April 23, 2024

VIA OVERNIGHT MAIL TO:

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

VIA EMAIL TO:
comments.pdab@maryland.gov

Re: PDASC Public Comments – Maryland Prescription Drug Affordability Stakeholder Council Meeting, April 29, 2024

Dear Members of the Maryland Prescription Drug Affordability Stakeholder Council:

AbbVie Inc. is submitting comments in connection with the Maryland Prescription Drug Affordability Stakeholder Council's ("PDASC's") April 29, 2024 meeting to discuss the drugs referred by the Maryland Prescription Drug Affordability Board (PDAB), including AbbVie's product SKYRIZI®. **As detailed further herein, given the value of SKYRIZI and its affordability to Maryland patients, AbbVie respectfully requests that the PDASC advise the PDAB to *not select* SKYRIZI for a cost review.**

AbbVie's mission is to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas – immunology, oncology, neuroscience, and eye care. For nearly 20 years, AbbVie has been a leader in the field of immunology through significant investment in research and the development of new, innovative medicines and programs that meet the needs of patients, physicians, and payers.

I. Background on SKYRIZI

SKYRIZI (Risankizumab-rzaa) is a prescription, biologic interleukin-23 antagonist that is indicated for the treatment of: (a) moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy; (b) active psoriatic arthritis in adults; and (c) moderately to severely active Crohn's disease in adults.[1] Since the U.S. Food and Drug Administration (FDA) first approved SKYRIZI in 2019, AbbVie has continued to sponsor research on the use of SKYRIZI to address unmet patient needs, including for rare diseases. For example, pursuant to an FDA orphan designation for the "[t]reatment of pediatric Crohn's

[1] Skyrizi®, Full Prescribing Information, https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.

disease,"[2] AbbVie currently is sponsoring a Phase 3, multicenter study to assess the pharmacokinetics, efficacy, and safety of SKYRIZI in pediatric participants with moderately to severely active Crohn's disease. The study began in December 2023, and is estimated to be completed in April 2029.[3]

II. SKYRIZI is a Valuable and Affordable Treatment Option for Maryland Patients

AbbVie urges the PDAB to view the value of SKYRIZI within a patient-centric context. As explained in further detail below, SKYRIZI is a valuable treatment option that fulfills an unmet need for patients with autoimmune conditions. Additionally, because SKYRIZI is affordable to patients, as well as the broader healthcare system, its selection for a cost review would not further the statutory purpose of the PDAB "to protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products."[4] Therefore, the PDAB should remove SKYRIZI from the list of drugs being considered for a cost review.

A. SKYRIZI® is an Important Treatment Option that Fulfills Unmet Patient Needs

SKYRIZI is a vital treatment option for patients with autoimmune conditions. For example, psoriasis is the most prevalent autoimmune disease in the United States, affecting three-percent of the U.S. adult population, or approximately eight million Americans.[5] In addition to the visible signs of psoriasis (*e.g.*, raised plaques, scales on skin), the associated physical, emotional, mental and social burden can negatively impact patients' quality of life.[6] Moreover, an estimated 30 percent of people with psoriasis will go on to develop psoriatic arthritis, which is characterized by painful swelling in the joints and reduced range of motion.[7]

Though advancements have been made in recent years for the treatment of these conditions, there remains significant need for the patients suffering from the diseases, the prescribers treating them, and entities budgeting for and covering the costs of therapies.

The effectiveness of psoriasis medicines – measured by levels of skin clearance – matters to patients. A lack of initial response to treatment or lack of sustained response to treatment

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[2] FDA, Search Orphan Drug Designations and Approvals: Risankizumab, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=544716.
[3] Clinical Trials, *A Study to Assess Adverse Events, Change in Disease Activity, and How Intravenous and Subcutaneous Risankizumab Moves Through the Body of Pediatric Participants With Moderately to Severely Active Crohn's Disease*, https://clinicaltrials.gov/study/NCT05995353?term=m16-194&rank=1.
[4] Md. Code Ann., Health-Gen. § 21-2C-02(b).
[5] National Psoriasis Foundation. Statistics. https://www.psoriasis.org/content/statistics.
[6] Boehncke WH, Schon MP. Psoriasis. Lancet. 2015;386(9997):983–994.
[7] Mease PJ, Gladman DD, Papp KA, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. Journal of the American Academy of Dermatology. 2013;69(5):729-735.

results in 62 percent of treatment discontinuations within the first year.[8] In clinical trials, SKYRIZI has demonstrated not only high levels skin clearance for patients with psoriasis, but lasting clearance over time with the convenience of every twelve-week dosing. These results include patients who are historically more difficult to treat, such as patients who weigh more, patients with severe disease and/or patients who have been treated with prior psoriasis medications.[9,10] Importantly, SKYRIZI also has demonstrated significant improvements in patients' psoriasis symptoms, and quality of life and depression/anxiety.[11]

SKYRIZI also offers meaningful benefits over alternative treatment options. It has a comparable safety profile to alternative therapies, such as ustekinumab, another commonly used biologic plaque psoriasis therapy, and provides predictability and durability between doses, over time, and across patient types with standard dosing regimen. [12] SKYRIZI also provides durable skin clearance through six years,[13] as demonstrated in our clinical trials/long-term extensions as well as a favorable benefit-risk profile and predictable real-world treatment patterns with the lowest rates of dose escalation and switching rates.

In network meta-analyses, SKYRIZI had one of the most favorable long-term benefit-risk profiles, with the highest Psoriasis Area and Severity Index (PASI) response rate and lowest safety event rates compared with other treatments.[14] In the real-world, up to ~32% of patients with psoriasis taking any class of biologic dose escalated in the first 12 months after initiating treatment and 26% of patients treated with biologics switched to another treatment within 2 years of initiation. Both dose escalation and switching are treatment patterns that can lead to additional healthcare costs for payers.[15]

Psoriasis patients that dose escalated their biologic treatment had substantial annual mean per person psoriasis-related outpatient prescription pharmacy costs across treatments from

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[8] Strober B, Zema CL, Holmes C, et al. Reasons for drug discontinuation among psoriasis patients in the Corrona Psoriasis Registry. Submitted to the 28th European Academy of Dermatology and Venerology. Oct 9-13, 2019; Madrid, Spain.

[9] Skyrizi (risankizumab-rzaa) [package insert]. North Chicago, IL: AbbVie Inc.

[10] Gordon KB, Strober B, Lebwohl M, et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomized, placebo-controlled and ustekinumab-controlled phase 3 trials. Lancet. 2018;392(10148):650-661.

[11] Augustin M, Lambert J, Zema C, Thompson EHZ, Yang M, Wu EQ, Garcia-Horton V, Geng Z, Valdes JM, Joshi A, Gordon KB. Effect of Risankizumab on Patient-Reported Outcomes in Moderate to Severe Psoriasis: The UltIMMa-1 and UltIMMa-2 Randomized Clinical Trials. JAMA Dermatol. 2020 Dec 1;156(12):1344-1353. doi: 10.1001/jamadermatol.2020.3617. PMID: 33052382; PMCID: PMC7557488.

[12] Strober B, Eyerich K, Hong HC, et al. Long-term efficacy and safety of switching from ustekinumab to risankizumab: results from the open-label extension LIMMitless. Presented at: 28th European Academy of Dermatology and Venereology (EADV) Congress; October 9-13, 2019; Madrid, Spain.

[13] Papp KA, et al. Long-term Safety and Efficacy of Risankizumab for the Treatment of Moderate-to-Severe Plaque Psoriasis: Final Analysis of Results From the LIMMitless Open-label Extension Trial For up to 6 Years of Follow-up. Poster 53833. Presented at the 2024 American Academy of Dermatology (AAD) Annual Meeting, March 8–12, 2024, San Diego, CA, USA

[14] Accessed at https://pubmed.ncbi.nlm.nih.gov/34862951/

[15] Bagel J, Glick B, Wu JJ, et al. Dose escalation and associated costs in biologic treatment of psoriasis based on real world data. J Med Econ. 2021;24(1):792-791 https://pubmed.ncbi.nlm.nih.gov/37154473/

$5,202 to $16,475. In addition, switching treatments within the first year of start was associated with a 28.2% higher mean total cost of care compared to patients who did not switch.[16] In the real-world, at the 30% threshold, the percentage of patients with dose escalation in the maintenance period was significantly lower with SKYRIZI (2.0%) compared with other biologics (adalimumab, ustekinumab, secukinumab, ixekizumab, and guselkumab; 17.9%, 10.0%, 15.7%, 18.0%, and 7.2%, respectively; $p < 0.0001$).[17] In addition, switch rates varied between specific biologics, with the lowest switch rates observed for patients treated with SKYRIZI at 8.5% followed by guselkumab at 15.7%, ustekinumab at 24.5%, ixekizumab at 25.1%, secukinumab at 30.4%, and adalimumab at 38.9%, over 24 months.[18]

SKYRIZI also is an important treatment option for patients with Crohn's disease (CD), a chronic, inflammatory bowel disease that affects nearly one in 100 Americans.[19] Specifically, SKYRIZI is the first advanced treatment to evaluate the impact of treatment on both clinical and endoscopic outcomes.[20] Head-to-head data compared to ustekinumab in patients with prior anti-TNF failure has shown superiority in terms of endoscopic remission at Week 48 (SEQUENCE trial) (31.8% for SKYRIZI and 16.2% for Stelara).-Secondary endpoints tested for superiority at Week 48 and included higher rates of clinical remission, steroid-free endoscopic remission, and steroid-free clinical remission at Week 48 for SKYRIZI.[21]

B. SKYRIZI is Affordable and Accessible to Patients and the Broader Healthcare System

Consistent with AbbVie's commitment to patient access, SKYRIZI is affordable for patients, including patients in Maryland. AbbVie offers patient support programs (PSPs) that set a new industry standard for patient service by focusing on a high-touch, highly personal, human health care experience delivered through a combination of personal interactions, digital solutions, and sophisticated data management. For example, eligible commercially insured patients may qualify for SKYRIZI Complete, which offers a Savings Card that reduces patient cost-sharing to as little as $5 per dose.[22] Additionally, under myAbbVie Assist, low-income patients who are uninsured, unemployed, or have recently lost insurance coverage may be eligible to receive SKYRIZI at no cost.[23]

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[16] Wu JJ, Patel M, Li C, et al. Real world switch rates of biologics and associated costs in patients with psoriasis. Presented at the 2023 American Academy of Dermatology Annual Meeting; March 17-21, 2023; New Orleans, LA.
[17] Accessed at https://pubmed.ncbi.nlm.nih.gov/37025014/
[18] Accessed at https://pubmed.ncbi.nlm.nih.gov/37154473/
[19] Crohn's and Colitis Foundation, Overview of Crohn's Disease, https://www.crohnscolitisfoundation.org/patientsandcaregivers/what-is-crohns-disease/overview.
[20] Skyrizi, Full Prescribing Information, *supra*.
[21] Peyrin-Biroulet L, Chapman JC, Colombel J-F, et al. Risankizumab versus ustekinumab for patients with moderate to severe Crohn's disease: Results from the phase 3b SEQUENCE study. Presented at the United European Gastroenterology Week (UEGW 2023), October 14-17, 2023. Copenhagen, Denmark, OP#LB01.
[22] Skyrizi® Complete, https://www.skyrizi.com/skyrizi-complete/save-on-skyrizi-costs./.
[23] myAbbVie Assist, https://www.abbvie.com/patients/patient-support/patient-assistance.html.

Moreover, AbbVie's understanding is that the PDAB is particularly interested in the cost of SKYRIZI for its state employee insurance plan members, who to our knowledge have coverage under a commercial plan/plans. If not otherwise restricted from doing so under your plans, your employees with commercial insurance coverage are eligible to apply for cost-sharing assistance from AbbVie according to program's terms and conditions. Specifically, each employee that received such assistance could pay as little as $5 per dose out of pocket.[24]

Further, we believe that the state of Maryland, for its employee insurance plan(s), may or has contracted with CVS Caremark under one of its PBM options; we are unaware due to the lack of records production to date whether the PDAB and Council has examined out of pocket cost for SKYRIZI per employee under said plan(s) and if not, we encourage you to do so.

Understanding our access programs and the individualized needs of patients, physicians, and payers is only one part of a large solution to the issue of access, and AbbVie is committed to working with all stakeholders to ensure patients receive the treatments they need to live their best life.

III. The Maryland PDAB Has Not Produced Records Requested by AbbVie Prior to the Comments Deadline of April 24, Adversely Impacting AbbVie's Ability to Effectively Participate in the Cost Review Process

By letter dated March 29, 2024, AbbVie submitted a public records request of the Maryland PDAB pursuant to the Maryland Public Information Act, Md. Code Ann., General Provisions §§ 4-101–4-601, seeking all documents and information related to the PDAB's selection of SKYRIZI for potential cost review and its referral to the PDASC. The PDAB notified AbbVie on April 10, 2024, that it would provide AbbVie with a response to its records request by April 29, 2024, the same date as the PDASC's meeting to discuss SKYRIZI and the other seven drugs referred by the PDAB. The requested records are critical to affording AbbVie a fair opportunity to engage with the PSADC and the PDAB about SKYRIZI. Indeed, the very purpose of the PDASC is to provide stakeholder input to assist the PDAB in its decision-making.[25] There is a member of the PDASC who specifically represents brand name drug corporations. As the manufacturer of a drug under consideration for cost review, AbbVie is a relevant stakeholder that must be afforded a meaningful opportunity to have its views heard.

AbbVie has serious concerns about its ability to develop and submit informed comments that effectively address the PDAB's rationale for referring SKYRIZI to the Stakeholder Council when we do not currently have meaningful insight into the methodology, standards, criteria, data, and other information underlying the PDAB's decision to select our product. Moreover, in the absence of same, we are unable to offer the PDASC our alternative view of the value, benefits and patient access and affordability of SKYRIZI. For example, based on what is in the public

[24] Skyrizi Complete, *supra*.

[25] Maryland Prescription Drug Affordability PDAB, "Prescription Drug Affordability Stakeholder Council, 2022 Stakeholder Council Meeting," at https://pdab.maryland.gov/pdab_stakeholder_2022.html ("The purpose of the Prescription Drug Affordability Stakeholder Council is to provide stakeholder input to assist the PDAB in making decisions to protect the State, its residents, and other stakeholders in the Maryland health care system").

domain, the PDAB's published data on patient out-of-pocket costs for the selected drugs including SKYRIZI does not seem to include manufacturer-provided copay assistance, which as highlighted above results in many patients paying as little as $5 per dose for SKYRIZI. Rather, the data appears to only represent the patient's annual prescription drug cost sharing, which includes a deductible, copay, or coinsurance defined by the patient's health insurance plan, providing an incomplete picture of a patient's actual cost.[26] Further, our understanding is that the underlying data files are limited to only privately fully-insured and self-insured non-ERISA health insurance plans for Maryland and Non-Maryland residents and do not include any ERISA plans.[27]

The deadline to submit comments to the PDASC pertaining to agenda items for its April 29 meeting is close of business on Wednesday, April 24, 2024. Importantly, the PDASC's website also states that "*[a] subsequent meeting may occur on Monday, May 6, 2024 at 3:00 PM if more time is required to obtain input beyond the time allocated for the April 29th meeting."[28] Given the anticipated timing of the PDAB's response to our records request, in a letter dated April 17, 2024, AbbVie petitioned the PDASC to delay its discussion of SKYRIZI to the PDASC's May 6, 2024 session and extend the related deadline for submitting comments. These reasonable concessions would permit our expedited review of the materials produced by the PDAB in response to our records request and allowed us to incorporate it into our comments.

On April 18, the PDAB denied AbbVie's petitions, advising us that its response to our records request and "the Stakeholder Council's regularly scheduled meeting—at which it will receive comments and discuss drugs referred by the PDAB—are not related." The PDAB further asserted that "[a]lthough [AbbVie] may believe that the [records request] response may assist [the Company] in formulating your comments, the two processes are not entwined and the Stakeholder Council referral process is a stand-alone procedure."

Without the benefit of the requested documents and related other information, AbbVie is unable to understand and analyze the methodology and underlying data that the PDAB used to identify which drugs to refer to the PDASC. At its April 29 meeting, the PDASC is discussing *the drugs referred by the PDAB*; based on such discussion and its evaluation of the public comments received, the PDASC will provide input to the PDAB that will inform the PDAB's decision whether to select a drug for cost review, a process that may ultimately result in establishment of an upper payment limit for a reviewed drug. The records request and cost review processes are inextricably intertwined.

At its March 25, 2024 meeting, several PDAB members expressed concerns about the quality of available data (*e.g.*, very dated claims information), raising legitimate questions regarding the veracity of the data and information the PDAB relied upon to select the eight drugs referred to the PDASC. AbbVie shares these concerns, as the PDAB's product selections may not accurately reflect the eligible drugs that pose actual affordability challenges to Maryland

[26] Accessed at *https://pdab.maryland.gov/cost_review_process.html*
[27] *Id*.
[28] Maryland Prescription Drug Affordability Stakeholder Council, April 29, 2024 Meeting, at https://pdab.maryland.gov/pdab_stakeholder_2024.html.

patients. The PDAB has only provided a limited subset of data in a public dashboard which, among other issues, lacks context and complete source information.[29] Impacted stakeholders like AbbVie are, therefore, unable to engage in the cost review process fairly and fully.

It is critically important that the PDAB provide manufacturers and other key stakeholders with an opportunity to provide meaningful and informed feedback during this process, and the PDASC's input for the Board consider *all* of the stakeholders it is charged with representing. Without the criteria and underlying data that the PDAB is relying on to determine which drugs are subject to a cost review, the PDASC and PDAB will not receive the information it needs for fulsome deliberations.

IV. Conclusion

We appreciate the opportunity to provide our comments on the list of drugs that are being considered for a cost review. However, as noted, we are unable to comment completely nor with the benefit of full public transparency into the PDAB's process to date including the inability of the PDAB to produce records. For these reasons and many others as outlined in this letter, AbbVie objects to the consideration of SKYRIZI for a cost review.

Given the value of SKYRIZI and its affordability to Maryland patients, AbbVie respectfully requests that the PDAB immediately remove SKYRIZI from consideration for a cost review.

Please contact Emily Donaldson at emily.donaldson@abbvie.com with any questions.

Sincerely,

Hayden Kennedy
Vice President, Global Policy & U.S. Access Strategies
Government Affairs
On behalf of AbbVie Inc

[29] *See* Maryland Prescription Drug Affordability Board, "Drugs Referred to the Stakeholder Council- Dashboard," at https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx.

Apfed
American Partnership
for Eosinophilic Disorders

713-493-7749
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PO Box 29545, Atlanta, GA, 30359

April 24, 2024

Prescription Drug Affordability Stakeholder Council
Maryland

Dear Councilmembers:

I write today on behalf of the American Partnership for Eosinophilic Disorders (APFED), a national 501c3 patient advocacy organization that was founded in 2001 to improve the lives of individuals with eosinophilic disorders through research, education, awareness, and advocacy.

Eosinophilic esophagitis (EoE) is a chronic, allergic inflammatory condition of the esophagus, the tube that connects the throat to the stomach. In EoE, the esophageal tissue becomes infiltrated with eosinophils, a type of white blood cell, in turn causing inflammation and tissue damage. The symptoms of EoE often include dysphagia (difficulty swallowing), chest pain, food impaction (food getting stuck in the throat), and reflux.

EoE is increasingly recognized as a cause of dysphagia, food regurgitation, and food impaction. EoE has an estimated prevalence of 1 out of 2,000 people in the United States,[1] and 50-100 per 100,000 individuals worldwide.[2] These prevalence estimates position EoE as a rare disease, as conventionally defined.[3]

In the U.S., the estimated annual health care cost for EoE is as much as $1.4 billion, underscoring the significant economic toll and disease burden.[4]

The exact cause of EoE is not fully understood, but it is believed to be related to both genetic and environmental factors. Allergies, particularly to foods, are often associated with EoE, and many people with EoE have a history of other allergic diseases like asthma, allergic rhinitis, or eczema.

Left untreated, EoE can lead to various complications and persistent symptoms that can significantly affect a person's quality of life. It can significantly impair a person's ability to eat and drink normally, leading to weight loss, malnutrition, and dehydration.

Chronic inflammation and scarring in the esophagus can contribute to difficulty swallowing and increases the risk of food impaction. Patients with poorly controlled EoE may require emergency medical services to manage dysphagia or food impactions.

Researchers analyzed data from a US Nationwide Emergency Department Sample to estimate weighted annual EoE-associated emergency department (ED) visits from 2009 to 2019 and found that volume of EoE-associated ED visits tripled within that time frame. The study authors noted that this is projected to further double by the year 2030.[5]

These findings underscore the significant and unexpected healthcare resource usage and highlights the opportunity to optimize outpatient EoE care.

Treatment of EoE is crucial to preventing complications and managing symptoms effectively. Treatment options for EoE may include dietary restrictions, proton pump inhibitors, swallowed corticosteroids, and in some cases, esophageal dilation to alleviate narrowing of the esophagus. The FDA has approved Dupixent®, a biologic, to treat EoE in pediatrics and adults.

Biologic drugs are designed to target specific parts of the immune system, inflammatory pathways, or disease processes. These groundbreaking treatments can offer hope to those living with complex and chronic conditions that conventional drugs can't adequately address.

For patients with EoE, Dupixent® can be life-changing and access to this biologic drug for EoE patients who rely on state-funded programs for their healthcare needs is critical.

Patient Experience

"We tried an elimination diet first, but my son still didn't get better. His eczema became a big comorbidity for him.

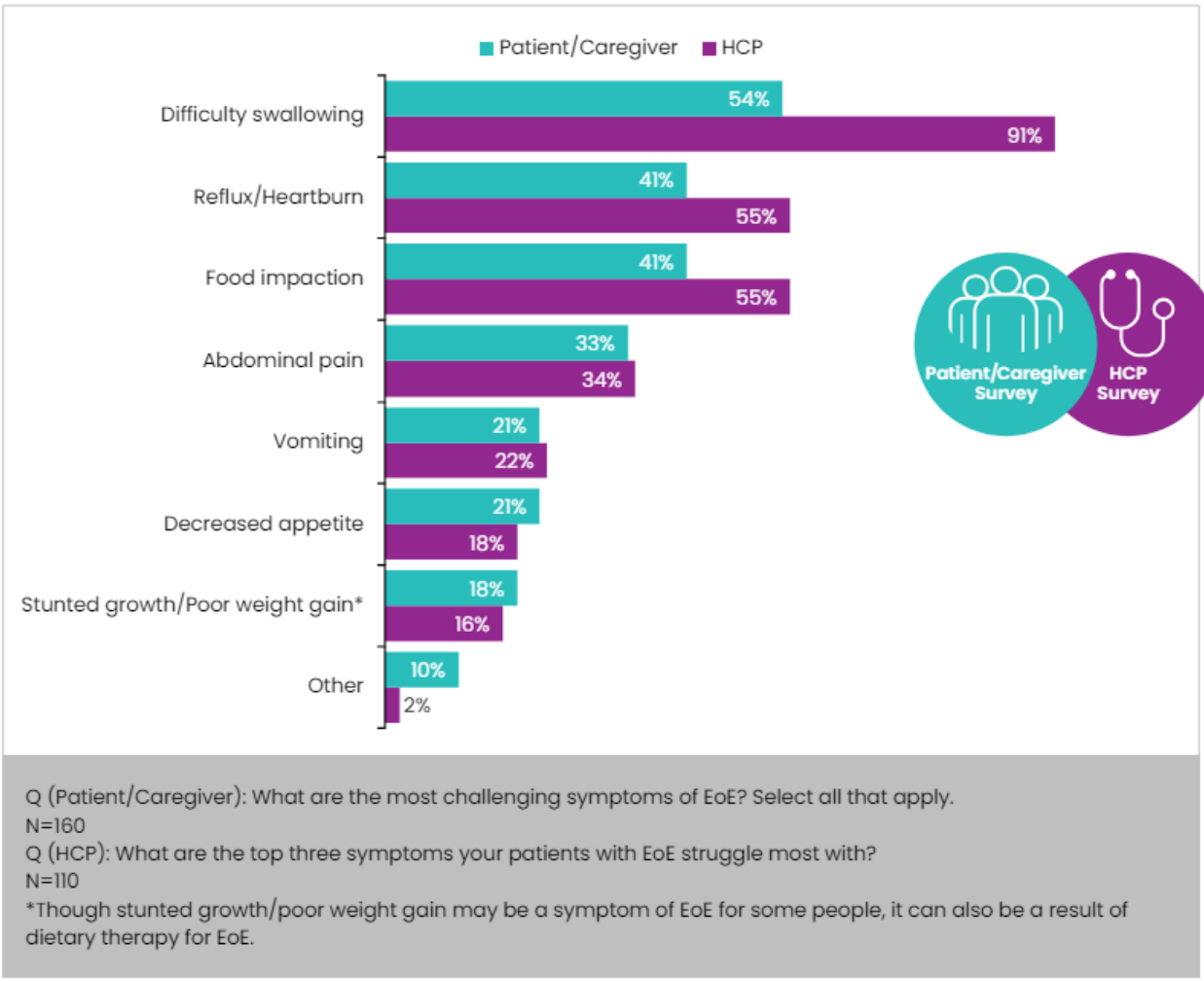
"They put him on budesonide and he had an allergic reaction. We stopped using budesonide, but the EoE and the eczema continued. He is now on the biologic which has helped him immensely."

– Lisa, caregiver to a 13-year-old son with EoE who was diagnosed at age 8.

Asthma and Allergy Foundation of America and American Partnership for Eosinophilic Disorders (2023). Life with EoE: The Patient Experience and Opportunities to Improve Care in the U.S. aafa.org/EoELife.

Most Challenging EoE Symptoms

Symptoms of EoE may vary from one individual to the next and often differ depending on age. The 2023 publication, "Life with EoE: The Patient Experience and Opportunities to Improve Care in the U.S.", found that adherence to treatment plans—particularly dietary therapies—poses the greatest challenge in managing EoE, as reported by patients and caregivers. Healthcare providers also reported adherence to dietary therapy significantly lower than pharmacological treatment.



Asthma and Allergy Foundation of America and American Partnership for Eosinophilic Disorders, (2023). Life with EoE: The Patient Experience and Opportunities to Improve Care in the U.S. Retrieved from aafa.org/EoELife.

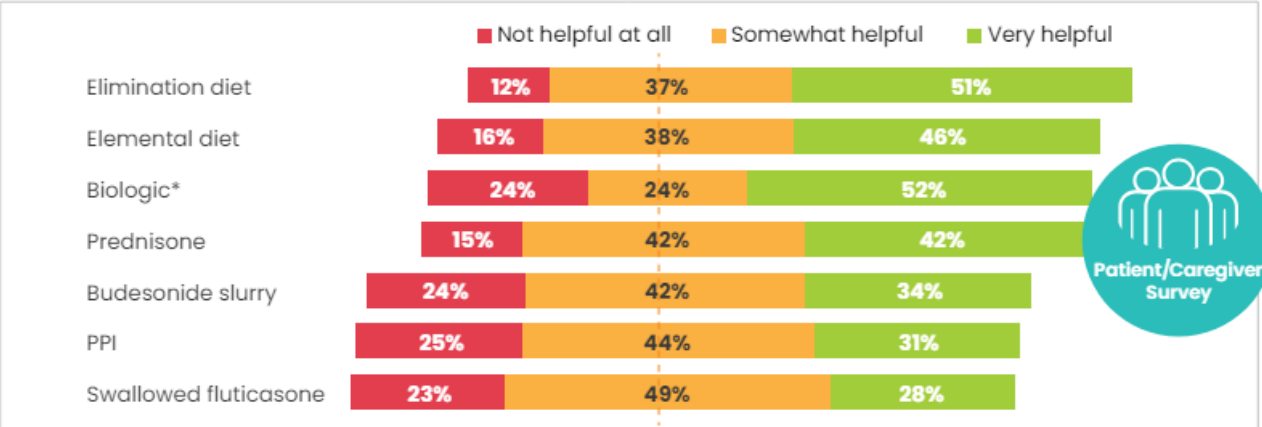
EoE can have a salient impact on many aspects of patients' and caregivers' lives. Beyond the physical impacts like EoE symptoms, inflammation, and esophageal damage, patients and caregivers experience social, emotional, and financial impacts as well. Studies have shown that EoE has been associated with anxiety and depression and has an impact on quality of life. [6]

Moreover, the cost of untreated or poorly managed chronic conditions can be astronomical, not just in healthcare expenses but also in lost productivity and decreased quality of life. By ensuring all patients with EoE can access Dupixent®, especially children, and especially those in Medicaid, will help the state to reduce long-term healthcare costs associated with untreated EoE, such as hospitalizations and emergency procedures, and improving mental health and emotional wellbeing.

Biologic drugs like Dupixent® can level the playing field for recipients of state-funded healthcare. Everyone deserves access to the best available treatments, regardless of their income or insurance status. Denying patients access to Dupixent® not only further limits their treatment options, but also perpetuates health disparities.

Patient Experience: Utility of Treatments

Though biologics are a new treatment option for EoE, patients/caregivers who utilize it report high utility of treatment, as depicted in the table below.



Q: How helpful were the following treatments in treating symptoms of EoE?
Options only shown who reported they are "currently using" or have "used in the past" each option.
n=21 (biologics); n=126 (elimination diet); n=37 (elemental diet); n=73 (prednisone); n=50 (budesonide); n=100 (PPI); n=87 (fluticasone)
*At the time of the patient/caregiver survey, the only FDA-approved biologic for EoE had only been approved for one month. Many respondents who reported using a biologic for EoE reported off label use.

Asthma and Allergy Foundation of America and American Partnership for Eosinophilic Disorders, (2023). Life with EoE: The Patient Experience and Opportunities to Improve Care in the U.S. Retrieved from aafa.org/EoELife.

In conclusion, ensuring ALL patients have access to Dupixent® to treat EoE is not just a matter of fairness, it's a matter of public health and economic sense. This medication has been shown to offer an effective, targeted treatment for EoE, which can ultimately reduce long-term healthcare costs and help bridge the gap in healthcare equity. Everyone deserves a chance at a healthier, more productive life, and Dupixent® can play a crucial role in making that possible for Maryland residents who have been diagnosed with EoE.

Thank you for your time and consideration. If I may answer any questions, please do not hesitate to contact me at mjstrobel@apfed.org, or 713-493-7749.

Mary Jo Strobel
Executive Director
APFED

References

1. Dellon, E. S., & Hirano, I. (2018). Epidemiology and natural history of eosinophilic esophagitis. Gastroenterology, 154(2), 319–332.e3. https://doi.org/10.1053/j.gastro.2017.06.067

2. Arias, Á., & Lucendo, A. J. (2020). Epidemiology and risk factors for eosinophilic esophagitis: lessons for clinicians. Expert Review of Gastroenterology & Hepatology, 14(11), 1069–1082. https://doi.org/10.1080/1747412 4.2020.1806054

3. Danese E, Lippi G. Rare diseases: the paradox of an emerging challenge. Ann Transl Med. 2018 Sep;6(17):329. doi: 10.21037/atm.2018.09.04. PMID: 30306068; PMCID: PMC6174191.

4. Jensen, E. T., Kappelman, M. D., Martin, C. F., & Dellon, E. S. (2015). Health-care utilization, costs, and the burden of disease related to eosinophilic esophagitis in the United States. American Journal of Gastroenterology, 110(5), 626–632. https://doi.org/10.1038/ajg.2014.316

5. Lam AY, Lee JK, Coward S, Kaplan GG, Dellon ES, Bredenoord AJ, Jairath V, Crowley E, Gupta M, Jijon H, Nasser Y, Andrews CN, Chehade M, Gonsalves N, Hirano I, Ma C. Epidemiologic Burden and Projections for Eosinophilic Esophagitis-Associated Emergency Department Visits in the United States: 2009-2030. Clin Gastroenterol Hepatol. 2023 Nov;21(12):3041-3050.e3. doi: 10.1016/j.cgh.2023.04.028. Epub 2023 May 8. PMID: 37164113.

6. Lucendo, A. J., Arias-González, L., Molina-Infante, J., & Arias, Á. (2018). Determinant factors of quality of life in adult patients with eosinophilic esophagitis. United European Gastroenterology Journal, 6(1), 38–45. https://doi.org/10.1177/2050640617707095

Supporting Medical Literature

A number of peer-reviewed publications are available that describe the benefits of dupilumab (Dupixent®). Three such examples include:

1. Inserro A. FDA approves dupilumab as first therapy for eosinophilic esophagitis. *The American Journal of Managed Care®*. May 20, 2022.

2. Evan S. Dellon, M.D., M.P.H., et al. Dupilumab in Adults and Adolescents with Eosinophilic Esophagitis. December 21, 2022 N Engl J Med 2022;387:2317-2330 DOI: 10.1056/NEJMoa2205982 VOL. 387 NO. 25

3. Syverson, Erin Phillips MD; Rubinstein, Eitan MD. Real World Experience With Dupilumab in Eosinophilic Esophagitis in Children and Young Adults at a Tertiary Care Pediatric Medical Center. JPGN Reports 3(2):p e180, May 2022. | DOI: 10.1097/PG9.0000000000000180

COMMUNITY ACCESS NATIONAL NETWORK

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Submitted for Public Comment: Maryland PDASC Meeting: April 29, 2024 Agenda Item: Public Comment, Cost Review Study

April 24, 2024
Maryland Prescription Drug Affordability Stakeholder Council16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Stakeholder Council,

About CANN: The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

We write today, deeply concerned with the Board's suggestion to begin a "cost-review study" of the antiretroviral medications used for both treatment and prevention of HIV, Biktarvy. We wish to begin with recognizing that the naming a medication for "cost review study" does not necessarily indicate any final determination of "affordable" nor does it dictate any imposition of an "upper payment limit" or regulated rate setting by another name. However, we are concerned the Board lacks sufficient knowledge to make appropriate considerations regarding any antiretroviral, the public health programs served through 340B rebates, and the very carefully constructed fashion in which public health is funded. The long and short of our concern is imposing an arbitrary reimbursement rate will necessarily divest from health equity efforts and harm efforts to achieve certain public health goals. We will explain in detail below and are grateful for your time in reviewing the information provided.

340B Entities Will Be Negatively Impacted by a UPL

Concerns related to 340B previously voiced have not been sufficiently addressed. Similar to the misleading testimony offered by a witness to the Vermont Senate in February, those 340B Grantee entities discussing concerns with Board have been told the equivalent of "a UPL will not effect 340B". This is not true.

340B finds its value in rebates which ultimately reduce acquisition costs for certain covered entities after reimbursements have been made. Straight forwardly, a reduction in allowable reimbursement rates necessarily reduces the rebate value realized by these covered entities. An upper payment limit below current reimbursements, therefore, reduces the realized savings and revenues which may be reinvested into public health programs, particularly among federal grantees (including but not limited to the state's AIDS Drug Assistance Program - ADAPs, STI Clinic Grantees – 318 Grantees, and Federally Qualified Health Centers – 330 Grantees).

In the instance of ADAPs, 318 Grantees, and 330 Grantees, 340B programmatic revenues are central to program design. Indeed, for many of these grantees, without 340B, these entities would not otherwise qualify for their grantee status due to a lower likelihood of sustainability. Each grantee is required to provide planning of sustainable programmatic revenues in order to qualify for the federal grant.

Let us describe how these dollars are reinvested and why imposing a UPL is a threat to health equity and public health programming in specificity.

ADAP: Maryland's AIDS Drug Assistance Program received about $24 million from the federal government in 2021 according to the most recent program monitoring report from the National Association of State and Territorial AIDS Directors (NASTAD). Maryland, however, did not provide detailed budgetary reporting to NASTAD. Instead, we must look at reporting from similarly situated states. Few states actually provide any state matching dollars to their ADAP and when they do, those dollars are often less than 10% of the federal award. However, rebate revenues generated from the program tend to exceed 16% (often times, quite a bit more) additional value in sustaining the program. In another state that received about the same amount as Maryland did in federal award, the ADAP also generated about $10 million in rebate revenues – a near 50% additional value. That value is reinvested in providing no-cost to patient antiretroviral medications to patients *or* used to pay for approved plan premiums to further overall access to care for recipients in Maryland living at or below 400% of the Federal Poverty Level but above Medicaid qualifying income levels. Revenues generated from 340B via the state's ADAP means the ADAP is sustainable, serves half again as many patients as it would otherwise, and helps move the state to achieving its health equity and public health goals.

Imposing an upper payment limit would reduce the value of those rebates, thus reducing how many patients the ADAP might be able to serve. Remember, ADAP serves severely patients who would not otherwise be able to afford or access their HIV medications.

STI Clinic Grantees and Subgrantees: 318 Grants are awarded to state and local health departments which then subcontract out to local clinics with expertise in delivering services. These grants are often relatively small compared to ADAPs, with awards often barely reaching some hundreds of thousands of dollars rather than millions. These subgrantees are some of the largest public providers of pre-exposure prophylaxis (PrEP) in the country. For some clarity as to exactly how well these programs work, while many subrecipients receive some financial support for their programming, some of the subgrantees only qualify for 340B because of in-kind agreements – which might just be HIV rapid test kits. In turn, these subgrantees are so efficient at delivering HIV screening and enrolling appropriately identified patients into PrEP services that their entire program model is based off realizing 340B savings.

A UPL would have even more of a dramatic effect on 318 subgrantees than it would on the ADAP.

Federally Qualified Health Centers: 330 grantees have a dedicated mission to serve impoverished communities "regardless of ability to pay". 330 grantees are required to offer healthcare services with sliding fee scales, limited to no collection practices, and are a key gateway for patients who need the most help. Some FQHCs utilize their 340B savings to offer food assistance, transportation, even housing in some situations. Others use their 340B savings to expand programming to include mental health and substance use services, particularly when state dollars are not readily available to support these non-profit healthcare providers. Each site is specifically selected due to the nature of the area necessarily being "underserved" – to be direct FQHCs serve communities that are more Black, more Brown, more Woman, and more Queer than their hospital counterparts. And they do so, at times, using those same rebates to provide patients with no-cost medication. Indeed, FQHCs are some of the best stewards of the program.

A UPL would necessarily reduce the rebate values realized by FQHCs and reduce those entities' ability to serve the most marginalized of Marylanders.

The Board Must First Establish Access Monitoring Prior to Beginning Any "Cost Review Study"
In order to appropriately appreciate the patient experience with regard to the issue of "affordability", the Board must first understand that "affordability" is but one arm of "access". An "affordable" medication means nothing if a patient cannot access that medication.

The Board has previously expressed concern regarding maintaining access – a comprehensive view of the patient experience. However, the Board has not established any definition of access nor has the Board meaningfully engaged in access monitoring deliberations. This must be done prior to proceeding with any additional steps, including "cost review study" or imposing rate setting. "Cost" cannot be sufficiently explored without distinguishing between particular cost burdens and the drivers of those burdens. For example, is "cost" comprehensive of transportation concerns in rural areas which may be prohibitive of any cost-sharing a patient might face at a pharmacy counter? Is "cost" comprehensive of an under reimbursement a pharmacy may face, resulting in not being able to fill a patient's needed prescription? Does "cost" include the necessary diagnostics or the even the provider visit required to get a prescription in the first place? How does the Board intend to differentiate throughout any "study"? What entities will the Board employ to ensure access is not harmed under a UPL? Is "cost" assessed to include those savings realized by diverted hospitalizations? Will "cost" consider the burden patients may face if additional utilization management is imposed to prefer a particular medication selected by the Board for UPL? Will the Board consider the accessibility of manufacturer patient assistance programs in determining "cost" to patients?

These questions deserve clear, precise answers prior to beginning any "cost review study".

Lessons From Colorado
As an organization lending our expertise and voice to people living with HIV across the nation, CANN was deeply involved in the "affordability review" process of Genvoya in Colorado. Genvoya is similarly situated to Biktarvy is some ways – to be clear, Genvoya may not be prescribed for PrEP and is no longer "first line treatment". Biktarvy, however, can be prescribed as PrEP and is considered "first line" for the treatment of HIV. Colorado's Board spent more than 50 hours across a few short months, in a deeply flawed process. Patient impact surveys suffered from design bias, asking leading questions, were not well distributed, and were open – initially – for a mere 21 days. To put this into context, Ryan White needs assessment surveys take the better part of a year to fully grasp program impact. In addition to this, Colorado engaged in "small group meetings" of patients, caregivers, providers, and manufacturers throughout the review data gathering process.

It was, in a word, **traumatic** for patients desperately concerned about losing access to their medications. Hours upon hours were spent explaining that sufficient systems exist to blunt out-of-pocket expenditures for patients through a variety of ways, including public programs like the AIDS Drug Assistance Program.

All of this to arrive to the decision that Genvoya was "not unaffordable" to patients in Colorado and, indeed, imposing a UPL would potentially harm public health programming dependent upon 340B savings generation.

Conclusions
CANN appreciates the very noble goal of reducing patient cost burdens. We recognize "affordability" is an essential arm of "access" and, ultimately, access to care for people living with HIV is our greatest priority. We share this goal with the Board. The unfortunate reality is that Board was not empowered by the legislature with an appropriate tool to address issues of access. Addressing discriminatory plan design, PBM abuses, under

reimbursement already harming non-chain, independent pharmacies, curbing utilization management practices that delay and deny care – all of these would better serve Marylanders than the process before you.

We wish to be one hundred percent clear: a "cost review study" is harmful to patients on an emotional level. People living with HIV are disproportionately Black and Queer. We already face discrimination elsewhere in our lives, struggles to access care, and harmful policies and practices which hurt our ability to trust institutions of power, including the healthcare system writ large. Including this very Board. Engaging in a process which will ultimately ask the question "Are you worth our dollars?" is not going to improve that situation.

Even the thought of imposing a UPL is a "threat" to our access to care through the ADAP, STI Clinics, and FQHCs because of mechanisms of funding outside of this Board's purview. Reducing the value of 340B by imposing a UPL necessarily divests from marginalized communities.

It is with a very sincere shared interest we ask this Board to halt the "cost review study" process, any determination of medications for review, particularly Biktarvy, and consider the content laid above.

- Establish access monitoring metrics
- Establish access monitoring processes
- Study the potential impacts to 340B served programs and entities
- Ensure "cost review study" content is appropriately designed and unbiased
- Ensure "cost review study" processes will not disadvantage, deprioritize, or otherwise harm patients

There is good work to be done by this Board but it won't be found with a "cost review study" as currently described or a UPL.

CANN looks forward to working with the Board and we are readily available to staff to discuss our concerns and find collaborative solutions.

Ever in your service,

Jen laws
President & CEO
Community Access National network

April 24, 2024

Via email (*comments.pdab@maryland.gov*)

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

Re: April 29 Prescription Drug Affordability Stakeholder Council Meeting

Dear Members of the Prescription Drug Affordability Stakeholder Council:

I am writing on behalf of Gilead Sciences, Inc. ("Gilead"), in response to the Prescription Drug Affordability Board's ("PDAB") recent identification of Biktarvy® for a potential cost review. Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines for people with life-threatening diseases in areas of unmet medical need, and has been a leading innovator in treatments for human immunodeficiency virus (HIV) for more than 30 years. Biktarvy is a single-tablet regimen that provides unique value and is recommended as an initial treatment regimen for most people with HIV by the U.S. Department of Health and Human Services' HIV treatment guidelines.[i]

Biktarvy is unique among the drugs being considered by Maryland's PDAB because it is an antiretroviral medication for the treatment of HIV. No other drug being considered for a cost review treats an infectious disease. HIV is a communicable, incurable, and deadly disease. Uninterrupted access to Biktarvy lowers overall costs to Maryland by preventing complications of the disease, reducing the development of resistant forms of the virus, and lowering transmission of HIV.

A cost review is a first step toward potential imposition of an upper payment limit ("UPL"), which would ultimately be harmful for people with HIV and increase costs to the state of Maryland. Governments that utilize price-setting also reduce access to medicines. This is shown by the fact that on average, patients in comparison countries with pharmaceutical price-setting have access to only 29% of medicines that launched over the past decade, while patients in the United States have access to 85%.[ii]. In addition, a UPL is not needed because Biktarvy is affordable and accessible to Maryland and people with HIV.

To avoid disrupting care for people with HIV, Gilead therefore recommends removing Biktarvy from the list of drugs being considered for a cost review. Our concerns are further detailed below.

I. Biktarvy is affordable and accessible to people with HIV

The PDAB's current UPL authority is concentrated on two populations: drugs purchased by or reimbursed by a health plan on behalf of state or local governments, or drugs reimbursed by Maryland Medicaid. Biktarvy is currently affordable and accessible for individuals in both these groups.

Maryland Medicaid does not currently require patients and their providers to complete prior authorization, in which they must provide documentation about why a medicine is needed, before receiving medicine to treat HIV. This means that people with HIV can obtain treatment in a timely way. Furthermore, enrollees in Maryland's Medicaid program who rely on Biktarvy fill their prescriptions for no more than $1.

Individuals who are insured through Maryland's health plans for state and local government employees have access to Biktarvy on their plan's preferred brand tier. This means that these people can receive the medicine and pay very low cost-sharing amounts. If these individuals continue to face challenges affording their medicines, Gilead's Advancing Access® program is available to reduce or eliminate out-of-pocket costs for Biktarvy.[iii]

On top of these programs, Marylanders with HIV can benefit from additional assistance through the Maryland AIDS Drug Assistance Program (MADAP).[iv] MADAP pays for HIV medicines for clients without insurance and assists individuals with insurance with copay and deductible payments. People eligible to participate in MADAP can obtain Biktarvy with a $0 copay.[v] To be eligible, a Maryland resident with HIV must not be on Medicaid and must earn 500 percent of the federal poverty level or less.

II. The State is overestimating its spending on Biktarvy

The PDAB recently released a "sample database" which includes data about the eight drugs identified by the PDAB for potential selection review. [vi] Because the public does not have access to the dashboard supporting this database or a detailed understanding of the data sources and methodology used by the PDAB, stakeholders with analytical expertise are limited in their ability to comment on potential errors, provide missing context, or explain discrepancies between the database and other sources. This is particularly concerning when the database grossly overestimates spending on a drug compared to other sources, like the manufacturers' own data. Gilead compared the "sample database" data to internal sales data for Biktarvy in the state and found that Maryland dramatically overestimated state spending on the drug. In addition, the "sample database" only includes data for medicines reimbursed by commercial and Medicare plans and does not align with the PDAB's authority to set a UPL (i.e., for drugs purchased by or reimbursed by a health plan on behalf of state or local governments, or drugs reimbursed by Maryland Medicaid). The sample database also reflects different years for each market segment (2022 for commercial and 2020 for Medicare).

III. A UPL on Biktarvy would disrupt access to a widely used HIV treatment in Maryland

While Maryland has not clarified how a UPL might be implemented, what is known is that a UPL on Biktarvy would result in unintended consequences, including treatment delays and interruptions. Extensive data from international comparisons show that price-setting policies like UPLs do, in fact, reduce patients' ability to access new medicines.[vii] For example, of infectious disease medicines launched in G20 countries over the past decade, 86% are available in the US, but only 43% are available in other countries.[viii]

Gilead also has significant concerns that Maryland has not determined how a UPL would be implemented prior to beginning selection of drugs for cost reviews. Without clarifying this process, unintended consequences associated with the UPL cannot be fully identified and evaluated. A UPL has potential to disrupt the HIV supply chain in a way that would challenge providers' ability to ensure access to Biktarvy. One clear example that should be explored before selection of drugs is highlighted by a letter from chain pharmacies to the Board noting that if a UPL is set too low it will cause pharmacies to make business decisions about whether it is profitable to carry the drug. [ix] This will lead to challenges in patient access and treatment interruptions that are harmful to the individual living with HIV and to the community. The Board's UPL Action Plan should be finalized and approved as noted in statute before drugs are selected for cost reviews.

To best support Maryland's goals of preventing new HIV infections and improving health outcomes for people with HIV,[x] the PDAB Stakeholder Council should refrain from introducing new barriers to people's ability to access HIV treatments or interrupting care for people who are currently effectively treating their HIV with Biktarvy. Disrupting patient access to Biktarvy through a UPL would be particularly concerning because the medicine is currently used to treat tens of thousands of people with HIV in Maryland.[xi]

IV. Treatment delays and interruptions in care for people on Biktarvy would result in further spread of HIV and progression to deadly AIDS, increasing total costs to the State

When medicines to treat HIV, like Biktarvy, are taken correctly and promptly, they can suppress the virus in the body. This slows progression of the disease to AIDS and reduces the risk of certain complications.[xii] Taking medicines to treat HIV as prescribed can also reduce the amount of HIV virus in the body to an undetectable level, which not only improves that individual's health but also prevents sexual spread of the virus. Researchers at the National Institutes of Health found that keeping HIV levels undetectable for at least six months results in people with HIV having no risk of sexually transmitting HIV to partners.[xiii]

This helps reduce healthcare costs. Avoiding just one new HIV infection can reduce lifetime healthcare costs by $850,557 on average. In addition, annual and cumulative healthcare costs were up to seven times higher for people with HIV compared to those without HIV.[xiv] State actions that delay initiation of HIV treatment, create gaps when an individual switches from one

regimen to another, or lead people to drop out of care altogether due to not being able to access a preferred regimen, will increase spread of HIV and costs to Maryland.

Biktarvy is the only unboosted single tablet HIV regimen that is recommended by the DHHS Guidelines for use in "Rapid Start," a process in which people with HIV can start treatment immediately upon diagnosis, even before initial lab results are available.[xv] Rapid Start leads to more patients starting HIV treatment and ongoing care, better health outcomes, and improved rates of suppression of the HIV virus, which may reduce new HIV infections.[xvi,xvii] Research has also found that starting treatment earlier reduces HIV transmission, progression to AIDS, and other serious medical conditions such as cardiovascular or vascular disease, liver disease, end-stage renal disease, and diabetes mellitus.[xviii] Restricting access to Biktarvy could deprive Marylanders of these benefits and lead to higher rates of HIV transmission and more patients falling out of care.

In addition, Biktarvy has been shown in numerous studies to be associated with higher adherence and persistence than other HIV medicines. [xix,xx,xxi,xxii,xxiii] Forcing a person with HIV to take a treatment that is not the best one for them, or which is harder for them to take – such as having to take multiple pills a day, will reduce their ability to take the medicine as prescribed and suppress the HIV virus.[xxiv] As described above, this increases the risk of transmission of HIV to additional people in Maryland and increases costs to the state.

V. Reduced access to Biktarvy would increase development of resistant forms of the virus, further increasing State costs

Drug resistance is another serious consequence that can occur when HIV treatment is disrupted. Resistance may mean that an individual can no longer take many other medicines to treat HIV (because they are in a similar class and work in a similar way) and can lead to progression of disease.[xxv] Drug-resistant forms of HIV require people to switch to other medicines that may be more expensive, more complicated to take, and have more side effects. This can lead to worse health for the individual and higher health care spending. People with HIV who are forced to take a medicine that is more difficult for them to take may not take their medicine as prescribed, and as a result, resistant forms of the virus can develop.[xxvi] In addition, the drug-resistant form of the virus can then be spread other people.[xxvii]

Biktarvy is different than other HIV medicines because it has a high and durable barrier to resistance.[xxviii] This means that the medicine greatly reduces the chance that drug resistance will develop in people who take Biktarvy as prescribed. Drug resistance may occur if people with HIV do not take the medicine exactly as prescribed or if people take certain medicines that do not have a high barrier to resistance. If people lose access to Biktarvy because of any action by the Board, the alternative treatments available may unfortunately more likely to result in resistance.

VI. A UPL for Biktarvy would be particularly harmful to historically disadvantaged populations

HIV disproportionately impacts socially marginalized and disenfranchised populations, particularly sexual minorities, and communities of color.[xxix] As an example, Black people represent 30.2% of Maryland's population but accounted for 71.3% of all people with HIV in the state and 70.6% of new HIV diagnoses in 2021.[xxx] In addition, people with HIV disproportionately experience the negative impacts of social determinants of health, such as stigma, poverty, and homelessness, that lead to higher barriers in accessing HIV care and attaining favorable treatment outcomes.[xxxi]

Therefore, state actions disrupting care for HIV would disproportionately harm some of the most vulnerable groups in Maryland who face many barriers that can limit their ability to access and adhere to treatment. Rapid Start, an initiative to get people newly diagnosed with HIV on treatment as quickly as possible, may be particularly crucial to ensure disadvantaged populations are linked to care quickly upon diagnosis and continue treatment. Biktarvy is recommended by the DHHS guidelines as an HIV medicine appropriate for Rapid Start with appropriate patients. Any disruption in HIV care would also undermine Governor Moore's commitment to "foster a healthcare system that improves health and wellbeing, and where all Marylanders have access to affordable health care services."[xxxii]

VII. The drug selection process should allow for stakeholder engagement

The PDAB and the Stakeholder Council should provide appropriate procedures for engagement with patients and other stakeholders to make reasoned cost determinations, including reasonable efforts to protect privacy and provide feasible commenting opportunities. To date, the PDAB has not established any process for patients or other stakeholders to share their experiences other than through general public comment. This process is inadequate for drugs like Biktarvy, considering stigma often associated with HIV and the socioeconomic barriers (e.g., low income and lack of social support) that confront many people with HIV may cause people not to appear during public comment opportunities. In addition, opportunities for public comment are arbitrary and unpredictable. Manufacturers have not been given enough information about drug selection to correct any inaccuracies, and the PDAB has not made recordings of its meetings available to the public, despite requests from the Stakeholder Council and General Assembly.

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Biktarvy is recommended as an initial treatment regimen for most people with HIV by the U.S. Department of Health and Human Services' HIV treatment guidelines due its many clinical benefits. To help Maryland achieve its ambition to end the HIV epidemic by 2030, it is crucial that access to Biktarvy remains uninterrupted. Rather than introduce new price-setting policies that are likely to disrupt care for people with HIV, there remains a significant need to improve diagnosis and treatment of HIV in the state. For these reasons, it would be prudent for the PDAB and its Stakeholder Council to avoid the risk of disrupting HIV treatment by not selecting Biktarvy, or any medicine to treat HIV, for a cost review.

Sincerely,

DocuSigned by:
Kristie Banks
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Kristie Banks
Vice President, Managed Markets
Gilead Sciences, Inc

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[ii] Richard Kane. PhRMA. New global analysis shows patient access challenges around the world. April 12, 2023. https://phrma.org/en/Blog/New-global-analysis-shows-patient-access-challenges-around-the-world.
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[viii] ibid.
[ix] *See,* NACDS letter to the Maryland Prescription Drug Affordability Board. Re: Upper Payment Limit Action Plan. November 13, 2023.
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Global Coalition on Aging

April 22, 2024

Re: Maryland Prescription Drug Affordability Board's Decision to Proceed with Drug Cost Reviews

Honorable Members of the Maryland Prescription Drug Affordability Stakeholder Council,

The Alliance for Health Innovation (Alliance) is a group of cross-sector stakeholders representing patients, providers, caregivers, academia, biopharmaceutical innovators, and business communities.

Led by the Global Coalition on Aging (GCOA), the Alliance is committed to establishing the importance of innovation in achieving healthy aging. We advocate for state policy solutions that support a thriving innovation sector, enabling Maryland residents and other communities to live longer and healthier lives.

We are writing to express our deep concerns about the decision to proceed with drug cost reviews. We are particularly troubled by the lack of clarity on how the PDAB will implement any upper price limit (UPL) that may be established through such a review. This uncertainty could potentially jeopardize access to life-saving medications, which we believe must be urgently addressed, particularly for communities disproportionately impacted by chronic and complex conditions such as HIV. Furthermore, we are concerned about the absence of clear safeguards to ensure that the perspectives of patients, caregivers, and other stakeholders are fully integrated into the review process.

Many diseases that once burdened aging populations have evolved into manageable chronic conditions due to modern, safer, and more effective treatments. These treatments allow many patients to live longer, healthier lives. Much of this progress is owed specifically to patient advocacy efforts and opportunities that patients have been given to weigh in on the value of treatments from their unique and individual perspectives.

UPL policies typically lead to significant patient access restrictions, which disproportionally affect the disadvantaged populations these policies are meant to protect. HIV is a powerful and critical example of this, as specific disadvantaged populations – such as older adults living with HIV – are even more dependent on access to innovative medicines than average. By 2030, over 70% of the HIV-positive population in the US will be over 50, and in 2021, over 53% of new HIV diagnoses in the United States were in people aged 50 and older. [1,2]

[1] Wing E. J. (2017). The Aging Population with HIV Infection. Transactions of the American Clinical and Climatological Association, 128, 131–144.
[2] Centers for Disease Control and Prevention. HIV in the United States by Age: HIV Diagnoses. https://www.cdc.gov/hiv/group/age/diagnoses.html

Thanks to years of biomedical investment and innovation, a person with HIV who starts treatment soon after their diagnosis can expect to live the same lifespan as an HIV-negative person. However, access to innovative medications is required – and in Maryland, only 61.8% of people living with HIV are virally suppressed. Further, 70.1% of the deaths associated with HIV in Maryland are in the Black community – who also account for 70.6% of the new diagnoses in the state.[3]

As people with HIV live longer, they can develop comorbidities that affect their health-related quality of life and are costly to treat. People living with HIV are more likely to develop additional health issues as they age and tend to develop them earlier than people who do not have HIV. Limiting access to other prescription drug products through the establishment of UPLs could have a similar effect – creating a problem at the population level that will extend generations into the future.

Already, Maryland has significant health disparities, with the widest life expectancy gap between counties in the United States – and this falls heavily upon racial and ethnic lines.[4] In Maryland, more than 71% of individuals living with HIV in 2021 were Black – with any interruptions in access to treatments having an outsized impact on the Black community and threatening efforts to end the epidemic in the state.[5] Yet, the Board is moving forward with drug cost reviews with incomplete plans that would be central to implementing any resulting decisions. In doing so, it is undermining the public and patients' voices and ability to make informed comments on the impact of such decisions.

We urge the Board to pause its activity and ensure that there is clarity on how the PDAB will implement any upper price limit (UPL) that may be established and allow for proactive engagement with patients, caregivers, and other stakeholders to ensure that concerns about access and innovation are carefully considered to prevent access barriers from excessively impacting the most vulnerable of Marylanders, such as those living with HIV.

Thank you for allowing us to share our concerns and for your commitment to finding solutions to the affordability challenges that Maryland patients face. We would be happy to discuss these concerns further or answer any questions.

Sincerely,

Michiel Peters, Head of Advocacy Initiatives, Global Coalition on Aging

[3] AIDSVu. Local Data: Maryland. https://aidsvu.org/local-data/united-states/south/maryland/
[4] Capital News Service. (2022). Maryland life expectancy data highlights racial disparities. Maryland Matters. https://www.marylandmatters.org/2022/10/26/maryland-life-expectancy-data-highlights-racial-disparities/
[5] AIDSVu. Local Data: Maryland. https://aidsvu.org/local-data/united-states/south/maryland/

Heart To Hand, Inc.
"A heart that cares with hands to help."

April 24, 2024

Maryland Prescription Drug Affordability Stakeholder Council
18900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Unintended Consequences of Upper Payment Limits on Maryland's HIV Community

Members of the Maryland Prescription Drug Affordability Stakeholder Council:

Heart to Hand, Inc. is a 501(c)(3), community-based public health organization based in Largo, Maryland that provides support services to those living with HIV/AIDS and other sexually transmitted infections (STIs). Our mission is to provide support, education, and resources that promote healthy lifestyles, decrease health disparities, and increase access to quality health care. Since 1999, Heart to Hand has been Prince George's County's leading provider for free and low-cost sexual health services such as rapid HIV testing, testing and treatment for STIs, and sexual health education.

With a treatment for HIV included on the initial list of drugs selected for review by the Maryland Prescription Drug Affordability Board (PDAB), we write to you today to express severe concerns about the unintended consequences of setting an upper payment limit (UPL) on HIV treatments and medicines for other complex, chronic conditions.

In Maryland, 71.3 percent of people living with HIV in 2021 were Black and over 70 percent of new HIV diagnoses were among Black individuals. For Black women, these disparities are particularly acute. The rate of Black females living with an HIV diagnosis is 17 times that of white females in Maryland. This data lays bare the urgent need to *increase* access to HIV testing, treatment, and care services in our state with a focus on those disproportionately impacted – not *threaten* access to treatments that can help Marylanders living with HIV achieve viral suppression and live healthier lives. Viral suppression – the goal of HIV treatment – means that the amount of HIV virus in a patient's blood is undetectable and therefore cannot be transmitted.

The PDAB is considering setting UPLs, or a ceiling amount that a payer can reimburse a provider for the purchase of a medication, on drugs they deem unaffordable. UPLs do not affect the cost to purchase a specific treatment but limit the reimbursement amount paid to the provider that stocks, stores, and administers the medication. Patients living with HIV work closely with their health care providers to find a treatment regimen that works for them in staying virally suppressed. UPLs threaten to impede upon this critical relationship by forcing providers to make the difficult decision between taking a financial loss on a medicine that will work for their patient or choosing not to prescribe that medication.

While the stated goal of implementing a UPL is to lower costs for Maryland patients, a recent report from the Partnership to Fight Chronic Disease (PFCD) found that a majority of payers surveyed did not anticipate that UPL-related savings would be passed on to patients in the form of lower premiums, deductibles, or cost sharing. The same report indicated that UPLs are likely to lead to increased utilization management protocols, which increase the administrative burden on both patients and their providers and can lead to disruptions in treatment. Even short delays in access to a treatment regimen working for a patient with HIV can cause viral resistance, making it much more difficult for a patient to achieve viral suppression.

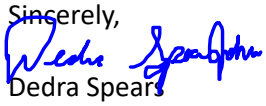
Heart To Hand, Inc.
"A heart that cares with hands to help."

April 24, 2024

At Heart to Hand, we believe that everyone deserves and benefits from sexual health and wellness, which includes access to treatments for HIV. **We are deeply concerned about the potential unintended consequences of conducting cost reviews and setting UPLs on treatments for complex conditions and failing to acknowledge the nuances and unique needs to patients living with or at increased risk for HIV.**

Heart to Hand encourages members of the PDAB and PDASC to continue learning from the unique perspectives and experiences of people living with HIV in Maryland and consider the impacts of their actions on those disproportionately impacted by the virus. We appreciate the opportunity to provide comments on the Board's proposed cost review process of the initial list of selected drugs. We welcome members of the Stakeholder Council and the PDAB to reach out via email at dspearsjohnson@hearttohandinc.org if Heart to Hand can answer any questions or provide any additional information.

Sincerely,



Dedra Spears
Executive Director, Heart to Hand, Inc.

HIV+HEP
POLICY INSTITUTE

April 24, 2024

Maryland Prescription Drug Affordability Stakeholder Council
18900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Stakeholder Council members,

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. Given the important nature of prescription drugs to the life-saving treatment of HIV and hepatitis B, and now, the cure of hepatitis C and the prevention of HIV, affordable access to prescription medications is extremely critical to the patients we serve.

While we support the Maryland Prescription Drug Affordability Board (PDAB) goal of addressing affordability of treatments, we believe the current approach of the Board to set upper payment limits (UPLs) on the proposed drugs for review will neither benefit patient health outcomes nor result in reduced out-of-pocket costs for patients.

As the Board considers the affordability of an initial list of eight prescription drugs, including a treatment for HIV, we urge the Board and Stakeholder Council to consider the unique needs of the patient populations impacted by each treatment and the specific public health implications of interruptions to treatment.

Unique Perspectives of People Living With HIV

As of 2022, over 31,000 Marylanders were living with HIV and 61 percent of those diagnosed were virally suppressed, meaning they cannot transmit the virus.[1] At both the individual and broader community levels, achieving viral suppression is critical to end the epidemic and address the impacts of HIV as a public health issue in Maryland and beyond. The U.S. Department of Health and Human Services (HHS) initiative, *Ending the HIV Epidemic in the U.S.,* launched in 2019 to reduce HIV infections nationwide starting with 57 priority jurisdictions, with three of those Phase 1 jurisdictions in Maryland (Prince George's County, Baltimore City, and Montgomery County).[2] These jurisdictions account for more than two-thirds of all diagnosed

[1] Maryland HIV County Overview Dashboard
[2] Ending the HIV Epidemic: A Plan for America

cases of HIV in the state. Along with diagnoses being concentrated by location, Black communities are disproportionately impacted–with Black patients accounting for over 70 percent of both new diagnoses and deaths due to HIV in the state.[3]

Drug pricing policy must also respect patient choice and providers' clinical judgment. Patients work closely with their health care providers to identify the best course of treatment for them. Each individual living with HIV has unique needs based on a wide variety of circumstances. Treatments outside of those recommended by their provider may not be as effective or result in side effects that negatively impact their health outcomes. For some patients, it may take years of trial and error to find a medication that works for them and their lifestyle. Interruptions to treatment for any reason–such as being unable to access a medicine due to cost or if a provider can no longer afford to stock and store the treatment–can have serious negative implications for those living with HIV. Even a brief delay in treatment can trigger viral resistance, which renders that medication, and the entire class of medications like it, an ineffective option for that patient.

Despite the significant potential consequences of setting UPLs on medicines to treat HIV and other complex conditions, the Maryland PDAB has yet to release its UPL action plan–a roadmap for the Board's decisions to set prices for the prescription drugs selected for review. To date, patients, providers, and caregivers have not been given the opportunity to review or provide input on the action plan–leaving them in the dark about how a UPL may impact access to care.

Existing Assistance Programs Help Link People Living With HIV to Treatment & Care

The inclusion of a treatment for HIV on the list of drugs selected for affordability review by the Maryland PDAB fails to recognize the role of existing state, federal, and industry assistance programs in increasing access to treatments for patients. Patients within the Board's scope–those on Medicaid and state-purchased plans–typically pay between zero and three dollars out-of-pocket for their treatments.

In 2020, the Maryland Insurance Administration (MIA) capped copay costs for drugs prescribed to treat HIV and AIDS for all insurance plans regulated by the agency.[4] Additional patient assistance programs, such as those administered by biopharmaceutical manufacturers and the AIDS Drug Assistance Program (ADAP), provide financial support around the costs of HIV treatment to those who qualify.[5] According to IQVIA, in 2022 manufacturer copay assistance brought down patient costs by nearly $19 billion and accounted for 23 percent of their out-of-pocket costs.[6] According to a study done by the Partnership to Fight Chronic Disease (PFCD) and Avalere, most payers do not anticipate that UPL-related savings will be passed on to patients in

[3] Maryland HIV County Overview Dashboard
[4] Maryland Attorney General: Patient Copayment and Coinsurance Costs Are Capped at $150 a Month for Specialty Drugs and Drugs that Treat Diabetes, HIV, or AIDS
[5] AIDS Drug Assistance Program: Maryland
[6] IQVIA Institute: The Use of Medicines in the U.S. 2022

the form of lower premiums, deductibles, or cost savings.[7] Setting a UPL on these treatments without considering unique patient experiences or demonstrating lower patient out-of-pocket costs as a result will only threaten to put treatments out of reach.

Price Setting is Complex and Is Not a Function of State Government

At the federal level, the government is facing litigation and implementation challenges as it attempts to set prices for some drugs in the Medicare program. While we acknowledge that processes surrounding drug pricing are highly opaque, we do know that it is based on multiple complicated factors. In the search for a successful launch of a new drug, pharmaceutical manufacturers are engaged in hundreds of research and development projects at one time. Years of research and billions of dollars are invested into the development of that one new drug, while at the same time hundreds of molecules and their combinations that do not result in a viable product are studied. While there is a lot of attention on the high list price of the drugs that do come to market, the cost of all the failures, and all other functions of a pharmaceutical company, must be embedded into a treatment's list price.

Additionally, drug companies rely on the profits of today to invest in the successes and failures of tomorrow. Companies engaged in R&D of HIV medicines are working on longer-acting treatment and prevention drugs, vaccines, and even a cure for the virus. Many companies are working on a cure for hepatitis B while so many others are working on better cancer treatments, and medications to treat countless other conditions. Drug companies operate in a global environment, as exemplified in the HIV and hepatitis arenas, and provide medications to millions of people in underdeveloped and underserved nations. Given the many complexities and factors that go into setting a price of a drug, we do not believe it is appropriate or possible for a state to fairly do it.

Setting prices on medications to treat HIV, and offering other drugs as alternative treatment options, fails to consider the nuances of HIV treatment and individual patient needs.

Thank you for the opportunity to comment on the Board's proposed cost review process of the initial list of selected drugs. If you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at cschmid@hivhep.org.

Sincerely,

Carl E. Schmid II
Executive Director

[7] Partnership to Fight Chronic Disease: Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies and Benefit Design but Won't Reduce Patient Cost

April 19, 2024

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

Dear Members of the Maryland Prescription Drug Affordability Board,

My name is Dr. Ian Cook, PharmD, and I am an HIV Clinical Pharmacist and HIV Clinical Director in Baltimore, Maryland. I am writing today to express my concerns regarding the inclusion of the HIV medication Biktarvy in the cost review process. There is a reason that Biktarvy is the current gold standard in HIV treatment and top recommendation in the current guidelines.

Taking one tablet a day, that is well tolerated, with minimal side effects, and few restrictions may seem normal in other disease states. In HIV medicine, we have waited decades for this to be a reality and finally reached this goal with Biktarvy. Patients living with HIV are excited when we can simplify the number of tablets they take every day and decreasing the number of times per day they need to take medication to one. Side effects can play a huge role in keeping patients on medication. Many HIV medications have side effects that can prevent patients from staying on therapy. Biktarvy is very well tolerated, and most patients experience no side effects. For my newly diagnosed patients, they are reassured that we can provide them with the gold standard in treatment from the beginning.

Biktarvy is one of the biggest tools we have to help End the HIV Epidemic. In Maryland, we have three jurisdictions that are on the Ending the HIV Epidemic list. This list was created by the US Department of Health and Human Services and includes the first 50 local areas that account for more than half of new HIV diagnoses, and seven states with a substantial rural burden. In Maryland, Baltimore City, Prince George's County and Montgomery County are on the list and Baltimore County almost made the list. As HIV providers, we have been working hard for decades to decrease HIV transmission, expand HIV testing, and keep patients on treatment. Without Biktarvy, I fear the progress we have made could all be at risk.

Finally, the implications of the cost review process are not clear and have not been made public. What are the consequences if Biktarvy is deemed "unaffordable" by the board? What are the financial, access, legal, and health consequences? There are so many unknowns about this process that a lifesaving medication should not be included.

Biktarvy is a life saving medication that patients living with HIV depend on everyday to allow them to live full, healthy lives. Restricting access to Biktarvy could have dire consequences for the almost 32,000 patients in Maryland living with HIV. I asked that the Maryland Prescription Drug Affordability Board remove Biktarvy from review.

Sincerely,

Ian A. Cook, PharmD, AAHIVP, BCACP, DPLA
HIV Clinical Director and HIV Clinical Pharmacist

April 24, 2024

Maryland Prescription Drug Affordability Board & Stakeholder Council
16900 Science Drive, Suite 112-114
Bowie, Maryland 20715
comments.pdab@maryland.gov

Dear Members of the Stakeholder Council,

The NAACP Maryland State Conference has been working to create and support Maryland's Prescription Drug Affordability Board since 2018, recognizing the critical role prescription drug affordability plays in the health and wellbeing of our members and communities. We are encouraged to see the Board and Stakeholder Council beginning the cost review process and would like to offer comment on the prescription drug products being considered for review.

While we are all hurt by the high cost of prescription drugs, Black Marylanders are faced with additional burdens due to persisting racial health inequities. One of the most prominent examples of this is diabetes and its care management, so the NAACP is appreciative of the inclusion of multiple products used to treat this disease in your initial list. Black Americans are 60% more likely to be diagnosed with diabetes than White Americans, and they are more than twice as likely to suffer from complications such as vision impairment or end-stage renal disease. Despite this, a recent report revealed that more than 70% of semaglutide prescriptions—like Ozempic—have gone to White patients.[1] Addressing the cost of products like this may in turn help to improve access for communities that have been excluded from these treatments do to economic and accessibility challenges.

There are similarly discouraging disparities in medication utilization for several other products being considered for review. A 2023 AJMC report revealed that Black patients diagnosed with psoriasis and other skin diseases are less likely to receive effective medications for their condition compared to White individuals.[2] ADHD medications also have large disparities in usage, with Black, Hispanic, and Asian children having lower rates of access to medications like Vyvanse— likely due to inequities in health coverage and affordability challenges.[3] We ask that you continue to center health equity in your decision-making and cost review processes, seeking direct input from patients and providers from diverse communities.

In addition to my role with the NAACP, I also am a Nurse Practitioner intern and Registered Nurse who has seen firsthand how patients are hurt by the high cost of prescription drugs. In my practice, I have witnessed clients forgo treatment because of an inability to pay. This can have devastating impacts on health outcomes, while the alternative—purchasing excessively

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[1] https://www.cnn.com/2023/09/27/health/semaglutide-equitable-access/index.html
[2] https://www.ajmc.com/view/examining-health-care-disparities-in-psoriasis-and-other-skin-diseases#

[3] https://pubmed.ncbi.nlm.nih.gov/35959536/#:~:text=Results%3A%20In%20adjusted%20analyses%2C%20compared,of%20having%20accessed%20ADHD%20medication.

expensive medications—can leave them in financial ruin. No Marylander should be forced to choose between their medication and their stability.

Thank you for the work you are all doing on this Council. We know that drugs don't work if people can't afford them and appreciate your efforts.

Dr. Danita Tolson
Maryland State NAACP 2nd Vice President
Maryland State NAACP Health Chair

950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

By Electronic Submission

April 24, 2024

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

Re: Maryland Prescription Drug Affordability Board: Cost Review Study Process

Dear Members of the Maryland Prescription Drug Affordability Board ("Board"):

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the presentation materials for the Board's March 25, 2024 meeting, including its Cost Review Study process presentation.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

PhRMA recognizes the Board's ongoing work to implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] However, consistent with our prior comment letters,[3] PhRMA has concerns about the approach taken by the Board, including the approach outlined in the Board's cost review presentation. Among other things, PhRMA continues to have concerns with the lack of adequate transparency offered by the Board throughout the drug selection and cost review study processes and the lack of clear standards to guide how the Board is conducting those processes.[4]

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[1] *See generally* Board, Cost Review Study Process (Mar. 25, 2024), https://pdab.maryland.gov/documents/meetings/2024/pdab_prst_cost_review_20240325.pdf (presentation materials for Mar. 25, 2024 Board meeting).

[2] *See* Md. Code Ann., Health-Gen. § 21-2C-01-16 et seq.

[3] *See* Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade- Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023). PhRMA incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Proposed Rules.

[4] In filing this comment letter requesting changes to the Proposed Rules, PhRMA reserves all rights to legal arguments with respect to the Maryland PDAB statute.

I. TRANSPARENCY

A. Board Activities

PhRMA requests that the Board revise its processes to provide additional transparency into the Board's activities. Greater transparency with respect to the Board's deliberations and decision-making will give stakeholders a clearer understanding of the Board's activities. This is especially critical given the ramifications that the Board's work could have on the health care industry and for many patients receiving prescription medicines in Maryland.

For instance, currently the Board does not publicly release recordings of its meetings and is the only Prescription Drug Affordability Board in the United States that does not do so. Instead, the Board posts a brief record of the minutes of each meeting.[5] These abbreviated meeting summaries do not provide adequate detail to allow members of the public to fully understand the Board's proceedings or the basis of the decisions it makes at those meetings, which impairs the ability of the public to meaningfully understand and provide comment on the Board's activities. Publishing video recordings of the Board's meetings would provide the public with a more complete record of the Board's deliberations and would be consistent with the principles of the Maryland Administrative Procedure Act and the Board's obligations under Maryland Open Meetings law.[6]

B. Other Issues

PhRMA provides below a non-exhaustive list of instances where the Board's drug selection and cost review process lack transparency:

- **Timeline for Cost Review Process.** PhRMA notes that while the Board has previously included a "Timeline" in its presentations that lays out the sequence of activities in its cost review process, that "Timeline" does not include the specific dates on which the Board plans to conduct those activities.[7] While the Board has indicated it can select drugs for cost reviews beginning with its May 2024 meeting, the specific timing of the rest of the cost review process remains unclear. Providing a clear timeline for when the Board anticipates conducting these activities would help to provide stakeholders with adequate notice so that they can provide timely input for the Board's consideration. PhRMA therefore urges the board to publicly release a complete timeline with specific dates and more detailed procedures for how drugs will be subjected to cost reviews.

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[5] *See, e.g.*, Board, Prescription Drug Affordability Board Meeting Monday, November 27, 2023 Minutes, *available at* https://pdab.maryland.gov/documents/meetings/2023/pdab_min_20231127.pdf.

[6] *United Parcel Serv., Inc. v. People's Couns. for Baltimore Cnty.*, 336 Md. 569, 577 (1994) ("[a] reviewing 'Court may not uphold [an agency's decisions] ... unless it is sustainable on the agency's findings and for the reasons stated by the agency,'"). *See also* Md. Code Ann., Gen. Prov. § 3-306(e)(2). We note that any meeting materials published by the Board, including recordings of the Board's deliberations, should protect confidential, proprietary, or trade secret information from improper disclosure consistent with the Board's obligations under federal and state law. *See* Letter from PhRMA to Board (May 1, 2023), 18-19. We also note that, while the Board's March 25, 2024 meeting agenda includes as an item "Approve January 29, 2024 Meeting Minutes," the Board's January 29, 2024 meeting minutes have not yet been posted as of the date of this letter. Both the January 29 and March 25, 2024 meetings involved consideration of which drugs the Board would refer to the Stakeholder Council. In addition to publicly posting recordings of its meetings, PhRMA asks that the Board revise its procedures to include prompt posting of its minutes and other meeting materials following its meetings.

[7] Board, Cost Review Process Study Process- Timeline (Jan. 29, 2024), *available at* https://pdab.maryland.gov/documents/meetings/2024/12924_cost_review_process.pdf (slides 14); Board, Cost Review Study Process (Mar. 25, 2024), *available at* https://pdab.maryland.gov/documents/meetings/2024/pdab_prst_cost_review_20240325.pdf (slide 2).

- **Removal of Listening Sessions from Timeline.** In the Board's January 29, 2024 presentation titled "Cost Review Study Process – Timeline," the Board's cost review process includes a series of "listening sessions" following the Stakeholder Council's review of the referred prescription drug products.[8] In the updated timeline in the Board's slides for its March 25, 2024 meeting, reference to the listening sessions was removed.[9] PhRMA has repeatedly expressed concern regarding the lack of adequate opportunities for stakeholder engagement with the full Board and is concerned that a lack of listening sessions will impede full and meaningful public engagement in the process, and we request clarification as to whether the Board still plans to hold listening sessions.[10]

- **Therapeutic Alternatives.** PhRMA reiterates its concerns with the Board's consideration of "therapeutic alternatives" in its cost review process, including with respect to the Board's definition of "therapeutic alternative" and the lack of clarity regarding how the Board determines which drugs meet that definition for a particular drug under cost review.[11] PhRMA requests that the Board publicly provide the specific criteria used to identify the therapeutic alternatives for a particular selected drug. PhRMA continues to urge caution in how the Board considers therapeutic alternatives for a particular drug, as not every drug product that has the same or similar indication can be considered a therapeutic alternative, and treatments that are the best option for some individuals may not be as effective for others.[12]

- **Eligible Drug Dashboard.** The Board's March 25, 2024 cost review process presentation states that it determined a total of 2,287 eligible National Drug Codes (NDCs) qualify for cost reviews by the Board.[13] However, to date the Board has only published a "sample database" of non-proprietary dashboard information for the drugs referred to the Stakeholder Council.[14] PhRMA reiterates its request that the Board make the full dashboard publicly available for all 2,287 NDCs, while continuing to protect confidential, proprietary, and trade secret information from public disclosure, so that stakeholders may review, verify, and provide a response to the Board on any drugs that may have been erroneously determined to be eligible.[15]

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[8] Board, Cost Review Process Study Process- Timeline (Jan. 29, 2024), *available at* https://pdab.maryland.gov/documents/meetings/2024/12924_cost_review_process.pdf (slides 14 & 15).

[9] Board, Cost Review Study Process (Mar. 25, 2024), *available at* https://pdab.maryland.gov/documents/meetings/2024/pdab_prst_cost_review_20240325.pdf (slide 2).

[10] *See, e.g.*, Letter from PhRMA to Board (Oct. 23, 2023), 3-4; Letter from PhRMA to Board (June 30, 2023), 2-3.

[11] *See* Letter from PhRMA to Board (Oct. 23, 2023), 5-6; Letter from PhRMA to Board (June 30, 2023), 3, 4; Letter from PhRMA to Board (May 1, 2023), 11-12.

[12] Md. Code Regs. 14.01.01.01(B)(61) (defining "Therapeutic alternative" as "a drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug.") *See also* McRae, J., Onukwugha, E. Why the Gap in Evaluating the Social Constructs and the Value of Medicines?. PharmacoEconomics (2021), https://doi.org/10.1007/s40273-021-01075-w. PhRMA is currently reviewing the additional information published by the Board on April 12, 2024 regarding therapeutic alternatives for the drugs it has referred to the Stakeholder Council, and may file additional comments on that information.

[13] Board, Cost Review Study Process (Mar. 25, 2024), *available at* https://pdab.maryland.gov/documents/meetings/2024/pdab_prst_cost_review_20240325.pdf (slide 7).

[14] *Available at*: https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx.

[15] *See* Letter from PhRMA to Board (May 1, 2023), 18-19 (describing the Board's obligations to protect confidential, proprietary, and trade secret information from improper disclosure).

II. LACK OF CLEAR AND MEANINGFUL STANDARDS

Consistent with concerns raised in previous comment letters, PhRMA believes that the Board's cost review process does not provide sufficient guardrails or adequately clear standards for the Board to avoid arbitrary and inconsistent decisions.[16] The procedures used by the Board to identify eligible drugs for a cost review lack detailed and concrete standards to guide the Board to consistently apply its criteria when analyzing each product on the eligible drug list. PhRMA encourages the Board to adopt and publish clear and meaningful standards for how it considers each of its criteria throughout the cost review process. Below, PhRMA also highlights specific, non-exhaustive examples of areas where the Board's cost review process lacks clear and meaningful standards.

A. Selection of Drugs

To date, the Board has not provided clarity into the specific data that it has used to determine which drugs to refer to the Stakeholder Council, and which drugs it will ultimately select for cost review. Instead, the Board has only provided a summary of the metrics involved in the Board's referral of certain drugs to the Stakeholder Council, and has not provided any information regarding how it will select drugs for cost review and how it will consider the statutory and regulatory factors for each specific drug.

This limited information published by the Board does not provide stakeholders adequate clarity into how the Board makes its decisions, nor does it create an sufficient record of the Board's decision-making.[17] For instance, information the Board has provided on the drugs it has referred to the Stakeholder Council only lists two to three eligibility criteria for each drug as well as four regulatory considerations.[18] However, under the Board's implementation regulations, the Board "may consider" the full range of statutory and regulatory metrics involved in the cost review process, as well as certain drug cost information and "[a]ny written or oral public comment" when it selects which drugs to refer to the Stakeholder Council.[19] It is not clear to what extent, if any, those criteria and the remaining unmentioned criteria played in the Board's drug selection process, or how the Board determined which criteria were relevant to its consideration.

Similarly, the Board's regulations state that it may consider whether a drug is in "active shortage status" when considering whether to refer that drug to the Stakeholder Council.[20] However, there is no indication in the Board's March 25, 2024 meeting materials as to whether the Board considered this factor and what role it may have played in the Board's determination. Notably, per the March 25, 2024 meeting materials, multiple drugs that the Board referred to the Stakeholder Council are currently subject to shortages.[21] We request that the Board clarify how it determines and considers a drug's shortage status in its drug selection and cost review processes.

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[16] *See, e.g.*, Letter from PhRMA to Board (June 30, 2023), 2; Letter from PhRMA to Board (May 1, 2023), 2-3.

[17] *See, e.g.*, *Harvey v. Marshall*, 389 Md. 243, 302 (2005) ("[A]n agency action nonetheless may be 'arbitrary or capricious' if it is irrationally inconsistent with previous agency decisions.").

[18] Board, Cost Review Study Process (Mar. 25, 2024), *available at* https://pdab.maryland.gov/documents/meetings/2024/pdab_prst_cost_review_20240325.pdf (slides 11-18). (Listing "§ 21-2C-08(c)(1)(i) - Launch WAC Greater than $30,000 … 14.01.04.02D(1)(a) - Top 100 prescription drug products with the highest total gross spending in the most recent available calendar year … 14.01.04.02D(2)(a) - Top 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year").

[19] Md. Code Regs. 14.01.04.03(C)(4), (D)(4); 14.01.04.05(C)(1)(g)(xii), (C)(2).

[20] Md. Code Regs. 14.01.04.03(B)(5), (D)(2). The Board's regulations further require the Board to consider, "to the extent practicable," a drug's shortage status as part of a cost review of that drug. Md. Code Regs. 14.01.04.05(C)(1)(g)(x).

[21] *See* Board, Cost Review Study Process (Mar. 25, 2024), *available at* https://pdab.maryland.gov/documents/meetings/2024/pdab_prst_cost_review_20240325.pdf (slides 15, 17, & 18).

The Board's approach raises concerns under the Maryland Administrative Procedure Act ("APA"). Maryland courts have consistently held that the APA requires agency's to provide a "reasoned analysis" that shows the "basis of the agency's action" and adequate "factual findings ... to support the agency's conclusions."[22] Under the reasoned analysis standard, such "[f]indings of fact must [also] be meaningful and cannot simply repeat statutory criteria, broad conclusory statements, or boilerplate resolutions."[23] PhRMA is concerned that the information provided by the Board to date lacks adequate detail to satisfy these requirements. We therefore ask that the Board revise its drug selection process to require a consistent and transparent examination of each of the listed criteria, as well a breakdown of which criteria it relied on in determining which drugs to refer to the Stakeholder Council.

B. Public Input

Similarly, although the Board's regulations state that it will provide an opportunity for public comments as part of its drug selection and cost review processes and that it may consider those comments in its drug selection and cost reviews, it has not detailed when and how or in what situations it will consider that information as part of its decision-making.[24] Because public comments are an important source of information for the Board, PhRMA requests that the Board detail when it considers public comment and how public comment informs its specific decisions in the drug selection and cost review process. Such information should be publicly posted on the Board's website on the meeting page where the comments were considered or in another publicly accessible location.

C. Data Review Process

PhRMA reiterates its request for the Board to establish processes that provide an opportunity for stakeholders to review and comment on potential errors in the data the Board relies upon in its decision-making.[25] The Board's processes involve consideration of significant volumes of data and information drawn from diverse sources, which creates an inherent risk of errors in the Board's consideration. As such, it is important that the Board establish a detailed process for stakeholder data review, including an opportunity for manufacturers to review, evaluate, and verify the data the Board considers, and meet with the Board and Board staff to provide information on issues with the Board's data, prior to that data being utilized in any of the Board's determinations. This process should include protections for confidential, proprietary, or trade secret information received by the Board from stakeholders or other sources from inappropriate disclosure.[26]

D. Drugs Subject to Medicare Price Negotiation

PhRMA continues to urge the Board not to unduly consider whether a drug has been selected for price negotiation under the federal Medicare Drug Price Negotiation Program as part of the Board's drug selection and cost review processes.[27] The Medicare Drug Price Negotiation Program infrastructure and process are still in their infancy, and it is premature to include the program as a consideration in the Board's decision-making. It will take years for the effect of the Medicare Drug Price Negotiation Program on patient affordability and access to be understood. The federal program methodology is also designed to target drugs commonly used in an older and/or more disabled Medicare population, not the broader, younger, and more diverse population of Maryland patients. We urge the

[22] *Elbert v. Charles Cnty. Plan. Comm'n*, 259 Md. App. 499, 509 (2023); *see also, e.g.*, *Mortimer v. Howard Research and Development Corp.*, 83 Md. App. 432, 442 (1990).
[23] *Bucktail, L.L.C. v. County Council of Talbot County*, 352 Md. 530, 553 (1999).
[24] Md. Code Regs. 14.01.04.03(D)(4).
[25] *See, e.g.*, Letter from PhRMA to Board (May 1, 2023), 7.
[26] For additional discussion of confidentiality issues, *see, e.g.*, Letter from PhRMA to Board (May 1, 2023), 18-19.
[27] *See* Letter from PhRMA to Board (June 30, 2023), 4.

Board to limit consideration of whether a drug is subject to Medicare price negotiation in its drug selection and cost review considerations until the federal program is fully implemented and the impacts it has on patients and drug affordability are fully understood.[28]

* * *

We thank you again for this opportunity to provide comments and feedback on the Board's drug selection and cost review processes and for your consideration of our concerns and requests for clarifications. Although PhRMA has concerns with these processes, we are ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide as the cost review process is further developed, please contact Kristin Parde at Kparde@phrma.org.

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Merlin Brittenham
Assistant General Counsel, Law

CC: Prescription Drug Affordability Board Stakeholder Council

[28] PhRMA previously objected to consideration of a drug's status under the Medicare Drip Price Negotiation Program in the Board's cost review process, *see* Letter from Board (June 30, 2023), 4, and we reiterate our concerns with its inclusion. While we recognize that the Board's regulations instruct it to consider a drug's status in the Medicare Drug Price Negotiation Program as part of its drug selection and cost review processes, we ask that the Board limit its consideration of that criterion for the reasons described above. Md. Code Regs. 14.01.04.03(B)(6), 14.01.04.05(B)(1).

sanofi

April 24, 2024

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

Re: Drugs Referred to the Stakeholder Council

Dear Members of the Maryland Prescription Drug Affordability Board Stakeholder Council,

Sanofi appreciates the opportunity to submit comments to the Maryland Prescription Drug Affordability Board Stakeholder Council ("Stakeholder Council") regarding the Maryland Prescription Drug Affordability Board's ("Board") list of referred drugs. For the reasons listed below, **we respectfully ask that the Stakeholder Council recommend that the Board remove Dupixent® from this list.**[1]

Dupixent, which Sanofi commercializes with its partner, Regeneron, is a biologic medication that blocks the signaling of two key sources of Type 2 inflammation (IL-4 and IL-13) and is currently indicated in the treatment of five conditions: eczema/atopic dermatitis; asthma; nasal polyps; eosinophilic esophagitis; and prurigo nodularis. Given these five indications, Dupixent's utilization is higher than if five separate drugs were developed to treat these conditions – evidence of the value it provides to the healthcare system and to patients. Dupixent was also the first advanced therapeutic approved to treat four of its five indications, and remains the only approved advanced therapy down to six months of age in atopic dermatitis and one year of age in eosinophilic esophagitis, representing transformative scientific breakthroughs for patients suffering from those diseases and further demonstrating the value and innovation it brings to patients and the healthcare system.

Dupixent was evaluated as part of the drug class used to treat atopic dermatitis by the Institute for Clinical and Economic Review (ICER) at its initial launch in 2017. ICER is a nonpartisan, independent organization that "transparently reviews all available evidence to help align a treatment's price with how well it improves the lives of patients and their families."[2] At that time, ICER found Dupixent's net price to be "well-aligned with the added benefit it provides to

[1] Sanofi reserves the right to supplement this submission with additional information to assist the Board's decision-making on this important topic.
[2] *See* Who We Are, *at* https://icer.org/who-we-are/.

patients. Dupilumab [i.e., Dupixent] represents a good value for money."[3] Since Dupixent's launch, Sanofi has taken reasonable and predictable price increases in line with our Pricing Policy.[4] This is reflected in the fact that ICER has never included Dupixent, or any other Sanofi medicine, in their annual "Unsupported Price Increase Report." This determination of cost effectiveness 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.

Dupixent, like all Sanofi medicines, is priced to reflect its value and our commitment to patient access, while minimizing our contribution to health care inflation. To maintain an environment that will continue to bring new healthcare solutions to patients, we must encourage a transition to a value-driven healthcare system that provides incentives for the highest quality care. This evolution will enable both affordable access to treatments and continued investment in medical innovation. Sanofi is committed to addressing this challenge and offers a copay card program for Dupixent patients in Maryland and nationwide to help ensure affordable access to this innovative treatment.[5] With the Dupixent MyWay® Copay Card, commercially insured patients may pay as little as $0* copay per fill of Dupixent.[6] All commercially insured patients are eligible for our copay card, and the enrollment process is quick and easy – as simple as filling out a form on our website.[7] In 2023, 4,649 Maryland patients received copay support from Sanofi for their Dupixent prescriptions. Additionally, through the Dupixent MyWay® Patient Assistance Program, qualified patients with incomes up to 600% of the Federal Poverty Level who are uninsured or whose insurance does not cover Dupixent will receive their medication at no cost.[8] The Dupixent MyWay® Support Team is available by phone 24/7 to help patients and healthcare providers to access the program.[9] In 2023, 1,280 Maryland patients qualified for and received their Dupixent prescriptions at no cost through our Patient Assistance Program. The Stakeholder Council should consider the breadth of these Sanofi programs, which lower or eliminate Maryland patients' out-of-pocket costs, in its input to the Board.

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[3] Institute for Clinical and Economic Review (ICER). (2017). Atopic Dermatitis: An assessment of crisaborole and dupilumab. (Retrieved from https://icer.org/wp-content/uploads/2020/10/MWCEPAC_AD_RAAG_060817.pdf).
[4] Sanofi Pricing Principles for the U.S. (2024). https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/diversity-equity-and-inclusion/employee-resource-groups/Employee-Resource-Groups/pricing-principles/Sanofi-2024-Pricing-Principles-Report.pdf.
[5] *Eligibility requirements and amount of assistance are subject to change. *See* Dupixent MyWay® Copay Card, *at* https://www.dupixent.com/support-savings/copay-card.
[6] *See* Dupixent Copay Card Enrollment, *at* https://www.dupixent.com/support-savings/copay-card-enrollment.
[7] Id.
[8] *See* Dupixent MyWay® Program, *at* https://www.dupixent.com/support-savings/dupixent-my-way.
[9] Contact 1-844-DUPIXENT (1-844-387-4936) to speak to a DUPIXENT MyWay Case Manager or representative.

Additionally, Sanofi asks the Stakeholder Council to consider that Dupixent's indication for eosinophilic esophagitis was approved as an orphan drug designation. Medicines approved to treat rare diseases are exempt from certain laws and regulations, as a recognition that a small patient population can only benefit when companies assume the risks involved in orphan drug development. Other state PDABs, such as Oregon,[10] exempt drugs with orphan indications.

Sanofi remains committed – and devotes significant resources - to exploring all potential disease states and patient populations that could benefit from Dupixent. A recent clinical trial showed positive results in some patients with chronic obstructive pulmonary disease (COPD) who were treated with Dupixent.[11] There are currently no biologic products approved to treat COPD, and many COPD patients' symptoms are not well controlled with currently approved therapies.

We believe that Dupixent will also benefit patients in other indications, and strongly encourage the Stakeholder Council to consider the potentially chilling effect that a price control could have on this type of innovation. In fact, Dupixent represents precisely the type of innovation and approach to pricing that should be expected from our industry – pursuing first in class or best in class medicines that have the potential to transform the practice of medicine for patients, and pricing those medicines in a manner that reflects the value they provide to patients and society.

Sanofi is reviewing the data that the Board recently posted to its website regarding the drugs it has referred to the Stakeholder Council.[12] At the outset, however, we note that Maryland's website describes the data as only a "sample database that includes non-proprietary data and data that has been approved for public display," which suggests that the data set is incomplete.[13] The chart itself does not address the Board's methodology, list its sources for the data it includes, describe how the Board identified the eight drugs for referral to the Stakeholder Council, nor show the data for any drug reviewed but not referred to the Stakeholder Council. Thus, Sanofi remains concerned that the methodology, data sources, and criteria used by the Board to identify drugs for inclusion in this list was not made available to the public and may not accurately prioritize drugs that pose actual affordability challenges for patients. More specifically, we note that the Board's chart includes out-of-date information, for example, Medicare patient out-of-pocket cost and spending data from 2020, which predates the Inflation Reduction Act's Medicare rebates that cap drug price increases to

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[10] Or. Rev. Stat. § 646A.694 (2021).
[11] Bhatt, Surya P., et. al. (2023). Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts. *New England Journal of Medicine*, 389, 205-214. DOI: 10.1056/NEJMoa2303951
[12] *See* Cost Review Study Process Updates, Drugs Referred to the Stakeholder Council-Dashboard, *at* https://pdab.maryland.gov/cost_review_process.html.
[13] *See* Cost Review Study Process Updates, *at* https://pdab.maryland.gov/cost_review_process.html.

economy-wide inflation for that program and reduce and cap patient out-of-pocket costs. The Stakeholder Council should point out these deficiencies to the Board and ask for more timely and complete information prior to supporting any drug cost review.

Finally, the list price of a drug is not the price that most patients pay at the pharmacy counter. A patient's copay is set by their health plan, not the manufacturer. Further, commercially insured patients' out-of-pocket costs are reduced by the drug manufacturer copayment support programs noted above, and many patients pay nothing for their drugs through patient assistance. Over-emphasizing the list price of a medicine in Maryland's cost review will fail to adequately address patient access and affordability challenges. A price control will likely also have unintended consequences such as impairing patient access to their medicines and undercutting pharmaceutical innovation. We encourage the Stakeholder Council and the Board to consider recommendations for broader reforms that will make the health care system work better for all patients.

Thank you for the opportunity to provide comments and for considering our concerns. We hope that after considering this information, **the Stakeholder Council will recommend against any drug cost review by the Board at this time, including any cost review of Dupixent**.

Please feel free to contact me at deanne.calvert@sanofi.com with any questions.

Sincerely,

Deanne Calvert
Head, State Government Relations, Sanofi

April 23, 2024

SUBMITTED VIA EMAIL TO: comments.pdab@maryland.gov

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

Re: Maryland Prescription Drug Subset List

Dear Members of the Maryland Prescription Drug Affordability Board Stakeholder Council,

On behalf of Takeda Pharmaceuticals America, Inc. ("Takeda"), I am writing regarding the list of drugs approved by the Maryland Prescription Drug Affordability Board ("PDAB") during the March 25, 2024 meeting for consideration for the cost review process and referral to the PDAB Stakeholder Council. We appreciate the opportunity to provide written feedback and respectfully ask that the Stakeholder Council advise the PDAB to remove Vyvanse® (lisdexamfetamine dimesylate) from consideration for the cost review process in part because numerous generic versions of Vyvanse, covering all dosage forms and strengths of the product, have been approved and launched beginning in August 2023.[1] Of the eight products on the PDAB-approved list, Vyvanse is the only product with generic alternatives.

Takeda is focused on creating better health for people and a brighter future for the world. We aim to discover and deliver life-transforming treatments. Together with our partners, we aim to improve the patient experience and advance a new frontier of treatment options through our dynamic and diverse pipeline.

Vyvanse is approved for the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older and moderate to severe binge eating disorder (BED) in adults. Patent protection covering Vyvanse and the associated FDA-granted regulatory exclusivity period expired in the U.S. in August 2023. Since that time, multiple manufacturers have launched AB-rated generic versions of lisdexamfetamine dimesylate. In fact, seven AB-rated generics launched immediately after Vyvanse loss of exclusivity occurred. To date, ten manufacturers have launched generic versions of lisdexamfetamine dimesylate, covering in total all dosage forms and strengths of Vyvanse. While the pricing by generic manufacturers varies, the weighted average Wholesale Acquisition Cost (WAC) for generic manufacturers across the six months from September 2023 to February 2024, was 47% lower than the Vyvanse WAC for the same period.[2]

Given the approval of multiple AB-rated generic versions of lisdexamfetamine dimesylate, alternative cost containment strategies under consideration by the PDAB, such as an upper payment limit (UPL), may prove to be redundant and/or unnecessary to achieve the PDAB's affordability goals. **For the aforementioned reasons, we kindly request that the Stakeholder Council recommend to the PDAB that Vyvanse be removed from the list of drugs under consideration for the cost review process**.

[1] Vyvanse formulations includes seven (7) capsule strengths (10mg-70mg) and six (6) chewable tablet strengths (10mg-60mg) all of which are also now approved by the FDA in generic version.
[2] Weighted average WAC Pricing information across generics based on WAC Pricing via Price Rx Feb 2024.

Takeda Pharmaceuticals America, Inc.
750 9th Street, NW, Suite 575, Washington, DC 20001
(202) 649-4000

* * *

Lastly, we would like to correct an error noted at the March 25, 2024, Board meeting regarding Vyvanse. In the meeting, PDAB staff presented cost review study data on the list of drugs that were subsequently approved for referral to the Stakeholder Council.[3] The materials inaccurately indicated that Vyvanse is in active shortage status. As noted in FDA's drug shortages record, Takeda is not experiencing manufacturing or supply delays for Vyvanse.[4] We remain confident in our capability to continue maintaining an adequate supply of Vyvanse to meet its U.S. forecasted demand.

Thank you for considering our comments. Should you have any questions, please contact me at william.gazda@takeda.com.

Sincerely,

William M. Gazda

William Gazda
Head – US Established Brands Portfolio
Takeda Pharmaceuticals America, Inc.

[3] PDAB Staff, "Cost Review Study Process,"
https://pdab.maryland.gov/documents/meetings/2024/pdab_prst_cost_review_20240325.pdf
[4] FDA, "Current and Resolved Drug Shortages and Discontinuations Reported to FDA,"
https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Lisdexamfetamine%20Dimesylate%20Capsule&st=c

Value of Care Coalition

April 24, 2024

Prescription Drug Affordability Stakeholder Council
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: ACCESS CONCERNS RESULTING FROM UPPER PAYMENT LIMITS

Dear Members of the Stakeholder Council:

As a broad coalition of advocacy organizations representing patients, caregivers and health care providers, we write to express concern with tools under consideration by the Prescription Drug Affordability Board to lower prescription drug costs in Maryland and the impact that they will have on therapeutic access for Marylanders.

We recognize the importance of lowering health care costs but are concerned that the processes and methods being considered by the Board – the setting of upper payment limits, in particular – present several shortcomings and may restrict patients' access to needed treatments. As the Stakeholder Council considers its recommendation to the board, we ask that members consider these concerns.

Patients Access May Decrease

Negotiations between pharmacy benefit managers and manufacturers play a significant role in formulary inclusions and placement, determining which treatments patients can access. A government-imposed price can create distortions in the market that reduce access to certain drugs, which in turn can harm patients.

Upper payment limits are also likely to lead to increased utilization management and changes in copays and coinsurance. In fact, a newly released study commissioned by the Partnership to Fight Chronic Disease, performed by Avalere, underscores this concern. The study surveys health insurance representatives about the impact that a board setting upper price limits will have on patient access. Quotes from the health plan representatives validate the concerns of patients and health care providers.

A few select quotes related to access include:

> *"Utilization management will undoubtedly go up with UPLs, whether for the drugs subjected to them or for competition. This is going to depend on how low or high the*

UPLs are set at and what changes this brings to classes and volume." – Vice President of Strategic Business Operations, Regional Plan

"UPLs will alter how formularies are determined by plans which will likely mean changes to patient copays and coinsurance amounts." – Vice President of Business Operations, Regional Plan [1]

When timely access to treatments is decreased, diseases may progress, symptoms can recur, and new side effects from different treatments can emerge. This can lead to missed work, recurring doctor visits, trips to the emergency room and hospitalizations.

With a narrow focus on regulating prices paid by health plans, the setting of upper payment limits risks Maryland patients losing access to the treatments they need.

Patient Savings Aren't Guaranteed

The board is granted the power to set an upper payment limit for prescription drugs for some Maryland health plans.

Patients' out-of-pocket costs are not determined by the list price of a medication but are set at an amount their health plan dictates. Further, payers are not required to pass any potential savings along to their enrollees. So, even if an upper payment limit lowers topline prices, this does nothing to reduce out-of-pocket costs for patients.

The Partnership to Fight Chronic Disease study validates this concern. A few payer quotes regarding the impact of upper payment limits on patient costs include:

"Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences." –Executive Director, Health Plan Services

"*There is a good chance beneficiaries on these (UPL) drugs also have hospitalization or physician expenses that would add to OOP max, UPLs won't change that." – CEO of Western Region, National Plan*[2]

[1] Partnership to Fight Chronic Disease. *Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs*. 2024 March. https://www.fightchronicdisease.org/sites/default/files/FINAL%20PFCD%20Avalere%20PDAB%20Insurer%20Research.pdf

[2] Ibid.

For the board to lower patient costs, it must address benefit design and out-of-pocket expenses rather than imposing upper payment limits.

Discriminatory Metrics Exacerbate Health Equity Concerns

Value assessments for prescription medications often rely on metrics that discriminate against certain patient populations. One example is the cost-per-quality adjusted life year, or QALY, which undervalues health improvements for older or sicker patients. Federal law prohibits certain federal programs from using QALY thresholds to determine coverage.

Maryland's Prescription Drug Affordability Board, however, is not prohibited from using discriminatory metrics like the QALY, exposing Marylanders to the potential for widening health inequities and unequal health care if an affordability review leads to price-setting action.

Conclusion

The authority granted to the Maryland Prescription Drug Affordability Board takes a narrow view of the true cost of health care.

By focusing on cost assessments and upper payment limits, the board ignores critical elements of health care cost and access. It ignores major costs added to the drug supply chain by powerful participants like pharmacy benefit managers, insurers and wholesalers. And it ignores the costs of health plan delays or denials, which lead to additional doctor appointments, hospital visits and missed work.

Lowering health care costs is a laudable goal, particularly when the focus is on lowering patient costs. However, upper payment limits do not lower patient costs but do present a broad threat to patient access and exacerbate disparities in health care. For those reasons, we ask you to take these concerns into account when making your recommendations to the board.

AfPA Alliance for Patient Access

American College of Allergy, Asthma & Immunology

AWIR Association of Women in Rheumatology

CSRO Coalition of State Rheumatology Organizations

HIV+HEP Policy Institute

Lupus and Allied Diseases Association, Inc.

NICA National Infusion Center Association

Patients Rising