagnosed with asthma.[3] Major disparities exist: 15.1% of multiracial adults in Maryland have been diagnosed with asthma, compared to 10% of white adults.[4] And, Marylanders with a household income under $25,000 have been diagnosed with asthma at higher rates than those with household income above $150,000 (14.2% v 9.1%). Among children in Maryland, 6% are living with asthma.[5]

In our annual analysis on "Asthma Capitals," AAFA ranks cities in the United States based on asthma prevalence, emergency department visits for asthma, and deaths due to asthma. Unfortunately, in 2026, Maryland was represented in our analysis of the places where asthma is hardest to live, with Baltimore ranking #16 overall, and #1 in asthma-related deaths.[6]

Dupixent

Dupixent is an injectable biologic drug that is FDA-approved for multiple indications important to AAFA's patient community.

Dupixent is a maintenance treatment for moderate-to-severe asthma caused by type 2 inflammation (which includes eosinophilic asthma and/or allergic asthma). Dupixent is also approved to treat moderate-to-severe atopic dermatitis (eczema), chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and prurigo nodularis.

For people living with moderate to severe asthma, Dupixent is one important treatment option. It is part of a small class of drugs that addresses the immunological pathway in

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[3] America's Health Rankings: Asthma in Maryland. Available at https://www.americashealthrankings.org/explore/measures/Asthma_a/MD
America's Health Rankings analysis of U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Behavioral Risk Factor Surveillance System, United Health Foundation, AmericasHealthRankings.org, accessed 2026.

[4] *Id.*

[5] American Lung Association. (2025, June 20). *Asthma trends brief: Data tables*. https://www.lung.org/research/trends-in-lung-disease/asthma-trends-brief/data-tables/asthma-current-state

[6] AAFA, "Asthma Capitals: The Most Challenging Places to Live with Asthma" (2026). Available at https://aafa.org/wp-content/uploads/2026/07/aafa-2026-asthma-capitals-report.pdf

asthma patients. Asthma is heterogenous, and different patients need different medications to effectively manage their disease. Barriers to specific drugs, including adverse tiering and corresponding high costs, can lead to worse disease management and more asthma attacks. Similarly, utilization management approaches such as step therapy or prior authorization can delay access to appropriate care and lead to more attacks and higher healthcare costs.

One patient with severe asthma shared that, "I am currently on the Dupixent injection. I was previously on 5 different medicines. Dupixent has worked really well for me."

Cost Challenges

People with asthma and allergies need access to affordable medications and devices. Unfortunately, patients can face large financial barriers to optimal treatment. As AAFA detailed in our "My Life with Asthma" report, our national survey of adults with asthma found that less than a quarter of respondents always used their asthma treatments as prescribed.[7] The top three reported reasons for not using treatments were related to cost: inability to afford treatment, treatment was too expensive, and lack of insurance coverage for the treatment.[8] High out-of-pocket costs hinder adherence, threaten the health of patients, and exacerbate disparities in health status.

Dozens of patients have reached out to AAFA and shared that high co-pays have affected their ability to take their Dupixent and keep their conditions controlled. One community member shared, "My girlfriend's son has severe eczema. He has been taking Dupixent, she was able to get the co-pay card but didn't know there was a $10,000 cap for it. We can't afford the co-pay. It costs $1,100 each month. His symptoms came back with a ferocity that leaves him not being able to do much at times. It will keep him awake all night. It hurts me to see him like this because we can't afford that amount of money."

Conclusion

We understand that a key element of the PDAB's role is to identify drugs that may create affordability challenges for Maryland's healthcare systems and patients. Regardless of

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[7] Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). Available at https://aafa.org/asthma-allergy-research/our-research/my-life-with-asthma-report/

[8] *Id.*

whether Dupixent is found to be one of those drugs, AAFA strongly supports policies that reduce the cost of Dupixent for patients while maintaining access. AAFA urges the PDAB and the Maryland legislature, in continuing to further assess such options, to ensure that drug price policies are implemented with sufficient oversight and guardrails to ensure that access is not unintentionally reduced.

Thank you very much for your time and attention. If you would like further information about Dupixent or other medications of importance to the allergy and asthma community, please contact AAFA's Vice President of Policy and Advocacy, Jenna Riemenschneider, at jennar@aafa.org.

Sincerely,



Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent

Neena Bhatti [redacted]t> Mon, Sep 14, 2026 at 7:19 PM
To: comments.pdab@maryland.gov

I am an allergist and have been using Dupixent since it came out in the market. I have treated adults and children with asthma, eczema, nasal polyps and eosinophilic esophagitis.
Dupixent has tremendously improved the symptoms and quality of life for my patients.
As a physician I do not want the price of the drug or other barriers to impact my decision making to help my patients.
Dupixent is a biologic that offers the opportunity to treat the youngest patients in my practice with eczema.
I recall treating a pediatric patient that was 2 yrs old at the time of starting Dupixent for severe eczema. She had scratched herself to the point of leaving big parts of skin open and had to be hospitalized for sepsis. I was grateful that Dupixent was available for a young patient like mine whereas there was no other option. I had given the patient everything topically and orally without significant improvement.
There should not be a barrier to therapies like Dupixent regardless of age and social status.
Another clinical case that made a big impact on me was a mother with nasal polyps who could not even smell her baby's dirty diaper and people in the restaurant had to tell her to change the diaper. I can give you countless examples of clinical cases that left their imprint on me because Dupixent improved the quality of my patients' life.
Neena Bhatti Md
Sent from my iPhone

[redacted]

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

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

FW: Dupixent comments

Angela Canady [redacted] > Tue, Sep 15, 2026 at 8:36 AM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

From: Angela Canady
Sent: Monday, September 14, 2026 7:00 PM
To: 'pdab@maryland.gov' <pdab@maryland.gov>
Subject: Dupixent comments

To Whom It May Concern:

I am a board-certified allergist/immunologist practicing in Maryland. I have been in practice since 2013 but have been employed with my current practice since 2024. I am the sole provider in a clinic within a lower socioeconomic area within Montgomery County, MD. Many of the patients that receive care in this clinic are covered under MD Medicaid plans, including but not limited to: Wellpoint, Maryland Physicians Care and Priority Partners. This clinic provides care to a large volume of pediatric patients, many of whom have atopic dermatitis and/or allergic asthma. Maryland Medicaid currently requires a prior authorization/step therapy before consideration of coverage for Dupixent. In many cases patients are required to try and fail multiple medium-high potency topical steroids and a topical calcineurin inhibitor before coverage is considered. Here are my concerns with this requirement:

1. Lack of coverage for standard of care treatment: Treatment algorithm for moderate-severe atopic dermatitis includes topical corticosteroids + TCI (steroid sensitive areas) with initiation of biologic therapy if inadequate response. Unfortunately, most of the Maryland Medicaid plans do not cover topical calcineurin inhibitors without failure to respond to at least two medium or high potency topical corticosteroids, this could result in a delay in appropriate therapy. Atopic dermatitis causes severe itching which can disrupt sleep and ability to focus during work or school.
2. Special consideration for certain populations: Dupixent is the only biologic on the market that has FDA approval for the treatment of moderate-severe atopic dermatitis in children. There are no other biologic therapies that have an FDA indication for the treatment of atopic dermatitis in this patient population. Prolonged application of moderate or high potency topical corticosteroids is not advisable in pediatric patients, especially those patients under the age of one, as these medications can have deleterious effects including skin-thinning, formation of telangiectasias in the skin or systemic steroid effects due to absorption through inflamed skin.
3. Burden of disease and impact to healthcare costs: Both atopic dermatitis and allergic asthma are chronic inflammatory conditions that may have frequent and severe exacerbations disrupting sleep and daily activities. These conditions are major contributors to missed days of work and school and can significantly impact productivity in the workplace. Failure to provide access to disease-modifying therapies such as Dupixent leads to inadequate control and higher risk of exacerbation. In many cases, patients seek treatment in ER and urgent care facilities due to accessibility and flexible hours. However, there are substantial costs associated with utilization of ER and urgent care facilities, including the cost of intravenous medications, radiology, EMS/ambulance services and hospitalization or ICU care. Consider the cost of one hospitalization for an acute asthma exacerbation and compare that to the cost of treatment with Dupixent therapy which has clinical evidence demonstrating reduction in asthma exacerbations and hospitalizations. Prevention of exacerbations and disease burden (morbidity) is more cost effective than treating poorly controlled asthma or other chronic disease state.

[redacted] [redacted]

Biologic medications are safe and effective treatments that are targeted at specific antibodies/proteins within the immune system, thus improving clinical response and clinical benefit. In addition, biologics create steady state symptom control and overall reduction in disease exacerbations with palpable improvement in the quality of life for patients. I highly recommend biologics like Dupixent for my patients with atopic dermatitis and allergic asthma. As such, I would not advocate for use of any treatment unless I have experience that it is tolerated and has proven clinical benefit. Thank you for your consideration with this important matter.

Sincerely,

Angela Canady, M.D.

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent comments

Castelo-Soccio, Leslie A. [redacted] Tue, Sep 1, 2026 at 11:40 AM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

I am a pediatric dermatologist. Dupixent is one of the most important medications for children in the last decade. It should be covered for all children with severe eczema/ atopic dermatitis. It has been life changing.

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[redacted]

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent

DENISE CHEVALIER [redacted]> Tue, Sep 15, 2026 at 9:07 AM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

Dear Ms. Cullison and Members:

I have been a practitioner of Allergy, Asthma and Immunology in Prince George's County and in Washington, DC for over 38 years. I have treated thousands of patients over the years and frequently these individual children and adults suffer with multiple allergic or immunologic manifestations. Those with allergic rhinitis often have sinus problems. Children with asthma also can suffer from eczema, rhinitis, food allergies and environmental allergies. Patients with sinusitis and nasal polyposis can develop life-threatening asthma with allergy to aspirin and other NSAIDs. Treatment of these patients with complex and severe manifestations often exceeds what is available with use of antihistamines, inhalers, steroids and immunotherapy. Biologics have made significant contributions to improving the management of many people of all ages whose lives have been limited by these diseases.

Dupilumab is the biologic that has the most disease indications in the Allergy and Asthma realm: atopic dermatitis, moderate to severe asthma, chronic rhinosinusitis with polyposis, eosinophilic esophagitis, COPD, prurigo nodularis, allergic fungal rhinosinusitis, bullous pemphigoid and chronic spontaneous urticaria.There are no other available biologics that have such a broad range of approved indications and for children, the earliest age ranges are far below other biologics in this category. For asthma, it is approved for age 6 yr and above, as are Nucala, Fasenra and Xolair. However,for atopic dermatitis the earliest age of approval is 6 months. For CSU, it approved down to age 2 yr, versus Xolair from age 12 yrs.I t is the only biological approved for eosinophilic esophagitis, which can be given down to age 1, and for allergic fungal sinusitis, down to age 6 yr.

No other biologic has studies confirming the safety and efficacy for children below the age of 12 for conditions other than asthma. If Dupixent is no longer available, these patients, both children and adults who may have multiple covered conditions, or rare conditions for which no other biologics are approved, with be left without the benefit of this very effective treatment for their diseases.

As I have experienced this year with patients whose Federally sponsored BCBS no longer covered Dupixent, patients who were forced onto other less effective biologics are again having asthma exacerbations.When you consider the costs of emergency care and admissions for those that relapse, lost work and school days, as well as the risk of disability and death, is it not worth the costs of this drug to keep patients controlled and safe?

Sincerely:

Denise Chevalier MD

[redacted]

September 11, 2026

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

Subject: Dupixent 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 eosinophilic esophagitis and other gastrointestinal conditions. I appreciate the Board's efforts to address prescription drug affordability and welcome the opportunity to comment on Dupixent.

Eosinophilic esophagitis is a chronic condition that can significantly affect a patient's ability to eat and maintain quality of life. Treatment decisions must account for the patient's symptoms, disease history, response to previous therapies, other medical conditions, and individual treatment goals. These decisions should be made through shared decision-making between the patient and treating physician.

For patients who are benefiting from Dupixent, uninterrupted access is important. A nonmedical switch, loss of coverage, or new utilization-management requirement could disrupt a treatment plan that is successfully controlling the patient's condition. Prior comments to the Board from stakeholders emphasized the importance of individualized treatment, shared decision-making, and protecting patients from access disruptions caused by coverage restrictions or nonmedical switching.

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

1. meaningfully reduces patients' out-of-pocket costs;
2. preserves access when Dupixent is clinically appropriate;
3. protects patients who are stable on treatment from nonmedical switching or interruptions in care; and
4. does not lead to additional prior-authorization, step-therapy, or formulary restrictions.

Affordability measures should help Maryland patients obtain needed treatment without interfering with individualized clinical decisions. I urge the Board to pursue an approach that makes Dupixent more affordable while preserving timely, clinically appropriate access.

Thank you for considering my comments.

Sincerely,

Erica R Cohen, MD

Capital Digestive Care

Maryland Prescription Drug Affordability Board

16900 Science Drive, Suite 112-114

Bowie, MD 20715

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

Dear Members of the Prescription Drug Affordability Board,

On behalf of the COPD Action Alliance, thank you for the opportunity to submit comments as the Board conducts its cost review of dupilumab and considers an upper payment limit (UPL) for the drug.

About the COPD Action Alliance

The COPD Action Alliance is a national nonprofit advocacy coalition that works to increase awareness, support grassroots advocacy, and improve policy that relates to chronic obstructive pulmonary disease. The coalition is comprised of nearly thirty members representing patients, providers, and communities impacted by COPD.

We appreciate the Board's mission to protect Marylanders from unaffordable drug costs, and we share the goal of a health care system that is both affordable and accessible. We write to urge the Board to ensure that any UPL placed on dupilumab is calibrated so that it does not inadvertently restrict access to this treatment for Medicaid beneficiaries and beneficiaries of other state health plans affected by the Board's determinations.

The Burden of COPD in Maryland

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, a prevalence of 4.8% of the adult population. COPD is responsible for approximately 1,736 deaths and 3,477 Medicare hospitalizations in Maryland each year. It also costs the state an estimated $595 million annually in treatment expenses while causing 414,920 lost workdays. These figures likely understate the true burden, as half of the national COPD population goes undiagnosed. The data also show that Marylanders with COPD are more likely to have less than a high school education (13.9% vs. 9.8%), more likely to live on less than $15,000 in household

income (9.3% vs. 5.2%), and more likely to report poor mental health, compared to adults without COPD.[1] The data further identifies people in rural communities, people with lower incomes, and people with lower educational attainment as those most likely to experience worse COPD outcomes and greater barriers to treatment. These are precisely the populations most likely to rely on Medicaid and other state-sponsored health plans, which is why the Board's treatment of dupilumab's UPL carries significant importance for health equity in Maryland.

Dupilumab's Significant Role in COPD Treatment

Treatment innovation in COPD has historically lagged behind other chronic diseases, leaving patients and clinicians with a limited selection of bronchodilators, inhaled corticosteroids, and other maintenance therapies that do not address the underlying inflammatory drivers of disease for many patients. In September 2024, the FDA approved dupilumab as the first-ever biologic medicine indicated for COPD, as an add-on maintenance treatment for adults with uncontrolled COPD and evidence of type 2 inflammation.[2] This approval opened an entirely new avenue of treatment for a subset of COPD patients who had few, if any, alternatives targeting this underlying biology. Given how few new COPD treatment options have reached patients in recent years, dupilumab stands out as one of the most promising therapies available today, and any policy that discourages its use or restricts access should be evaluated with particular care.

Potential Unintended Consequences of a UPL

CAA recognizes that the Board's UPL authority is intended to address high drug costs, not to restrict access to needed medications. However, if a UPL for dupilumab is set without sufficient attention to downstream effects on coverage and formulary design, it risks doing exactly that. Health plans, pharmacy benefit managers (PBMs), and other payers make coverage and formulary decisions based on a range of financial incentives, and a poorly calibrated payment ceiling can distort those incentives in ways that make a drug more difficult for patients to obtain.

We ask the Board to consider how UPLs interact with the rebate-driven dynamics of the current formulary system. When a manufacturer's list price for a drug is effectively lowered, whether directly or as a consequence of a state-imposed UPL, the rebate available to the health plan or PBM shrinks accordingly, since rebates are typically calculated as a percentage of list price. A smaller or eliminated rebate reduces the plan's financial incentive to place that drug favorably on its formulary. In practice, this can mean a drug becomes subject to a higher cost-sharing tier, more restrictive prior authorization or step-therapy requirements, or removal from preferred formulary status altogether. The result is a paradox in which a policy intended to control spending on a medication instead makes that very medication more difficult for beneficiaries to access. We urge

[1] COPD State Briefs Maryland
[2] 2024-09-27-13-35-00-2954551-en.pdf

the Board to consider these formulary and utilization-management effects carefully before finalizing a UPL for dupilumab. We also urge the Board to build in safeguards, such as continued formulary parity or non-discrimination requirements, to prevent this outcome for Medicaid beneficiaries and beneficiaries of other affected state plans.

Recommended Course of Action

The COPD Action Alliance respectfully requests that the Board take the following steps. First, ensure that any upper payment limit established for dupilumab does not create financial disincentives for health plans and PBMs to maintain favorable, accessible formulary placement for Medicaid beneficiaries and beneficiaries of other affected state plans. We also believe that the Board could establish an access-monitoring mechanism following implementation of any UPL, so that the Board can identify and respond to unintended reductions in utilization or access among affected beneficiaries. Finally, it is critical that the Board weighs the potential long-term impact of a restrictive UPL on continued innovation in COPD treatment, an area that has seen relatively few new therapeutic options reach patients.

We appreciate the Board's diligence in undertaking this cost review and its commitment to protecting Maryland patients from unaffordable prescription drug costs. We ask that the Board pursue that goal in a manner that preserves access to dupilumab for the Medicaid beneficiaries and other state plan beneficiaries living with COPD who stand to benefit most from this innovative therapy.

Thank you for considering these comments. We would welcome the opportunity to provide additional data or to discuss these concerns further with the Board or its staff.

Respectfully submitted,

Sarah Hoffman
Director
COPD Action Alliance

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent Comments

[redacted]

Tue, Sep 15, 2026 at 1:14 PM

To: comments.pdab@maryland.gov

[redacted]

[redacted] [redacted]

To the Maryland Prescription Drug Affordability Board,

I am writing to urge the Maryland Prescription Drug Affordability Board to retain Dupixent on the State employee formulary. As a Family Nurse Practitioner practicing in Allergy and Immunology, I see firsthand the substantial burden that uncontrolled type 2 inflammatory disease places on pediatric and adult patients and their families.

Dupixent is an important targeted treatment for appropriately selected patients with moderate-to-severe atopic dermatitis, moderate-to-severe eosinophilic or oral corticosteroid-dependent asthma, eosinophilic esophagitis, and other serious allergic and inflammatory conditions. These chronic diseases are not minor inconveniences. They can cause persistent itching, disrupted sleep, skin infections, school and work absences, emergency care, oral corticosteroid exposure, impaired nutrition or swallowing, and marked limitations in daily functioning and quality of life.

For children with severe atopic dermatitis, uncontrolled disease can mean sleepless nights from itching, painful and extensive skin involvement, missed school, and significant stress for the entire family. Dupixent is particularly important because it is an FDA-approved systemic option for moderate-to-severe atopic dermatitis in children as young as 6 months when topical therapies are insufficient or not advisable. It offers an evidence-based alternative to repeated courses of systemic corticosteroids or less targeted systemic immunosuppressive therapies.

For pediatric and adult patients with moderate-to-severe asthma, Dupixent can reduce exacerbation risk and improve pulmonary function in appropriate patients with type 2 inflammation or oral corticosteroid-dependent disease. Preserving access helps avoid the consequences of uncontrolled asthma, including urgent visits, hospitalizations, missed school and work, and the cumulative adverse effects associated with recurrent or chronic oral corticosteroid use.

Many patients have overlapping allergic conditions, such as asthma, atopic dermatitis, allergic rhinitis, chronic rhinosinusitis with nasal polyps, and eosinophilic esophagitis. For these patients, Dupixent may address a shared underlying inflammatory pathway and can provide meaningful clinical benefit across more than one disease manifestation. Removing coverage may fragment care, force avoidable treatment changes, and expose patients to therapies that may be less effective, less tolerable, or associated with greater monitoring and safety burdens.

Formulary decisions should appropriately consider affordability, but they must also account for the clinical and downstream financial consequences of loss of disease control. Restricting or removing access to Dupixent may increase costs related to urgent and emergency care, hospitalizations, repeated systemic corticosteroid courses, additional office visits, rescue therapies, missed work, and caregiver burden. Most importantly, it may destabilize patients who are currently well controlled on an individualized, clinically appropriate treatment plan.

Dupixent is not interchangeable with other therapies for every patient. Biologic selection is individualized based on a patient's diagnosis, age, inflammatory phenotype, comorbid conditions, prior treatment response, tolerability, and treatment goals. A formulary removal that requires stable patients to discontinue or switch treatment without a clinical indication may lead to preventable disease flares and avoidable harm.

I respectfully request that the Board maintain Dupixent as a covered treatment option on the State employee formulary for pediatric and adult patients who meet appropriate clinical criteria. Continued access is essential to preserve patient stability, prevent disease-related complications, reduce reliance on systemic corticosteroids when possible, and support the health and productivity of Maryland State employees and their families.

Sincerely,

Abby Davis, NP

[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

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent Comments

Marc Dubin <[redacted]> Wed, Sep 9, 2026 at 4:26 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

Dear Members of the Maryland Prescription Drug Affordability Board,

As a practicing otolaryngologist in Maryland, I am writing to express my concern regarding the potential removal of Dupixent coverage from health plans serving Maryland state employees and their families.

I routinely treat patients with chronic rhinosinusitis with nasal polyps (CRSwNP), including individuals with severe disease that persists despite appropriate medical therapy and sinus surgery. These patients can suffer for years with profound nasal obstruction, loss of smell and taste, recurrent infections, impaired sleep, and a substantial reduction in quality of life. For appropriately selected patients, Dupixent has fundamentally changed our ability to control this disease.

Before biologic therapies became available, patients with persistent or recurrent nasal polyps frequently cycled through systemic corticosteroids and additional sinus surgeries. Neither is without consequence. Repeated oral steroid exposure is associated with significant health risks, including diabetes, hypertension, osteoporosis, cataracts, psychiatric effects, and infection. Revision surgery carries its own risks and costs and does not guarantee that inflammatory disease will not recur.

For this reason, the cost of Dupixent cannot reasonably be considered in isolation. Removing coverage may reduce spending on one medication while shifting costs elsewhere in the healthcare system. A patient whose disease becomes uncontrolled may require additional physician visits, imaging, systemic medications, emergency care, and revision surgery. Those costs, as well as the impact of missed work and reduced productivity, should be part of any meaningful assessment of drug affordability.

I am also concerned that removing Dupixent from coverage may simply force patients onto another biologic rather than generate substantial overall savings. These medications are not necessarily interchangeable for every patient. Requiring a stable patient to discontinue an effective therapy and undergo another authorization process or trial of a different biologic can result in treatment delays, disease recurrence, additional office visits, and unnecessary administrative expense. If the substituted therapy does not provide equivalent disease control, the patient may ultimately require steroids, surgery, or a return to the original medication.

Clinical decisions regarding biologic therapy should remain individualized. Physicians select these treatments based on a patient's disease severity, prior treatment failures, comorbid conditions, available clinical evidence, FDA approved indications, and established treatment guidelines. A broad coverage exclusion removes that clinical judgment from the equation and is particularly troubling for patients who are already stable and doing well on treatment.

I appreciate the Board's responsibility to address the rapidly rising cost of prescription medications. That is an important goal. However, efforts to control drug spending should not inadvertently increase the total cost of care or deprive patients of therapies that are successfully controlling serious chronic disease.

I therefore respectfully ask the Board to reconsider any policy that would broadly eliminate Dupixent coverage for Maryland state employees and their dependents. At a minimum, any affordability policy should preserve access for patients with established evidence-based indications, protect patients who are already stable on therapy, provide a meaningful physician directed exception process, and avoid mandatory substitution when the treating physician believes an alternative is clinically inappropriate.

The goal should be both affordability and appropriate patient care. Those objectives do not have to be mutually exclusive.

Thank you for considering the perspective of physicians caring for Maryland patients affected by these diseases.

Sincerely,

Marc G. Dubin, MD, FACS

President Elect, American Rhinologic Society

Board of Directors and Executive Committee, American Academy of Otolaryngology-HNS



Marc Dubin, MD
Chief Medical Officer
[redacted]

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EACH PIC COALITION

September 15, 2026

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

RE: Comments on Dupixent 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 Dupixent, 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 Dupixent 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 Dupixent 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 Dupixent, 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
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

EACH PIC COALITION



Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent Comments

Dr. Raghav Gupta <[redacted]> Mon, Sep 14, 2026 at 3:54 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

To the Members of the Maryland Prescription Drug Affordability Board:

As a practicing pulmonary and critical care physician caring for patients with severe asthma and COPD, I appreciate the opportunity to provide clinical perspective on the cost review of **Dupixent (dupilumab), BLA 761055**. I support efforts to improve drug affordability. However, any Upper Payment Limit (UPL) or other affordability intervention should preserve **timely, uninterrupted access for appropriately selected patients** and avoid unintended formulary, reimbursement, or specialty-pharmacy barriers.

Clinical Value and Evidence

Dupilumab inhibits IL-4 and IL-13 signaling, key drivers of type 2 airway inflammation.

In **Severe asthma**, phase 3 trials demonstrated substantial reductions in severe exacerbations, improved lung function, and significant reductions in oral corticosteroid requirements among steroid-dependent patients.

In **COPD with type 2 inflammation**, the phase 3 BOREAS and NOTUS trials evaluated patients with blood eosinophils ≥300 cells/μL who remained symptomatic and at risk for exacerbations despite optimized inhaled therapy. Dupilumab:

- Reduced annualized moderate-to-severe COPD exacerbations by approximately **30% in BOREAS and 34% in NOTUS**.
- Produced clinically meaningful and sustained improvements in lung function.
- Improved respiratory symptoms and health-related quality of life.

Reducing exacerbations also decreases exposure to systemic corticosteroids and their well-established complications, including osteoporosis, diabetes, cataracts, adrenal suppression, and myopathy.

Existing Access Barriers

Patients already face substantial prior-authorization requirements, specialty-pharmacy coordination, and appeals before receiving biologic therapy. Additional reimbursement or administrative barriers could further delay clinically appropriate treatment and expose high-risk patients to preventable exacerbations, systemic corticosteroids, emergency visits, and hospitalization.

Recommendations

If the Board considers a UPL or other affordability intervention, I respectfully urge that it:

1. **Preserve formulary access** and avoid additional non-medical step therapy or forced switching.
2. **Maintain adequate reimbursement** so specialty pharmacies and health systems can continue dispensing therapy without interruption.
3. **Protect continuity of treatment** for patients who are clinically benefiting from dupilumab.
4. Ensure that **cost savings reach patients directly** through lower copays and out-of-pocket costs.

Affordability and access should be complementary goals. Dupilumab has demonstrated meaningful reductions in exacerbations and improvements in lung function in appropriately selected patients with severe asthma and eosinophilic COPD. Efforts to lower its cost should ensure that these clinical benefits remain accessible to the patients most likely to benefit.

Thank you for considering the perspective of clinicians caring for these high-risk patients.

Respectfully submitted,

Raghav Gupta, MD
Pulmonary & Critical Care Medicine
[redacted]

ALLERGY AND ASTHMA CLINIC OF MARYLAND

Vasif C. Kalfa, M.D. | Allergy & Clinical Immunology

8630 Fenton Street, Suite 522 • Silver Spring, MD 20910
Tel: (240) 531-2902 • Fax: (240) 847-7061

Date: September 15, 2026

TO: Pharmacy & Therapeutics (P&T) Committees, Medical Directors, and Healthcare Insurers

RE: Clinical Recommendation for Dupilumab Formulary Coverage and Timely Patient Access

To Whom It May Concern:

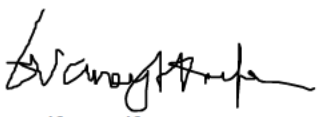
I am writing this recommendation as a practicing allergy and clinical immunology physician with the Allergy and Asthma Clinic of Maryland. The purpose of this letter is to strongly advocate for the inclusion and unimpeded formulary coverage of dupilumab across commercial, Medicare, and Medicaid health plans when clinically indicated. In our subspecialty practice, we manage complex patient populations suffering from debilitating Type 2 inflammatory disorders. Over extensive clinical experience utilizing various approved biologic therapies, dupilumab has consistently distinguished itself as an essential, life-transforming medication.

> **Proven Therapeutic Efficacy Across Core Indications:**
>
> - **Severe Atopic Dermatitis:** Significant, rapid pruritus relief, sustained epidermal clearance, and marked reduction in secondary cutaneous infections.
> - **Severe Asthma:** Marked decrease in severe acute exacerbations, stabilization of pulmonary function (FEV1), and meaningful reduction or elimination of systemic corticosteroid dependence.
> - **IgE-Mediated Food Allergies:** Crucial immune modulation that substantially raises reaction thresholds against accidental exposures, preventing severe anaphylaxis.
> - **Chronic Spontaneous Urticaria (CSU):** Profound control over refractory wheals and angioedema in patients unresponsive to standard high-dose antihistamines.

In addition to robust clinical efficacy, dupilumab demonstrates an exceptional safety profile. Across our treated cohort, the medication has been well-tolerated with minimal and readily manageable side effects. Unlike prolonged or recurrent systemic corticosteroid regimens—which carry well-documented, catastrophic risks of osteopenia, adrenal suppression, metabolic dysregulation, and immunosuppression—dupilumab offers targeted interleukin-4 and interleukin-13 blockade without broad-spectrum immunosuppressive toxicities.

Physician Independence & Neutrality: I explicitly confirm that neither I nor the Allergy and Asthma Clinic of Maryland maintain any financial connection, consulting relationship, speaker bureau affiliation, advisory role, or pecuniary interest with the manufacturer of dupilumab (Sanofi / Regeneron). This clinical recommendation is formulated with complete independence, founded solely on peer-reviewed clinical evidence and observable real-world patient outcomes.

When biologic intervention is clinically indicated, timely access is paramount. Excessive administrative barriers, burdensome prior authorization hurdles, and formulary exclusions routinely delay essential therapy, leading to disease progression and preventable emergency room utilization. I respectfully urge insurance carriers and formulary committees to ensure that dupilumab remains an available, accessible, and covered therapeutic choice for eligible patients.



Vasif C. Kalfa MD

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

dupixent comments

Kewalramani, Anupama <[redacted]> Sat, Sep 5, 2026 at 11:59 AM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

To whom it may concern:
I am a Pediatric Allergist and I am writing about the concerns around Dupixent's cost. I am have been in the Department of Pediatrics for 20 years.
I have been using Dupixent since it was FDA approved for eczema in 2017. It has now been approved for multiple other conditions such as asthma, eosinophilic esophagitis and chronic spontaneous urticaria. These are all conditions that I see regularly and treat.
First and foremost, there is no other FDA approved biologic that treats eosinophilic esophagitis and children less than 12 with eczema.
There are no other biologic substitutions for eosinophilic esophagitis. They have all been studied and no other biologic works. Although there are other treatments such as food restrictions, proton pump inhibitors and swallowed topical steroids they frequently do not work and are all associated with significant side effects. We have a specialized clinic at UMD that treats pediatric patients with this disease and without Dupixent EoE patients would suffer with food impactions and poor quality of life around something as simple as eating
Young children with eczema who are on Dupixent have tried every topical medication out there and the only reason they are on Dupixent is that nothing has worked. To see a child who after Dupixent feels confident about wearing short sleeve shirts and shorts because their skin looks normal (or almost normal) is nothing short of miraculous.
It is true that there are other biologics to treat asthma; however, the advantage of Dupixent is that it can be used to treated multiple allergic conditions at the same time which we, as Allergist, see very frequently.
This is an important drug in our arsenal in treating all of our patients.
Thank you.

Anu Kewalramani, MD, FAAAAI
Associate Professor
Department of Pediatrics, Division of Pulmonology/Allergy
Director of Pediatric Allergy
Co-Director Eosinophilic Gastrointestinal Disease Program (EGDP)
University of Maryland School of Medicine
[redacted]

[redacted]

Dear Maryland Prescription Drug Affordability Board,

My name is Charlotte Lanphear and I am Physician Assistant in Dermatology. I see hundreds of patients in Maryland who will be negatively impacted if a medication like Dupixent becomes unaffordable. It has come to my attention that Dupixent is being reviewed for cost adjustments and I want to ensure it is being reviewed to make this drug more affordable and accessible to my patients, not the opposite.

I see an average of 25 unique patients per month who I have prescribed Dupixent. A majority of these patients are able to afford their medications but I still have a large number of patients who cannot afford their copay and who are on patient assistance. I also have dozens of patients who cannot afford their Dupixent but do not qualify for patient assistance and therefore cannot get this life-changing medication.

For example, I see a 17-year-old patient with severe atopic dermatitis (eczema). Her atopic dermatitis covers her body head to toe and is so itchy that she routinely misses school and is unable to sleep through the night. Her current, STATE insurance, requires she try FIVE different topical medications before they will even consider approving her Dupixent; talk about expensive. Topical medications are honestly laughable given the extent of her disease. Because she has been unable to get Dupixent and unable to afford it, she has gone to the local emergency room twice this past summer for secondary bacterial infections. This is wasted Maryland tax payer money as she could have avoided these trips with the proper medication that her family can afford.

Please do the right thing and make Dupixent even more affordable for these patients who are in desperate need of an FDA approved, highly effective medication.

Thank you,

Charlotte Lanphear, PA-C

[redacted]

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

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent Comments

Benjamin Lockshin [redacted] Thu, Sep 10, 2026 at 8:52 AM
To: comments.pdab@maryland.gov

Dear Members of the Maryland Prescription Drug Affordability Board,

I am a board-certified dermatologist practicing in Rockville, Maryland, and I direct a clinical trials center focused on inflammatory skin disease. I am writing to share my clinical perspective on dupilumab (Dupixent) as the Board reviews this medication.

In more than two decades of practice, dupilumab, over the past 10 years, has represented a genuinely formative change unlike any other medication I have used for patients with TH2-driven diseases. I could offer hundreds of examples of dramatic and transformative responses, but one in particular stays with me. A teenage girl came to me with severe atopic dermatitis and asthma. She was withdrawn and visibly depressed, because her disease kept her from doing the ordinary activities any child her age wants to do. Within a few months of starting dupilumab she was a completely different person: her itch was gone, her skin involvement was minimal, and her asthma was finally controlled without the chronic steroids she had previously depended on.

What makes this medication distinctive is that it does not treat atopic dermatitis in isolation. To this day I am aware of no other therapy that safely treats atopic dermatitis while also addressing its well-established comorbidities. That combination is precisely what allowed my patient to reclaim her life across multiple conditions at once, and it is a benefit I see repeated across my practice.

Losing access to this medication would be detrimental to my patients and would substantially limit my ability to treat them effectively. I would urge the Board to weigh the real clinical value of dupilumab, and the comorbid disease burden it addresses, when evaluating the impact of its decisions on patient care.

In the interest of full transparency, I disclose that I serve as a speaker and clinical investigator for several pharmaceutical companies, including manufacturers of therapies in this space. The perspective above reflects my own clinical experience and observations from patient care.

Thank you for the opportunity to contribute to this process.

Respectfully,

Benjamin Lockshin, MD, FAAD
Assistant Professor, Georgetown University, Department of Dermatology
Director of the Clinical Trials Center at US Dermatology Partners
EVP of Strategic Initiatives, US Dermatology Partners

[redacted] 1/1

[redacted] [redacted]

Maryland

Support Pdab <support.pdab@maryland.gov>

Dupixent

Scott London <[redacted]>
To: support.pdab@maryland.gov

Mon, Sep 14, 2026 at 8:35 PM

Dear Members of the Maryland Prescription Drug Affordability Board,

I am writing as an otolaryngologist (ENT physician) who cares for patients with chronic rhinosinusitis with nasal polyps and other severe inflammatory diseases. I am deeply concerned about the proposal to eliminate coverage of Dupixent for Maryland state employee health plans.

For many of my patients, Dupixent is not simply another medication—it is a life-changing therapy. Patients with severe chronic rhinosinusitis with nasal polyps often experience years of nasal obstruction, loss of smell, recurrent infections, sleep disruption, and repeated courses of oral corticosteroids and sinus surgeries. Despite appropriate medical management and surgery, many patients continue to have debilitating disease. Dupixent is one of the few therapies that directly addresses the underlying type 2 inflammation responsible for these conditions.

Removing access to this medication would have significant consequences. Many patients would experience recurrence of nasal polyps, worsening symptoms, and diminished quality of life. As their disease progresses, they are likely to require repeated oral steroid courses, which carry well-documented risks including diabetes, osteoporosis, hypertension, cataracts, mood disorders, and increased infection risk. Others will require revision sinus surgery, increasing healthcare utilization and costs that may ultimately exceed the savings anticipated from restricting access to biologic therapy.

Moreover, eliminating coverage of Dupixent is unlikely to produce meaningful savings for the state. In practice, patients who are denied access to their established therapy will often be required to try another biologic through a prior authorization process, even when the alternative may be less appropriate for their specific disease or may have less supporting evidence for their clinical circumstances. This type of forced substitution can create additional administrative costs, treatment delays, medication changes, and avoidable office visits. If the alternative therapy is less effective or poorly tolerated, patients may ultimately require additional medications, oral corticosteroids, emergency care, or surgery. These downstream costs could offset or exceed any short-term savings from restricting Dupixent coverage.

As physicians, our treatment recommendations are based on clinical evidence, FDA-approved indications, and national practice guidelines. Coverage decisions that broadly eliminate access to an evidence-based therapy undermine the physician-patient relationship and prevent individualized treatment decisions. Patients who have finally achieved disease control after years of suffering should not lose access to the medication that has restored their health because of a non-clinical coverage policy.

While I recognize the importance of addressing prescription drug affordability, policies should preserve access for patients with the greatest medical need. Broad exclusions of clinically appropriate therapies risk worsening patient outcomes and increasing long-term healthcare expenditures through avoidable complications, hospitalizations, and surgeries. Any cost-containment approach should account for the total cost of care rather than focusing narrowly on the acquisition price of a single medication.

I respectfully urge the Board to reconsider any proposal that would broadly restrict access to Dupixent for Maryland state employees and their families. Any affordability strategy should include mechanisms that protect patients with evidence-based indications, avoid automatic substitution with

[redacted] [redacted]

potentially inferior alternatives, and allow treating physicians to determine the most appropriate therapy for each individual patient.

Thank you for your thoughtful consideration of the impact this proposal would have on patients and the physicians who care for them.

Sincerely,

Dr scott london

[redacted]

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

DUPIXÉNT

Asek Makia [redacted] > Thu, Sep 10, 2026 at 3:53 PM
To: comments.pdab@maryland.gov

My name is Dr Asek Makia , an allergist and immunologist with offices in MD and DC. I treat a lot of my patients with severe asthma and atopic dermatitis with dupixent and found it to be the most effective treatment for them. The need for oral steroids and hospitalization greatly reduced thereby reducing health care cost , oral steroids reliability and improving patient satisfaction and quality of life . I am therefore urging that Dupixent be kept on formulary. Thanks!!!

Sent from Yahoo Mail for iPhone

[redacted]

MARYLAND HEALTH BENEFIT EXCHANGE

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

September 1, 2026

Re: MHBE - DOSSIER COMMENT – DUPIXENT (dupilumab)

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

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, Dupixent accounted for a significant portion of total drug claims costs in the individual market - **267 enrollees received at least one prescription of various formulations of Dupixent** [2], accounting for **1.93% ($6.61M)** alone of brand name prescription drug claims costs in the individual market. Further, Dupixent accounted for a significant portion of individual market drug claims costs by enrollees in the SRP as well. Just **208 enrollees who received at least one prescription of various formulations of Dupixent** accounted for **2.2% ($6.14M)** 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] DUPIXENT 300 MG/2 ML SYRING, 300 MG/2 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
Baltimore, MD 21202
marylandhbe.com

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

3307 Northland Dr, Ste 160 ▪ Austin, TX 78731
www.infusioncenter.org ▪ info@infusioncenter.org

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

September 8, 2026

Re: Dupixent (dupilumab) 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 Dupixent (dupilumab) 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 Dupixent, we urge you to carefully consider how potential affordability policies could affect patients who receive Dupixent in a clinical setting or rely on healthcare providers to support the administration and management of their therapy.

When Dupixent is furnished and administered by a healthcare provider, reimbursement must adequately account for the provider's cost of acquiring and delivering the therapy. This distinction is particularly important when considering policies such as an Upper Payment Limit (UPL). A limit on what a health plan reimburses for Dupixent would not necessarily reduce the amount a provider must pay to acquire the drug. If reimbursement falls below or too close to acquisition and operating costs, community-based providers may be unable to sustainably provide the treatment.

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

- Travel farther to receive treatment or clinical support;
- Transition to a different site of care;

NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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- Experience disruptions or delays in ongoing therapy; or
- Face fewer options for accessing treatment in the setting most appropriate for their needs.

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 Dupixent, to distinguish between reducing costs within the healthcare system and reducing the reimbursement needed for providers to acquire and deliver 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 involved in patient care. We encourage the Board to pursue approaches that improve affordability without jeopardizing access to community-based treatment.

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

Sincerely,



Brian Nyquist, MPH
President and CEO
National Infusion Center Association

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent Comments

Roshni Padhiar <[redacted]> Tue, Sep 8, 2026 at 4:10 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

To whom this may concern,

Dupixent has been a revolutionary medication in the dermatology world. It is the first of its kind regarding efficacy as well as safety. Being able to help children as young as 6 months old has not only helped their skin improve, but also has impact on their growth. As eczema is flaring for a child - or anyone - it can severely interfere with daily living and be uncomfortable. The skin can break and bleed and interfere with sleep, school, and work to name a few scenarios.

Dupixent is our office's first line option for moderate-severe eczema that cannot be controlled with topicals/too much BSA is affected. Dupixent has helped change patient's lives and allowed them to achieve their life goals without having to deal with such a debilitating condition. Eczema can also come hand in hand with allergies and asthma, and Dupixent can even help mitigate some of these associated symptoms for patients. With increasing indiciations, we are confident with Dupixent's efficacy and safety profile, allowing us to help more and more people and skin conditions.

We hope you would consider the coverage for Dupixent to be as important as we see it as dermatology providers.

Roshni Padhiar, PA-C
Board Certified Physician Assistant

Dermatology Partners - Sparks
[redacted]

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,

Terry Wilcox

Terry Wilcox
Co-Founder and CEO
Patients Rising

REGENERON
SCIENCE TO MEDICINE®

777 Old Saw Mill River Road
Tarrytown, NY 10591-6707
914.847.7400

September 15, 2026

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

Re: Dupixent® (dupilumab) Comments

Dear Members of the Maryland Prescription Drug Affordability Board:

Regeneron appreciates the opportunity to communicate with the Maryland Prescription Drug Affordability Board ("PDAB" or "Board") about Dupixent® (dupilumab). As the Board is aware, Regeneron co-commercializes Dupixent with its partner, Sanofi. For the comment period posted August 31, 2026, Regeneron respectfully directs the Board to its July 2025 response to the request for information related to Dupixent to demonstrate the value of Dupixent in addressing Type 2 inflammation, a common cause of autoimmune diseases, and the importance of ensuring that Maryland patients retain affordable access to Dupixent. To the extent our commercialization partner, Sanofi, submits a comment to the Board in response to the current solicitation, Regeneron also directs the Board to that comment.

As Regeneron and Sanofi intend to demonstrate over the course of this cost review process, Dupixent is vital to the patient populations it treats (including rare disease and orphan drug designated populations), and use of Dupixent is rapidly increasing across multiple diseases. Further, Dupixent has a well-documented history of being responsibly priced.

Notwithstanding the foregoing, Regeneron has concerns about the limited visibility into the Board's administration of the cost review process. Solicitation of input and consideration of information provided by stakeholders, including the manufacturers of drugs under review, is essential to ensuring a fair and robust review process. Limiting comment periods to only 15 days, including for this upcoming meeting, unduly restricts the ability of interested parties to provide substantive analysis and meaningfully engage in the cost review process, and risks undermining Maryland patients' access to life-saving treatments. To that end, Regeneron looks forward to providing feedback on the proposed amendments to the Board's regulations published earlier this month and continuing to work with the Board to increase fairness, balance, and transparency in the cost review study process. In addition, Regeneron reserves all rights with respect to the current cost review process for Dupixent, including the right to supplement our responses to the Board in the future.

Sincerely,

Mark O'Rourke

Mark O'Rourke
Director, State Government Relations
Regeneron Pharmaceuticals, Inc.

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent Comments

Douglas Reh [redacted] Wed, Sep 9, 2026 at 10:11 AM
To: comments.pdab@maryland.gov

Dear Members of the Maryland Prescription Drug Affordability Board,

I am writing as an otolaryngologist (ENT physician) who cares for patients with chronic rhinosinusitis with nasal polyps and other severe inflammatory diseases. I am deeply concerned about the proposal to eliminate coverage of Dupixent for Maryland state employee health plans.

For many of my patients, Dupixent is not simply another medication—it is a life-changing therapy. Patients with severe chronic rhinosinusitis with nasal polyps often experience years of nasal obstruction, loss of smell, recurrent infections, sleep disruption, and repeated courses of oral corticosteroids and sinus surgeries. Despite appropriate medical management and surgery, many patients continue to have debilitating disease. Dupixent is one of the few therapies that directly addresses the underlying type 2 inflammation responsible for these conditions.

Removing access to this medication would have significant consequences. Many patients would experience recurrence of nasal polyps, worsening symptoms, and diminished quality of life. As their disease progresses, they are likely to require repeated oral steroid courses, which carry well-documented risks including diabetes, osteoporosis, hypertension, cataracts, mood disorders, and increased infection risk. Others will require revision sinus surgery, increasing healthcare utilization and costs that may ultimately exceed the savings anticipated from restricting access to biologic therapy.

Moreover, eliminating coverage of Dupixent is unlikely to produce meaningful savings for the state. In practice, patients who are denied access to their established therapy will often be required to try another biologic through a prior authorization process, even when the alternative may be less appropriate for their specific disease or may have less supporting evidence for their clinical circumstances. This type of forced substitution can create additional administrative costs, treatment delays, medication changes, and avoidable office visits. If the alternative therapy is less effective or poorly tolerated, patients may ultimately require additional medications, oral corticosteroids, emergency care, or surgery. These downstream costs could offset or exceed any short-term savings from restricting Dupixent coverage.

As physicians, our treatment recommendations are based on clinical evidence, FDA-approved indications, and national practice guidelines. Coverage decisions that broadly eliminate access to an evidence-based therapy undermine the physician-patient relationship and prevent individualized treatment decisions. Patients who have finally achieved disease control after years of suffering should not lose access to the medication that has restored their health because of a non-clinical coverage policy.

While I recognize the importance of addressing prescription drug affordability, policies should preserve access for patients with the greatest medical need. Broad exclusions of clinically appropriate therapies risk worsening patient outcomes and increasing long-term healthcare expenditures through avoidable complications, hospitalizations, and surgeries. Any cost-containment approach should account for the total cost of care rather than focusing narrowly on the acquisition price of a single medication.

[redacted] [redacted]

I respectfully urge the Board to reconsider any proposal that would broadly restrict access to Dupixent for Maryland state employees and their families. Any affordability strategy should include mechanisms that protect patients with evidence-based indications, avoid automatic substitution with potentially inferior alternatives, and allow treating physicians to determine the most appropriate therapy for each individual patient.

Thank you for your thoughtful consideration of the impact this proposal would have on patients and the physicians who care for them.

Sincerely,

Douglas Reh

Douglas D. Reh, MD, FACS, FARS
Rhinology and Sinus Surgery
Partner, Director of Clinical Research, ESP/Centers for Advanced ENT Care, LLC

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sanofi

September 15, 2026

VIA ELECTRONIC MAIL

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

Re: Dupixent Comments — Written Comment Request Posted August 31, 2026, Regarding the Cost Review Study Process for Dupixent (dupilumab)

Dear Members of the Maryland Prescription Drug Affordability Board,

Sanofi writes in response to the Maryland Prescription Drug Affordability Board's (the "Board's") August 31, 2026 request for written comments regarding "patient experience and clinician input" related to Dupixent. Sanofi agrees with the Board that patient experience is particularly important when evaluating Dupixent because many of its approved indications involve chronic, debilitating diseases that affect far more than traditional clinical outcomes. For many patients and families, the impact of these conditions is reflected not only in symptoms and healthcare utilization, but also in sleep, daily functioning, mental health, participation in school and work, and overall quality of life.

However, Sanofi is concerned that the Board's 15-day comment period, which falls over a holiday weekend, does not afford patients, caregivers, clinicians, and other stakeholders a reasonable opportunity to develop and submit meaningful feedback on topics that the Board has identified as of "particular interest." This concern is especially acute for a medicine such as Dupixent that is approved across nine different indications, each with distinct patient experiences and treatment considerations. By providing such a compressed opportunity for participation, the Board unreasonably limits the breadth and quality of the very perspectives it has requested and may not develop a complete record on these important topics. A comment period that suits parties who monitor the Board's proceedings may not reach those who do not, and for patients, caregivers, and treating

clinicians, learning of the request, deciding whether to participate, and preparing a useful account of their experience takes time this period does not sufficiently allow. Nor is a later comment period a substitute. A patient or caregiver who does not learn of this request has no greater reason to learn of the next. Sanofi asks that the Board take more time to collect meaningful, representative, public comment.

Consistent with the Board's request for information regarding patient experience, Sanofi submits the following information to supplement its July 28, 2025 request for information submission (the "RFI submission"). As discussed below, evidence of patient experience demonstrates the important role Dupixent plays in addressing significant unmet need, improving patients' daily functioning and quality of life, supporting individuals living with one or more type 2 inflammatory diseases, reducing burdens on caregivers and families, and potentially altering the long-term course of disease. These benefits, coupled with the affordability of Dupixent, underscore the therapy's substantial clinical value and reinforce the importance of maintaining access to this effective treatment.

Dupixent, which Sanofi commercializes with our partner, Regeneron, is a first-in-class biologic medication that inhibits the signaling of two key drivers of type 2 inflammation (IL-4 and IL-13). Its broad therapeutic value is reflected in its current FDA-approved indications across nine different conditions: eczema/atopic dermatitis (AD); asthma (AS); chronic rhinosinusitis with nasal polyps (CRSwNP); eosinophilic esophagitis (EoE); prurigo nodularis (PN), chronic obstructive pulmonary disease (COPD), chronic spontaneous urticaria (CSU), bullous pemphigoid (BP), and allergic fungal rhinusinitis (AFRS).[1] Given that Dupixent is approved across nine indications spanning distinct diseases, patient populations, age ranges, and treatment settings, its overall utilization and expenditures necessarily reflect the breadth of its approved uses—not a single, uniform value proposition. Each indication addresses a different clinical need and, by effectively treating disease and reducing its burden, may help avoid downstream healthcare utilization and costs associated with uncontrolled disease, including additional treatments, acute care, and other medical interventions. Taken together, Dupixent's breadth of approved uses and ability to address significant unmet needs underscore its substantial clinical and economic value across diverse patient populations.

Dupixent Addresses Significant Unmet Need and Meaningfully Improves Patients' Daily Lives

Dupixent's patient experience value begins with its ability to address significant unmet needs across multiple chronic inflammatory diseases, many of which previously lacked effective targeted therapies or adequate treatment options, while also improving patients'

ability to function, participate in daily activities, and manage the broader burden of disease. Dupixent is the only biologic approved to treat moderate-to-severe AD in children as young as six months of age; the only approved treatment for BP and AFRS; the only targeted advanced therapy approved to treat EoE; the only biologic approved to treat CSU in children under twelve years of age; and the only targeted medicine approved for oral corticosteroid-dependent asthma. [1] These approvals are meaningful not simply because they represent regulatory milestones, but because they provide treatment options for patients who previously had few or no approved alternatives.

In addition, Dupixent recently received FDA approval in February 2026 for the treatment of AFRS in adults and pediatric patients aged six years and older who have a history of sino-nasal surgery. AFRS is a chronic inflammatory condition that can result in recurrent symptoms, repeated medical interventions, and meaningful impacts on patient quality of life. Prior to Dupixent's approval for AFRS, no FDA-approved therapies specifically addressed the condition, leaving patients to rely primarily on surgery, prolonged courses of systemic corticosteroids, and other approaches that focused on symptom management rather than the underlying type 2 inflammatory pathway.[2] For eligible patients living with AFRS, a chronic and frequently recurrent disease associated with nasal obstruction, facial pressure, loss of smell, repeated medical interventions, and substantial quality-of-life impacts,[3] the availability of the first FDA-approved therapy specifically for the condition represents a meaningful advancement in care and an important patient experience benefit.

In April 2026, Dupixent was also approved for the treatment of CSU in children ages 2 to 11 and remains the only approved biologic treatment for this patient population.[4] This approval, along with Dupixent's approval for AFRS, reflects continued investment in research and development to expand treatment options for patients with significant unmet medical needs. These post-approval innovations have brought new biologic treatment options to patient populations that previously had none, underscoring the importance of continued investment in developing therapies that address areas where treatment options remain limited. Sanofi continues to make significant investments into research exploring Dupixent's potential to treat additional rare conditions and address unmet patient needs.

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[1] *See* DUPIXENT® (dupilumab) Injection, Prescribing Information (rev. April 2026), https://www.regeneron.com/downloads/dupixent_fpi.pdf.

[2] *Andy J. Chua, Ali Jafar & Amber U. Luong, Update on Allergic Fungal Rhinosinusitis, 131 Ann. Allergy Asthma & Immunology 300, (2023), https://doi.org/10.1016/j.anai.2023.02.018.*

[3] *See* L. T. Roland et al., *Allergic Fungal Rhinosinusitis Diagnosis, Management, Associated Conditions, Pathophysiology, and Future Directions: Summary of a Multidisciplinary Workshop*, 15 Int'l F. Allergy & Rhinology 626, 631–32 (2025), https://doi.org/10.1002/alr.23582.

[4] Sanofi & Regeneron, *Sanofi and Regeneron's Dupixent Approved in the U.S. as the First Biologic Medicine for Young Children with Uncontrolled Chronic Spontaneous Urticaria* (Apr. 22, 2026).

Patients with type 2 inflammatory diseases also frequently experience multiple related conditions concurrently, and these comorbidities can have a substantial impact on patient and disease outcomes.[5] In a real-world study of patients with moderate-to-severe type 2 inflammatory diseases, 24% of patients with asthma, 36% with CRSwNP, and 16% with atopic dermatitis had at least two additional type 2 comorbidities.[6] By targeting the shared IL-4/IL-13 pathway that underlies multiple manifestations of type 2 inflammation, Dupixent may provide a single treatment option for patients with multiple coexisting conditions for which Dupixent is indicated, helping to reduce both disease burden and treatment burden for patients.[7]

Beyond expanding and simplifying treatment options, Dupixent may meaningfully improve patients' ability to participate in everyday life. As outlined in Sanofi's RFI submission, moderate to severe atopic dermatitis, for example, is associated with sleep disruption, worse health-related quality of life, symptoms of anxiety and depression,[8] impaired daily functioning, psychological distress,[9] and substantial healthcare utilization.[10] Studies cited in Sanofi's RFI submission found that treatment with Dupixent was associated with improvements in patient-reported disease control, daily functioning, better sleep quality, and reductions in anxiety or depression—as well as sustained improvements in disease severity, symptoms, and quality of life.[11] Importantly, those improvements were

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[5] See Justin P. McCormick & Jivianne T. Lee, *Insights into the Implications of Coexisting Type 2 Inflammatory Diseases*, 14 J. Inflammation Rsch. 4259, 4259 (2021), https://doi.org/10.2147/JIR.S311640.

[6] *See* David Khan et al., *Prevalence and Severity Distribution of Type 2 Inflammation-Related Comorbidities in Patients with Moderate-to-Severe Type 2 Inflammatory Diseases*, 13 J. Asthma & Allergy 117, 117 (2023), https://doi.org/10.2147/JAA.S397010.

[7] *See Anju T. Peters et al., Coexisting Type 2 Inflammatory Conditions in Patients with Asthma Treated with Dupilumab: The RAPID Registry, 43 Adv. Therapy 3230, 3230–42 (2026) (demonstrating that among patients initiating Dupixent for asthma, 92% of patients had at least one ongoing type 2 inflammatory coexisting condition and 62.9% had multiple ongoing type 2 coexisting conditions); Jennifer D. Hamilton et al., Dupilumab Suppresses Type 2 Inflammatory Biomarkers Across Multiple Atopic, Allergic Diseases, 51 Clinical Experimental Allergy 915, 915–31 (2021) (finding that frequent baseline comorbidities across the underlying clinical-study populations—e.g., allergic rhinitis in 42.5%–70.1% across indications and asthma in 33.3–59.5% of the atopic dermatitis and chronic rhinosinusitis with nasal polyps patient populations).*

[8] *See* Jonathan I. Silverberg et al., *Sleep Disturbances in Atopic Dermatitis in US Adults*, 33(6 Supp.) Dermatitis, at 4–5 (2021), https://dermatology.upenn.edu/wp-content/uploads/sites/11/2022/06/Sleep_Disturbances_in_Atopic_Dermatitis_in_US_AOM_0622.pdf; Jonathan I. Silverberg et al., *Association of Atopic Dermatitis With Sleep Quality, Psychological Well-being, and Functional Impairment*, 157 JAMA Dermatol. 1115 (2021), https://jamanetwork.com/journals/jamadermatology/fullarticle/2783857.

[9] Cloe Kern et al., *Association of Atopic Dermatitis and Mental Health Outcomes Across Childhood*, 157 JAMA Dermatology 1200, 1200–01, 1204–05 (2021), https://jamanetwork.com/journals/jamadermatology/fullarticle/2783857 (finding that severe atopic dermatitis was associated with depressive symptoms and internalizing behaviors across childhood and adolescence, with sleep quality partially mediating the association).

[10] Piergiacomo Calzavara-Pinton et al., *One-Year Insights into the GLOBOSTAD Multinational Prospective Observational Study of Patients Receiving Dupilumab for Atopic Dermatitis*, 42 Adv. Therapy 720, 721, 726–29 (2023), https://link.springer.com/article/10.1007/s12325-024-03049-8.

[11] *See Bruce Strober et al., Treatment Outcomes Associated With Dupilumab Use in Patients With Atopic Dermatitis: 1-Year Results From the RELIEVE-AD Study, 158 JAMA Dermatology 142 (2022), https://jamanetwork.com/journals/jamadermatology/fullarticle/2787271; see also Zhixiao Wang et al., Dupilumab Improves Health-Related Quality of Life and Work Productivity Among Adults With Moderate-to-Severe Atopic Dermatitis*

accompanied by substantial reductions in healthcare utilization, with the proportion of follow-up patients reporting an atopic dermatitis-related hospitalizations and emergency room or urgent-care visits declining significantly after one year.[12]

These improvements are meaningful because they translate into tangible benefits that patients experience every day. Effective disease control can help patients sleep through the night, participate more fully in school and work, engage in family and community activities, and experience fewer disruptions associated with emergency care, hospitalizations, or disease exacerbations. Treatment with Dupixent was associated with improvements in sleep, daily activities, health-related quality of life, and work and activity impairment—outcomes that may help patients participate more fully in work, family, and community activities.[13] Reductions in atopic dermatitis-related emergency room or urgent-care visits and hospitalizations may further reduce disruptions to patients' daily lives.[14] For patients living with chronic inflammatory diseases, these outcomes are often as important as traditional clinical endpoints and should remain central to the Board's assessment of patient experience.

The Patient Experience Includes Caregivers and Families

For many of Dupixent's approved indications, especially those affecting children, the patient experience is closely linked to the experience of the caregivers and families who share the burden of chronic disease. Recent U.S. data further underscore the broader health care burden of pediatric AD, finding that children with more severe disease experienced substantially higher health care utilization and costs—including higher rates of hospitalization and emergency or urgent care visits—highlighting the potential value of effective treatment in reducing the downstream burden of uncontrolled disease.[15] As discussed above, several of Dupixent's approvals extend to pediatric populations with no other FDA-approved biologic treatment, including atopic dermatitis in children as young as six months of age. When the patient is a young child, parents, family members, and other caregivers perform the daily work of managing chronic inflammatory disease. As a result, any assessment of patient experience that focuses exclusively on the patient risks

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in Clinical Practice: 5-Year Follow-up Results From the RELIEVE-AD Study, , J. of the Am. Acad. of Dermatology (2025), https://www.jaad.org/article/S0190-9622(25)01441-0/abstract; Calzavara-Pinton et al., supra note 8, at 721, 726–29.

[12] *See Calzavara-Pinton et al., supra note 8, at 728 (finding that the proportion of follow-up patients reporting an atopic dermatitis-related hospitalization or emergency room/urgent-care visit during the preceding three months decreased from 11.1% at baseline to 1.7% at month 12).*

[13] Strober et al., *supra* note 9, at 142, 146.

[14] *See Wang et al., supra note 9.*

[15] *See Jonathan I. Silverberg et al., Healthcare Resource Utilization and Costs in Pediatric Patients Under 6 Years Old with Atopic Dermatitis in the United States: A Retrospective, Observational, Cross-Sectional Study, 28 JAAD Int'l 25, 25 (2026), https://doi.org/10.1016/j.jdin.2026.04.025.*

overlooking a substantial portion of the real-world burden imposed by these conditions and the corresponding benefits that effective treatment may provide to families and caregivers.

Published evidence suggests that effective treatment can alleviate these burdens. In a post hoc analysis of a placebo-controlled phase 3 study, children between six months and five years of age with moderate-to-severe atopic dermatitis received treatment with Dupixent plus low-potency topical corticosteroids or placebo plus corticosteroids. Dupixent was associated with improvement in caregiver-reported measures of symptoms and quality of life, including sleep quality.[16] Similarly, reductions in hospitalizations, emergency visits, and other healthcare utilization are meaningful not only for patients but also for caregivers and families, for whom each healthcare encounter carries its substantial demands on time, attention, and family routine.[17] Taken together, this evidence demonstrates that the benefits of effective disease control are experienced by entire families rather than by patients alone, and the Board's assessment of patient experience should incorporate caregiver experience alongside patient outcomes.

Dupixent May Alter the Long-Term Course of Disease Through Attenuation of the Atopic March and Support Healthy Growth in Children

The Board should consider emerging observational evidence suggesting that Dupixent may provide value not only by treating existing disease, but also by being associated with a lower risk of subsequent allergic march progression in pediatric patients with atopic dermatitis. Atopic dermatitis is increasingly understood as the early manifestation of a group of related atopic conditions that share type 2 inflammatory mechanisms, and children with early onset atopic dermatitis may later develop coexisting conditions such as food allergy, allergic rhinitis, asthma, and eosinophilic esophagitis, a phenomenon commonly referred to as the "atopic march."[18] For patients and families, slowing or preventing this progression could mean avoiding additional illnesses, diagnoses, treatments, symptoms, and disruptions that accumulate over time and affect quality of life.

Emerging observational evidence suggests that Dupixent may not simply improve atopic dermatitis symptoms but may also attenuate progression along the atopic march. In a 2024 retrospective, propensity-score matched cohort study, children with atopic dermatitis treated with Dupixent experienced a 32% lower risk of progression of the allergic march, a 40% lower risk of developing asthma, and a 31% lower risk of developing allergic rhinitis

[16] *See* Amy S. Paller et al., *The Effect of Dupilumab on Caregiver- and Patient-Reported Outcomes in Young Children with Moderate-to-Severe Atopic Dermatitis: Results from a Placebo-Controlled, Phase 3 Study*, 92 J. Am. Acad. Dermatology 116, 116–20, 122–23 (2025), https://www.jaad.org/article/S0190-9622(24)02896-2/fulltext.
[17] *See* Calzavara-Pinton et al., *supra* note 8 at 721, 728.
[18] *See* American Academy of Pediatrics, *Allergic March*, https://www.aap.org/en/patient-care/allergic-march.

over approximately three years of follow-up compared with children receiving conventional therapies.[19]

Moreover, a recent post hoc analysis suggests that Dupixent treatment was associated with improved linear growth in children ages six to eleven with severe atopic dermatitis.[20] Among children who were shorter than expected for their age, children treated with Dupixent were more likely than children receiving placebo to show gains in height over sixteen weeks.[21] The study also found improvements in a blood marker associated with bone growth.[22] From a patient-experience perspective, these potential benefits extend beyond management of current symptoms and raise the possibility of reducing future disease burden, treatment burden, and impacts on patients' and caregivers' daily lives. Accordingly, the Board should consider not only how Dupixent improves patients' health today, including its potential to support healthy growth in children with severe atopic dermatitis, but also its potential to help patients avoid additional allergic disease and its associated burdens in the future.

Dupixent is Affordable to Maryland Patients

Dupixent has demonstrated strong value while remaining an important and affordable treatment option for Maryland patients. At the time of its initial approval in 2017, the Institute for Clinical and Economic Review (ICER)[23] deemed Dupixent's launch price "cost effective," reflecting both its clinical benefits and the healthcare costs it helps avoid.[24] ICER concluded that Dupixent was priced "in line with its value,"[25] with its Chief Medical Officer concluding that "the drug was priced in a way that aligns well with the benefit it provides to

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[19] *See* Teng-Li Lin et al., *Reduced Atopic March Risk in Pediatric Atopic Dermatitis Patients Prescribed Dupilumab Versus Conventional Immunomodulatory Therapy: A Population-Based Cohort Study*, 91 J. Am. Acad. Dermatology 466, 466–73 (2024), https://doi.org/10.1016/j.jaad.2024.05.029. In a 2024 retrospective cohort study, children with atopic dermatitis who were prescribed Dupixent were at lower risk of allergic march progression, of developing asthma, and of developing allergic rhinitis than children receiving conventional immunomodulatory therapy, with hazard ratios of 0.68 for incident asthma or allergic rhinitis combined, 0.60 for asthma, and 0.69 for allergic rhinitis over approximately three years of follow-up.

[20] *See* Alan D. Irvine et al., *Dupilumab Treatment Improves Linear Growth and Bone Biomarkers in Children with Atopic Dermatitis: Post Hoc Analysis of a Phase 3 Randomized, Placebo-Controlled Clinical Trial and an Open-Label Extension Study*, J. Am. Acad. Dermatology (2026), https://www.jaad.org/article/S0190-9622(26)03071-9/fulltext.

[21] *Id.* at 2. Among children below the 40th height percentile at baseline, 31.3% of children receiving Dupixent experienced an increase of at least five height percentiles by week 16, compared with 15.5% of children receiving placebo ($P < .05$).

[22] *Id.*

[23] ICER, *What is ICER?*, https://icer.org/what-is-icer/; ICER, *Value Assessment Framework, About ICER,* at 2 (2023), https://icer.org/wp-content/uploads/2023/09/ICER_2023_VAF_For-Publication_092523.pdf (ICER is an "independent non-profit research organization that evaluates medical evidence and convenes public deliberative bodies to help stakeholders interpret and apply evidence to improve patient outcomes and control costs.").

[24] ICER, *Dupilumab and Crisaborole for Atopic Dermatitis: Effectiveness and Value* (Jun. 8, 2017), https://icer.org/wp-content/uploads/2020/10/MWCEPAC_ATOPIC_FINAL_EVIDENCE_REPORT_060717.pdf.

[25] *See ICER, Dupilumab and Crisaborole, supra note* 24.

patients."[26] Even pharmacy benefit manager (PBM) executives agreed that Dupixent's launch price was in line with its value. Upon launch on 2017, Express Scripts Chief Medical Officer Steven Miller described Dupixent's list price as a "responsible price" that would have a have a "beneficial effect" on patient outcomes and on healthcare costs.[27] In a subsequent 2021 review that was last updated in 2023, ICER reaffirmed that Dupixent remains more cost effective than alternatives in treating AD.[28] Since Dupixent's launch, Sanofi has taken reasonable and predictable price increases in line with our Pricing Policy.[29] This determination of value at launch, coupled with our commitment to responsible price increases leads to a conclusion that Dupixent remains a good value to patients and to the system.

In its cost review study process, MD PDAB should be focused primarily on the medicine's affordability to patients and the value it delivers. The price that matters to patients is the amount they pay at the pharmacy counter, and Sanofi does not control that amount. Health plans, in coordination with their PBMs, set the patient out-of-pocket cost as part of their benefit design. Even though drug manufacturers offer substantial discounts in the form of rebates to health plans, those plans continue to calculate patient cost-sharing as a percentage of the price of the drug the pharmacy is reimbursed—not reflecting the manufacturer rebates that reduce the actual amount that plans pay. The Board should consider the primary role that PBMs and insurance companies play in setting patient out-of-pocket responsibility when analyzing what factors are actually driving patient affordability challenges. This is especially important for medicines, like Dupixent, that were priced responsibly at launch and have seen very modest, if any, annual net price increases after launch.

For its part, Sanofi is committed to patient affordability, offering both a copay card program for commercially insured patients, as well as free medicine for low- and middle-income

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[26] ICER, *Institute for Clinical and Economic Review's final report on treatments for atopic dermatitis provides policy recommendations to support appropriate patient access to dupilumab* (Jun. 8, 2017), https://icer.org/news-insights/press-releases/institute-for-clinical-and-economic-reviews-final-report-on-treatments-for-atopic-dermatitis-provides-policy-recommendations-to-support-appropriate-patient-access-to-dupilumab/.

[27] Wall Street Journal, FDA Approves Regeneron and Sanofi's Dupixent for Eczema (Mar. 28, 2017), https://www.wsj.com/articles/fda-approves-regeneron-and-sanofis-dupixent-for-eczema-1490716597; Eric Sagonowsky, Tough-and-Vocal PBM Executive Steve Miller Says Pharma May Be Coming Around on Pricing, Fierce Pharma (July 17, 2017), https://www.fiercepharma.com/pharma/pharma-s-starting-to-come-around-pricing-express-script-s-steve-miller-says.

[28] ICER, *JAK Inhibitors and Monoclonal Antibodies for the Treatment of Atopic Dermatitis: Effectiveness and Value* 47 (Aug 17, 2021, *updated* Feb. 27, 2023), https://icer.org/wp-content/uploads/2023/02/Atopic-Dermatitis_Final-Evidence-Report_Unmasked_02272023.pdf ("Compared to dupilumab, baricitinib and tralokinumab were found to be less costly and less effective whereas abrocitinib (using a placeholder price) and upadacitinib did not meet commonly cited cost-effectiveness thresholds.")

[29] Sanofi Pricing Principles for the U.S. (2026). https://www.sanofi.us/en/our-company/social-impact/responsible-business-values/pricing-principles.

patients, in Maryland and nationwide to help ensure affordable access to this innovative treatment. The Board should also consider the significant investment that Sanofi makes in its affordability programs, which lower or eliminate Maryland patients' out-of-pocket costs, in evaluating Dupixent's affordability. All commercially-insured Maryland patients are eligible for our copay card regardless of income level, and the enrollment process is quick and easy—as simple as filling out a form on our website: https://www.dupixent.com/support-savings/copay-card. Additionally, through the Dupixent MyWay® Patient Assistance Program, qualified patients, including those on Medicare, who are uninsured or underinsured and meet financial need criteria, may receive their medication at no cost. The Dupixent MyWay® Support Team is available by phone at 1-844-DUPIXENT (1-844-387-4936) 24/7 to help patients and healthcare providers to access the program.

Ultimately, the Board's cost review study process should distinguish between the price of a medicine and the factors that determine what patients actually pay, and consider the broader health care system dynamics that drive patient affordability.

* * *

Much of what patients, caregivers, and clinicians experience does not appear in claims data. The cumulative burden of coexisting conditions, the demands that fall on caregivers and families, and the potential to avoid future allergic disease cannot be fully measured through pharmacy and medical claims alone. An assessment focused primarily on utilization and claims-based measures therefore risks understating the value Dupixent provides to patients, caregivers, and families. Sanofi urges the Board to give substantial weight to this evidence when evaluating Dupixent.

If the Board has any questions, I can be reached at andrea.todd-harlin@sanofi.com or (651) 334-3444.

Sincerely,

Andrea Todd-Harlin
Head, State Government Relations, Sanofi

To: Maryland Prescription Drug Affordability Board
Re: Public Comment – Dupixent (dupilumab), BLA761055 – Cost Review Study Process
Date: September 6, 2026

Dear Members of the Prescription Drug Affordability Board,

I am writing as a practicing allergist/immunologist in private practice in Maryland to submit comment on the Board's cost review of Dupixent (dupilumab). I prescribe this medication routinely across the many of its FDA-approved indications and want to share my clinical perspective on its value, its unique role in my practice, and my concerns about the cost analysis.

Dupixent is currently approved for approximately nine distinct conditions, more than any other biologic on the market. In my practice, I regularly treat patients who carry two or more of these diagnoses simultaneously, such as atopic dermatitis with comorbid asthma, or eosinophilic esophagitis with comorbid asthma. For these patients, a single agent addressing multiple disease processes means one biologic instead of two or three. If Dupixent were less available, many of these patients would not simply go untreated — they would potentially receive multiple separate biologics targeting each condition individually, which would increase, not decrease, total system cost.

My understanding is that Dupixent's average wholesale price is in line with other biologics used in the same therapeutic categories. I see the Board's report suggested that Dupixent is driving increased utilization and cost within the dermatologic biologic class. In practice, however, several other agents in that class are priced comparably to Dupixent but offer far fewer indications and far less flexibility for patients with overlapping disease. If Dupixent were restricted or made less accessible, patients would not stop using biologics in this class — prescribing would simply shift to these alternative agents at similar cost, with no clear savings to the system and a real loss of clinical flexibility for multi-condition patients.

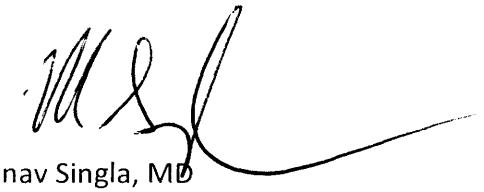
With the exception of eosinophilic esophagitis, most of Dupixent's indications have at least one alternative biologic available. For eosinophilic esophagitis, Dupixent remains the only FDA-approved biologic option. I have treated a substantial number of EoE patients with this medication with a high degree of clinical success, including those covered by Medicare or Medicaid. Restricting access or affordability for this population would leave them with no approved biologic alternative for this condition.

In the interest of full transparency, I disclose that I have in the past received compensation from Regeneron and Sanofi for promotional speaking activities related to Dupixent. This submission is

unrelated to any promotional engagement, is not compensated, and reflects solely my independent clinical judgment and concern for continued access on behalf of my patients.

Thank you for the opportunity to comment. I would be glad to provide additional clinical detail or patient-level context if helpful to the Board's review.

Sincerely,



Manav Singla, MD
Allergy Asthma Specialists of Maryland
msingla AT mdallergy.net

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent comments

ksutherland@annapollendocs.com [redacted]> Tue, Sep 15, 2026 at 2:47 PM
To: comments.pdab@maryland.gov

[redacted] [redacted]

To the Maryland Prescription Drug Affordability Board,

Re: Preserve State Employee Formulary Coverage for Dupixent

I am writing to urge the Maryland Prescription Drug Affordability Board to retain Dupixent on the State employee formulary. As a Family Nurse Practitioner practicing in Allergy and Immunology, I see firsthand the substantial burden that uncontrolled type 2 inflammatory disease places on pediatric and adult patients and their families.

Dupixent is an important targeted treatment for appropriately selected patients with moderate-to-severe atopic dermatitis, moderate-to-severe eosinophilic or oral corticosteroid-dependent asthma, eosinophilic esophagitis, and other serious allergic and inflammatory conditions. These chronic diseases are not minor inconveniences. They can cause persistent itching, disrupted sleep, skin infections, school and work absences, emergency care, oral corticosteroid exposure, impaired nutrition or swallowing, and marked limitations in daily functioning and quality of life.

For children with severe atopic dermatitis, uncontrolled disease can mean sleepless nights from itching, painful and extensive skin involvement, missed school, and significant stress for the entire family. Dupixent is particularly important because it is an FDA-approved systemic option for moderate-to-severe atopic dermatitis in children as young as 6 months when topical therapies are insufficient or not advisable. It offers an evidence-based alternative to repeated courses of systemic corticosteroids or less targeted systemic immunosuppressive therapies.

For pediatric and adult patients with moderate-to-severe asthma, Dupixent can reduce exacerbation risk and improve pulmonary function in appropriate patients with type 2 inflammation or oral corticosteroid-dependent disease. Preserving access helps avoid the consequences of uncontrolled asthma, including urgent visits, hospitalizations, missed school and work, and the cumulative adverse effects associated with recurrent or chronic oral corticosteroid use.

Many patients have overlapping allergic conditions, such as asthma, atopic dermatitis, allergic rhinitis, chronic rhinosinusitis with nasal polyps, and eosinophilic esophagitis. For these patients, Dupixent may address a shared underlying inflammatory pathway and can provide meaningful clinical benefit across more than one disease manifestation. Removing coverage may fragment care, force avoidable treatment changes, and expose patients to therapies that may be less effective, less tolerable, or associated with greater monitoring and safety burdens.

Formulary decisions should appropriately consider affordability, but they must also account for the clinical and downstream financial consequences of loss of disease control. Restricting or removing access to Dupixent may increase costs related to urgent and emergency care, hospitalizations, repeated systemic corticosteroid courses, additional office visits, rescue therapies, missed work for the patients themselves but also the caregivers.

Thanks for your time,

Karli Sutherland CRNP

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent Comments

Sue Talbott [redacted] Tue, Sep 15, 2026 at 7:06 PM
To: Comments PDAB -PDAB- <comments.pdab@maryland.gov>

Members of the **Prescription Drug Affordability Board**, Stakeholder Council, and Staff:

I am writing as a patient who takes Dupixent to express concern over the cost of this medication. I am fortunate to have insurance coverage that makes this drug affordable for me and allows me to find relief from my symptoms; however, I know so many others are not so fortunate. While I have no monthly co-pay for Dupixent, I am well aware that the true cost of this medication is a financial burden for many others.

At $3000/month, the cost of Dupixent is undoubtedly contributing to rising health insurance premiums, its list price is impacting out-of-pocket responsibilities for patients, and I'm sure it is a strain on tight government budgets looking to provide coverage for employee health plans.

Dupixent is prescribed by my dermatologist; it works for me. I am very very glad I am able to afford it. No patient should be forced to compromise on taking prescribed medication because of excessive cost. I believe the cost of Dupixent is excessive even as it remains one of the most advertised drugs in the world. I urge the **Prescription Drug Affordability Board** to do a full cost review of Dupixent so that Marylanders can see what a fair, affordable cost would be.

Very sincerely yours,

Susan W. Talbott, RN, MA, MBA

[redacted]

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent importance

Leonardo Tjahjono [redacted] > Tue, Sep 15, 2026 at 3:56 PM
To: comments.pdab@maryland.gov

To Whom It May Concern:

I am writing to strongly advocate for broad and timely formulary access to dupilumab (Dupixent) for patients with its dermatologic indications, including atopic dermatitis, prurigo nodularis, chronic spontaneous urticaria, and bullous pemphigoid.

As a dermatologist who cares for patients with complex and severe inflammatory skin disease, I believe it is important for formulary decision-makers to understand that these conditions are not simply “rashes.” They can cause profound physical suffering, sleep deprivation, infection, functional impairment, psychiatric burden, repeated healthcare utilization, and, in the case of bullous pemphigoid, substantial morbidity and mortality. For appropriately selected patients, dupilumab can fundamentally alter the course and lived experience of these diseases.

Atopic Dermatitis

Moderate-to-severe atopic dermatitis can be a debilitating systemic inflammatory disease. Patients may experience relentless pruritus, widespread inflammation, excoriations, skin pain, sleep disruption, recurrent infections, and major impairment in school, work, and family life. Severe disease can lead to emergency visits, hospitalization, and repeated exposure to systemic corticosteroids or other immunosuppressive therapies.

Dupilumab transformed the treatment of atopic dermatitis by providing effective long-term disease control without the broad immunosuppression associated with many traditional systemic therapies. Its impact extends beyond improvement in visible dermatitis. Effective treatment can restore sleep, reduce itch and pain, improve daily functioning, and allow patients to return to work, school, and normal social activities.

For many patients, this is not a cosmetic improvement. It is the difference between living with uncontrolled chronic disease and being able to function normally.

Prurigo Nodularis

Prurigo nodularis is among the most intensely pruritic diseases encountered in dermatology. Patients may suffer from dozens or hundreds of excoriated and painful nodules accompanied by nearly continuous itching. The itch-scratch cycle can become extraordinarily difficult to interrupt and may persist for years.

The consequences extend far beyond the skin. Severe pruritus can profoundly disrupt sleep, concentration, employment, relationships, and psychological well-being. Historically, patients with prurigo nodularis had few evidence-based systemic treatment options, and many were exposed to therapies with substantial toxicity and inconsistent efficacy.

[redacted]

Dupilumab represented a major change in the management of this disease by providing a targeted, evidence-based therapy capable of substantially reducing itch and skin lesions. For a patient who has spent years unable to sleep through the night because of severe pruritus, successful treatment can be genuinely life-changing.

Chronic Spontaneous Urticaria

Chronic spontaneous urticaria can produce recurrent hives and debilitating pruritus, often accompanied by angioedema. For patients with inadequately controlled disease, the unpredictability itself can be disabling. Patients may repeatedly seek urgent or emergency care because swelling can be frightening and difficult to distinguish from potentially dangerous allergic reactions.

Patients with refractory disease may require repeated systemic corticosteroids or escalation to other systemic therapies. Effective biologic treatment can therefore have implications not only for symptom control but also for corticosteroid exposure, acute-care utilization, work productivity, and quality of life.

Dupilumab provides an important targeted therapeutic option for appropriate patients whose disease remains inadequately controlled. Maintaining formulary access is particularly important because chronic spontaneous urticaria is heterogeneous, and not every patient responds adequately to the same therapeutic pathway.

Bullous Pemphigoid

The importance of dupilumab in bullous pemphigoid deserves particular emphasis.

Bullous pemphigoid disproportionately affects older adults, including medically fragile patients with multiple comorbidities. It is not merely a blistering rash. Severe disease can involve widespread blistering, erosions, intense pruritus, pain, secondary infection, functional decline, hospitalization, and substantial mortality.

Historically, systemic corticosteroids and other immunosuppressive agents have been central to treatment. In an elderly population, however, prolonged systemic immunosuppression carries substantial risks, including serious infection, hyperglycemia, osteoporosis, cardiovascular and metabolic complications, and other treatment-related morbidity.

The availability of dupilumab therefore represents much more than the introduction of another dermatologic medication. For appropriate patients, an effective targeted treatment that can control bullous pemphigoid while reducing reliance on systemic corticosteroids and broad immunosuppression has the potential to prevent serious complications and may, in some circumstances, be life-saving.

This distinction is particularly important when formulary decisions are made based primarily on medication acquisition cost. The relevant comparison should not simply be the cost of dupilumab versus the cost of an inexpensive corticosteroid. The appropriate comparison includes the downstream consequences of inadequately controlled disease and treatment toxicity: emergency department visits, hospitalizations, infections, laboratory monitoring, complications of corticosteroids and immunosuppressants, loss of independence, and other healthcare utilization.

The Importance of Timely Formulary Access

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For all four diseases, formulary policies should recognize that delays in obtaining appropriate therapy have consequences. Requirements for repeated failure of therapies that are unlikely to provide adequate disease control—or that expose patients to avoidable toxicity—can prolong suffering and generate additional healthcare utilization.

Reasonable utilization management is understandable. However, step-therapy requirements should be clinically appropriate, evidence-based, and sufficiently flexible to account for disease severity, comorbidities, contraindications, previous treatment failures, and the judgment of the treating specialist.

Dupilumab is particularly valuable because its targeted mechanism has allowed it to address multiple type 2 inflammatory diseases while avoiding many of the cumulative toxicities associated with conventional systemic immunosuppression. Its value should therefore be evaluated not solely according to pharmacy expenditure but according to its broader ability to reduce disease burden and potentially reduce reliance on corticosteroids and other systemic immunosuppressants.

As physicians, our goal is not simply to make a patient's skin look better. We seek to restore sleep, reduce pain and itch, prevent infection and hospitalization, preserve function and independence, minimize treatment toxicity, and allow patients to participate fully in their families, communities, schools, and workplaces. In our most vulnerable patients—particularly elderly patients with bullous pemphigoid—effective and safer disease control may also help prevent severe and potentially life-threatening complications.

I therefore strongly urge your organization to maintain broad formulary access to dupilumab for its approved dermatologic indications and to minimize unnecessary administrative barriers and clinically inappropriate step-therapy requirements. Coverage policies should allow treating clinicians to select dupilumab when medically appropriate and should provide an efficient pathway for patients with severe disease or contraindications to alternative therapies.

For many patients, access to dupilumab is not a matter of convenience. It can mean the difference between persistent uncontrolled disease and meaningful disease control; between repeated corticosteroid exposure and targeted therapy; between sleepless nights and restored function; and, for some of our most medically vulnerable patients, potentially between recurrent serious complications and a substantially safer course of disease.

Thank you for considering the clinical realities faced by patients living with these serious dermatologic diseases and for recognizing the importance of preserving access to therapies that can profoundly change their lives.

Sincerely,

Leonardo Tjahjono, MD, FAAD
Assistant Professor of Dermatology
George Washington University Department of Dermatology
Director, Inpatient Dermatology Consult Service
Director, Rheumatology–Dermatology Clinic
Director, Dermatology Pre-clerkship Curriculum
Director, Rheumatology Dermatology Fellowship

[redacted]

[redacted] [redacted]

Maryland

Comments PDAB <comments.pdab@maryland.gov>

Dupixent Comments

Lexi Cole [redacted] Tue, Sep 15, 2026 at 3:29 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

Dear Members of the Prescription Drug Affordability Board,
I am writing as a practicing family nurse practitioner for allergy and immunology in private practice in Maryland to submit comment on the Board's cost review of Dupixent (dupilumab). I prescribe this medication routinely across the many of its FDA-approved indications and want to share my clinical perspective on its value, its unique role in my practice, and my concerns about the cost analysis.
Dupixent is currently approved for approximately nine distinct conditions, more than any other biologic on the market. In my practice, I regularly treat patients who carry two or more of these diagnoses simultaneously, such as atopic dermatitis with comorbid asthma, or eosinophilic esophagitis with comorbid asthma. For these patients, a single agent addressing multiple disease processes means one biologic instead of two or three. If Dupixent were less available, many of these patients would not simply go untreated — they would potentially receive multiple separate biologics targeting each condition individually, which would increase, not decrease, total system cost.
My understanding is that Dupixent's average wholesale price is in line with other biologics used in the same therapeutic categories. I see the Board's report suggested that Dupixent is driving increased utilization and cost within the dermatologic biologic class. In practice, however, several other agents in that class are priced comparably to Dupixent but offer far fewer indications and far less flexibility for patients with overlapping disease. If Dupixent were restricted or made less accessible, patients would not stop using biologics in this class — prescribing would simply shift to these alternative agents at similar cost, with no clear savings to the system and a real loss of clinical flexibility for multi-condition patients.
Also, I see many young children who need biologic therapy for uncontrolled atopic dermatitis, for these children (under 12 years old) Dupixent is the only FDA approved biologic therapy.
This submission is unrelated to any promotional engagement, is not compensated, and reflects solely my independent clinical judgment and concern for continued access on behalf of my patients.
Thank you for the opportunity to comment. I would be glad to provide additional clinical detail or patient-level context if helpful to the Board's review.
Sincerely,
Alexandria Tolmie, FNP-C
Allergy Asthma Specialists of Maryland
[redacted]

Alexandria Tolmie
[Quoted te t hidden]

[redacted]



September 15, 2026

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

RE: DUPIXENT COST REVIEW

Dear Members of the Board,

As a broad coalition of organizations representing patients, caregivers and health care providers, we write concerning the value of Dupixent (dupilumab), chosen by the Prescription Drug Affordability Board for cost review and consideration of affordability. The Coalition has previously submitted comments expressing concern that the limited 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 treatment 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.

Dupixent is a biologic approved for a broad range of conditions, including atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, and prurigo nodularis, with approval extending to children as young as six months for some indications. Prescribers value Dupixent for its versatility, and that versatility is not incidental. These five conditions share an underlying type 2 inflammatory process, and as a result they cluster together in the same patients far more often than chance would predict.

Up to 67 of every 100 patients with chronic rhinosinusitis with nasal polyps also have asthma.[1] Among patients with eosinophilic esophagitis, roughly 85 to 90 percent have at least one other atopic or allergic diagnosis, and most have more than one.[2] Patients with prurigo nodularis are many times more likely than the general population to also have atopic dermatitis.[3] And atopic dermatitis itself is well recognized as an early step in a broader progression, sometimes called the atopic march, toward asthma and allergic rhinitis later in life. For a meaningful share of the patients living with these diseases, the relevant clinical question is not which single condition to treat, but how to treat two or three overlapping conditions at once 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 diagnosis with a single, well-studied mechanism has value that a condition-by-condition accounting will not capture.

From the patient perspective, this matters concretely. Nasal polyps can cause chronic congestion, loss of smell and taste, facial pain, and the need for repeated sinus surgery,[4] and poorly controlled asthma contributes to roughly ten deaths nationwide every day, deaths that are almost entirely avoidable with proper treatment.[5] Severe eczema, a disease affecting an estimated 10 percent of Americans. [6] Clinical evidence shows that severe flares can bring complications so serious that patients hospitalized for the condition die an average of 8.3 years younger than the general population.[7] Eosinophilic esophagitis can leave a patient unable to swallow safely, at real risk of a medical emergency if food becomes lodged in the esophagus, while prurigo nodularis brings a level of itch that patients consistently rate as more severe than other chronic skin disease. For a patient managing two or more of these conditions at once, a single effective therapy is not a convenience. It is the difference between one course of treatment and several, and between a disease that is manageable and one that is not.

Therefore, any list of therapeutic alternatives list the Board considers should meet the same criteria. A treatment approved for one of these five conditions is not automatically an

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[1]Allergy & Asthma Network, Chronic Rhinosinusitis with Nasal Polyps (CRSwNP), https://allergyasthmanetwork.org/health-a-z/chronic-rhinosinusitis-with-nasal-polyps-crswnp/
[2]LIBERTY-EoE-TREET trial data, cited in "Atopic, Allergic Comorbidities Prevalent Among Patients With Eosinophilic Esophagitis," Healio, https://www.healio.com/news/allergy-asthma/20230329/atopic-allergic-comorbidities-prevalent-among-patients-with-eosinophilic-esophagitis
[3]Li Y, et al., "Association between atopic dermatitis and prurigo nodularis: a systematic review and meta-analysis," International Journal of Dermatology, cited in HCPLive, https://www.hcplive.com/view/atopic-dermatitis-closely-linked-to-prurigo-nodularis-in-meta-analysis
[4]Mayo Clinic, Nasal Polyps, https://www.mayoclinic.org/diseases-conditions/nasal-polyps/symptoms-causes/syc-20351888
[5]Asthma and Allergy Foundation of America, Asthma Facts, https://aafa.org/asthma/asthma-facts/
[6]National Eczema Association, Eczema Facts, https://nationaleczema.org/research/eczema-facts/
[7]Egeberg A, et al., "Ten-year mortality is increased after hospitalization for atopic dermatitis," *Journal of the American Academy of Dermatology*, cited in PubMed, https://pubmed.ncbi.nlm.nih.gov/27742169/

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 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.

It may be difficult to quantify precisely what a full night's sleep, a restored sense of smell, or an avoided hospitalization 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 to the patients and families living with these diseases, perhaps with greater cost down the line.

The Value of Care Coalition asks that as the Board evaluates the affordability of Dupixent, 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