Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

May Board Meeting Comments

1 message

Melissa Abrams [redacted] > Wed, May 15, 2024 at 4:25 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>
Cc: Melissa Abrams <[redacted]

Dear Members of the Prescription Drug Affordability Board,

I write to you today with grave concern regarding the recent decision made by the Prescription Drug Affordability Board (PDAB) concerning Dupixent (Dupilumab), a vital medication for the treatment of atopic dermatitis, also known as eczema. As a pediatric dermatologist in Montgomery County, Maryland, with nearly 15 years of clinical experience, I have witnessed firsthand the significant impact that eczema has on the lives of children and their families. Therefore, I implore you to reconsider the potential implications of limiting access to Dupixent for those in need.

Eczema is not merely a cosmetic concern; it is a chronic inflammatory disease with no known cure that profoundly disrupts the lives of those affected by it as well as their family members. From incessant itching and discomfort to the psychological toll it takes on patients and their families, eczema poses a substantial burden. As a dermatologist specializing in pediatric care, I have treated thousands of children battling this condition, and I have seen the detrimental effects it can have on their quality of life.

Dupixent stands as a beacon of hope for those with moderate to severe atopic dermatitis who have not responded to topical treatments (including the topical posed as an alternative treatment, as all patients on dupixent have failed tacrolimus ointment). Topical treatment is a stop gap for patients with atopic dermatitis. Dupixent is as close as we have to a cure as it modulates the skin cell immune system to prevent atopic dermatitis. It is currently the only safe (non immunosuppressant) therapeutic option available for this demographic, providing relief and improving their overall well being. However, the decision to potentially limit access to Dupixent through the establishment of an upper payment limit (UPL) threatens to deprive patients of a crucial lifeline.

Delaying or denying access to Dupixent not only compromises patients' quality of life but also has far reaching consequences. Families may face financial strain due to missed work and school days, while the increased risk of super-infections of the skin further exacerbates the already challenging situation, increasing visits to doctors and potentially emergency rooms and urgent care facilities. Additionally, the proposed biologic or oral therapeutic alternatives are only FDA-approved for patients twelve years and older, leaving a significant gap in care for younger individuals. Finally, the proposed alternatives do not have a safety profile that is as favorable as Dupixent.

It is imperative to recognize that denying access to Dupixent is tantamount to denying patients the opportunity for a better quality of life. As healthcare professionals, it is our duty to advocate for the well being of our patients and ensure they have access to the treatments they need. Therefore, I

urge you to reconsider the decision regarding Dupixent and prioritize the health and welfare of those suffering from atopic dermatitis.

In conclusion, I respectfully request that the Prescription Drug Affordability Board intervene in this matter and advocate for the continued availability of Dupixent for all patients suffering from atopic dermatitis. Delaying or denying access to this essential medication is simply unacceptable, and it is incumbent upon us to take action to rectify this situation.

Thank you for your attention to this critical issue, and I trust that you will give it the careful consideration it deserves.

Sincerely,

Melissa Lynn Abrams, MD, FAAD

Pediatric Dermatologist, US Dermatology Partners

Apfed
American Partnership
for Eosinophilic Disorders

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May 15, 2024

Prescription Drug Affordability Stakeholder Board
Maryland

Dear Board members:

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.

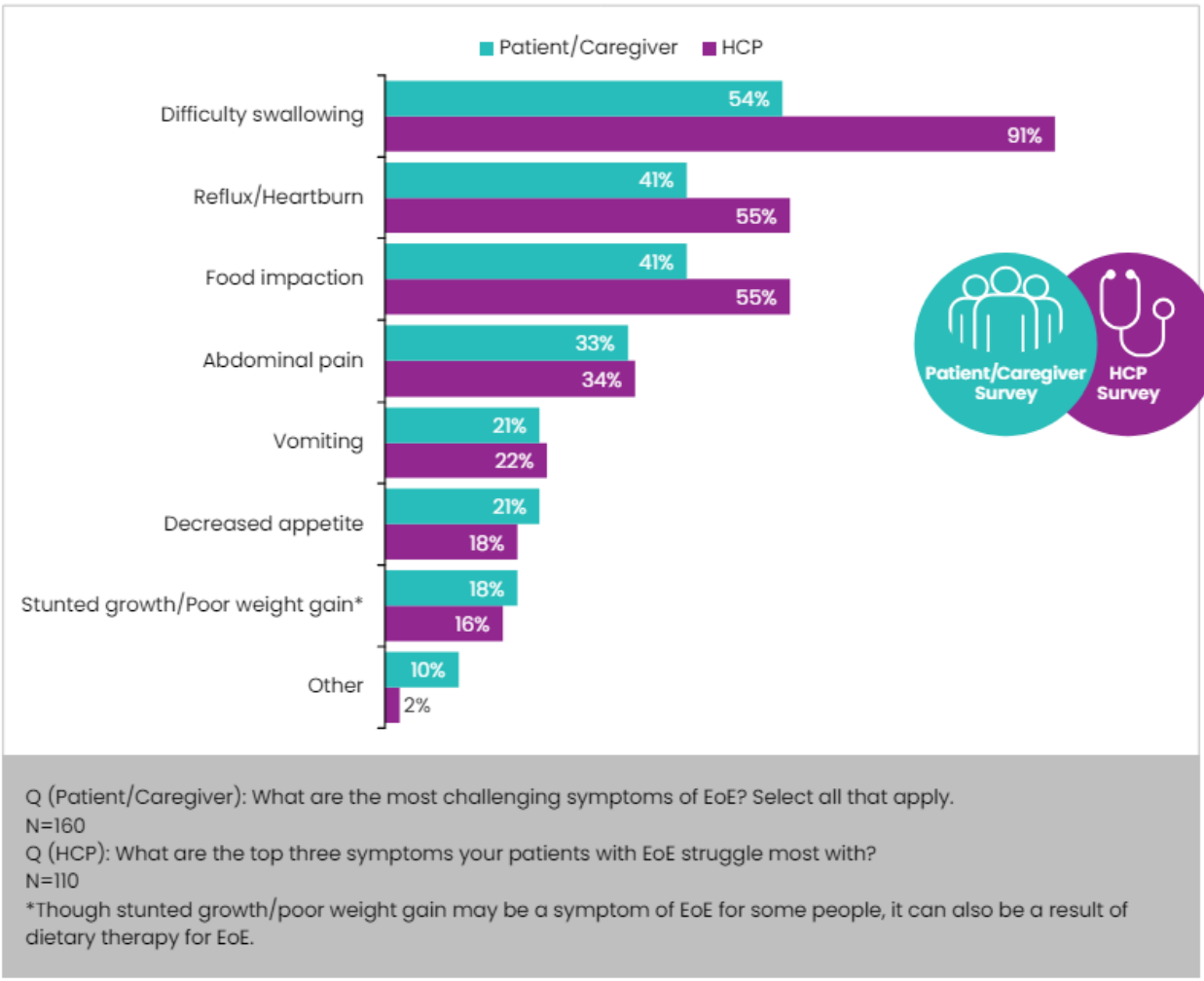
"They put him on budesonide and he had an allergic reaction. We stopped using budesonide, but the EoE and the eczema continued. He is now on the biologic which has helped him immensely."

– 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.

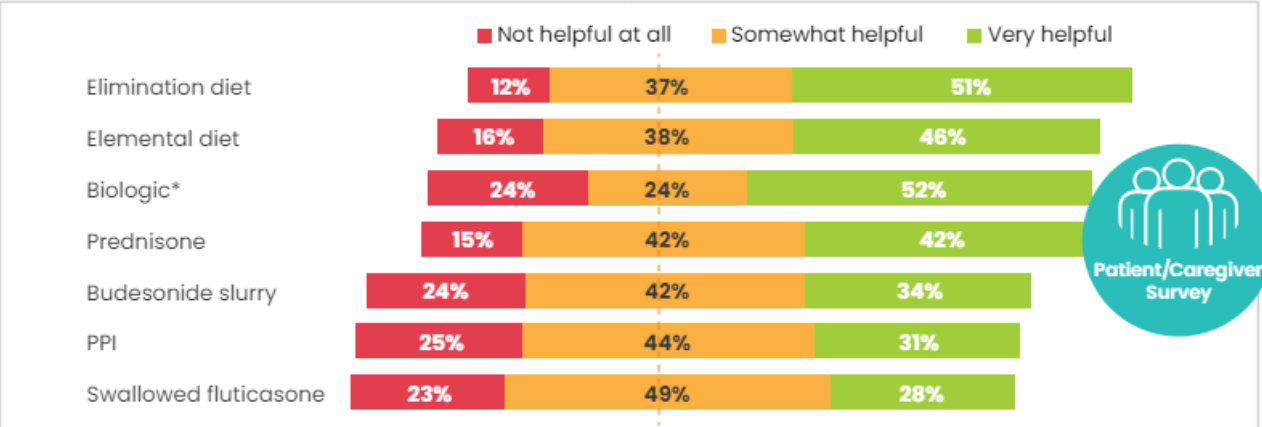
EoE can have a salient impact on many aspects of patients' and caregivers' lives. Beyond the physical impacts like EoE symptoms, inflammation, and esophageal damage, patients and caregivers experience social, emotional, and financial impacts as well. Studies have shown that EoE has been associated with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

My name is Oluyomi Amoye. I am a retired tax economist and father of three, 65 years old, and a resident of Laurel, Maryland.

In 2010, I was diagnosed with Type 2 diabetes and prescribed Jardiance. I am currently on Medicaid and my Medicare health insurance coverage plan is expected to kick in in February. Under Medicaid alone, I would be paying $282 a month just for Jardiance, and still don't know what that total might be under Medicare. This might not seem like a lot to pay for a necessary medication, but that is a lot for me to pay as someone who is retired and living on a fixed income.

Thankfully, the only way I have been able to surpass the financial challenges of getting Jardiance for my diabetes, here in the United States, has been by leaving the country and sourcing it elsewhere. It is more cost effective for me to fly to the UK to get my three months' worth of Jardiance than if I just paid to buy it here at my regular pharmacy.

Being diagnosed with Type 2 diabetes has also not been an easy sentence that is now written on my daily page of life going forward. I have already had to change my diet and lifestyle to accommodate this very humbling disease, as I have already had to nickel and dime myself to pay for my medications. This is simply unfair. This is the medication that I need to survive and be there for my family. I should not have to spend my retirement worrying about paying for the drugs I need to survive. This should be the time that I take to relax and enjoy.

My experience and story with Jardiance is the main reason I believe in lower prescription drug prices. People need this medication to survive. Many people need access to lower-cost and affordable prescription drugs to overcome challenging or horrible health conditions. We should not have to lose an arm and leg to pay for them.

AstraZeneca
1800 Concord Pike
Wilmington, DE 19850
astrazeneca.com

May 15, 2024

VIA ELECTRONIC MAIL TO *COMMENTS.PDAB@MARYLAND.GOV*

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

Re: May Board Meeting Comments

Dear Members of the Maryland Prescription Drug Affordability Board:

AstraZeneca ("AstraZeneca" or "the Company") is submitting comments in response to the Maryland Prescription Drug Affordability Board's (the "PDAB's" or the "Board's") referral of the Company's product, FARXIGA® (dapagliflozin) ("FARXIGA") to the Maryland Prescription Drug Affordability Stakeholder Council ("Stakeholder Council") and which is posted on the May PDAB Meeting agenda to be considered during the May 20, 2024 PDAB Meeting.

As a Board member indicated during the PDAB's March 25, 2024 meeting, one of the key reasons FARXIGA appears to have been selected by the Board as one of the eight drugs for potential cost review is because the product was also selected for the 2026 Medicare Drug Price Negotiation Program under the Inflation Reduction Act. As a general matter, we object to the Board using FARXIGA to test Maryland's cost review process against the federal government's given the potential access risks to patients and associated burdens imposed on the Company as a result when the drug is demonstrably affordable and clinically valuable and is expected to lose patent exclusivity at the end of 2025 or in early 2026.

Moreover, when there is a more complete look at the cost-effectiveness for FARXIGA, it is clear that the drug does not create affordability issues for Maryland patients and was inappropriately included in the set of drugs under consideration by the Board. We believe the PDAB's consideration of FARXIGA generally, and selection of FARXIGA for a cost review specifically, are arbitrary and inefficient uses of the Board's resources.

BACKGROUND

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas: Oncology, Cardiovascular, Renal and Metabolism, and Respiratory. Based in Cambridge, UK, AstraZeneca is committed to developing innovative, lifesaving medicines and making these medicines accessible to patients.

FARXIGA is a first-in-class, oral, once-daily sodium-glucose cotransporter 2 ("SGLT2") inhibitor indicated: (1) to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression; (2) to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure; (3) to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either

established cardiovascular disease or multiple cardiovascular risk factors; and (4) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.[1]

FARXIGA IS A CLINICALLY EFFECTIVE AND AFFORDABLE TREATMENT FOR MARYLAND PATIENTS

AstraZeneca participates in the Medicaid Drug Rebate program, providing rebates to the federal government and states in exchange for coverage for Medicaid beneficiaries. As of January 1, 2024, AstraZeneca provides rebates of over 100% for FARXIGA utilization in the Medicaid segment. This accounts for a significant number of people who would be subject to a UPL in Maryland. The patent exclusivity of FARXIGA is expected to expire at the end of 2025 or in early 2026. Rapid generic entry is projected which will further reduce the cost of FARXIGA to the state of Maryland.

AstraZeneca also offers a variety of assistance programs that enable patients, including those in Maryland, to access our drugs at prices they can afford. AstraZeneca also demonstrates its commitment to patients through our collaboration with Commercial payers, providing substantial discounts to ensure FARXIGA formulary positions provide the lowest possible out-of-pocket cost for Commercial patients. This translates into substantial savings for patients and payors alike. For example, the average FARXIGA Commercial copay is $46; and for those who cannot afford this co-pay, AstraZeneca also makes a significant investment in our AZ&Me Prescription Savings Program to support access to FARXIGA for all qualified Medicare enrollees. Moreover, we extensively publicize information about our assistance offerings to both patients and health care providers to ensure the widest dissemination of this important information.[2]

Significantly, because it has multiple indications, FARXIGA's utilization is higher than if separate drugs were developed to treat these conditions. This is additional evidence of the value it provides to the healthcare system and to patients.

WE HAVE SUBSTANTIAL CONCERNS REGARDING THE INTEGRITY AND COMPLETENESS OF THE DATA THE BOARD HAS CONSIDERED IN CONNECTION WITH ITS DRUG SELECTION PROCESS AND THE BOARD'S METHODOLOGIES AND PROCESSES MORE BROADLY, PARTICULARLY ITS LACK OF TRANSPARENCY

To date, the PDAB has made public very limited information regarding the eight drugs, including FARXIGA, it referred to the Stakeholder Council. Most of the data is years old and largely focuses on the commercial market, whereas under existing law, an upper payment limit ("UPL") established for a drug by the Board would only apply to payments or reimbursements for drugs in state funded programs.

We have legitimate questions regarding the veracity of the data and information the PDAB relied upon to select FARXIGA. For example, at its March 25, 2024 meeting, several PDAB members expressed concerns about the quality of available data (*e.g.*, very dated claims information). In addition, the information included in the PDAB's dashboard states that FARXIGA's exclusivity expires in 2040, when the actual earliest date FAXIGA is

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1 AstraZeneca, FARXIGA® Product Website, at https://www.farxiga.com/.

2 *See, e.g.*, AstraZeneca, FARXIGA® Product Website for Patients, "Cost and Affordability," at https://www.farxiga.com/savings-support/insurance-support; AstraZeneca, FARXIGA® Product Website for Health Care Professionals, "Savings and Access Support for Your Patients," at https://www.farxiga-hcp.com/access-and-affordability.

expected to lose patent exclusivity is at the end of 2025 or early 2026. There was also discussion during the April 29, 2024 Stakeholder Council meeting about how the information in the state's All-Payers Claims Database ("APCD") is incomplete, especially as it relates to out-of-pocket costs. Among other things, the APCD does not include crucial information on rebates, discounts, and patient and other assistance programs offered by manufacturers. All of these factors are significant in determining what patients ultimately pay out of pocket for their medications and as such, are a critical part of any discussion regarding whether a drug may present affordability challenges. The PDAB should not "put the cart before the horse," but instead should focus its efforts first on gathering pertinent data, as opposed to considering drugs for potential cost review based on incomplete and inaccurate metrics.

Further, in contrast to other jurisdictions with prescription drug affordability boards, the PDAB has not granted stakeholders access to its full dashboard of disclosable information or provided relative rankings with respect to where each eligible drug sits for the categories where drugs are on the top 100 list. This information is crucial for stakeholders to understand, analyze, and independently verify the methodology and underlying data that the PDAB used to identify which drugs to consider for potential cost review and refer to the Stakeholder Council. The PDAB must 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, including manufacturers.

The PDAB also seems to be disproportionately focused on the list prices of drugs. However, in many state funded programs that would be in scope of a UPL established by the Board, what patients ultimately pay for medications is a function of health benefit plan design and not set by the drug manufacturer. In addition for many types of insurance coverage, pharmacy benefit managers have a significant role in drug benefit design, formulary placement, and the prices that patients ultimately pay for their medications, with little to no transparency into their practices. These disconnects will introduce additional market distortions in an already complex prescription drug supply chain. We urge the PDAB to be thoughtful when it comes to unintended consequences related to the tools it has been given to complete its work.

Please let us know if you have any questions or require any additional information at this point.

Sincerely,

Geoffrey A Gallo
Head of State Government Affairs

Baltimore-Washington Conference
The United Methodist Church

REV. DR. STACEY COLE WILSON
EXECUTIVE MINISTER OF BELOVED COMMUNITY
TEL. 240-581-5366 OR 443-983-4112

May 14, 2024

Dear Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff,

As escalating expenses associated with prescription medications pose a pressing concern for residents across Maryland, we, the Baltimore-Washington Conference of the United Methodist Church Advocacy and Action reach out to convey our gratitude for the crucial efforts of the Prescription Drug Affordability Board. We acknowledge the indispensable role that affordable prescription drugs play in fostering the health and welfare of our members and the communities we serve. We find assurance in witnessing the Board and Stakeholder Council actively engaging in the process of reviewing costs, bringing us one step closer to tangible solutions. We commend the PDAB for their diligent selection of drugs for cost assessment and urge swift action to enhance affordability for state and local governments, with the hopeful anticipation of extending these benefits to all individuals in due course. Thank you for ensuring that Health care is a basic human right and for working in the best interests of all citizens, particularly those in considered most vulnerable.

With gratitude,

Rev. Dr. Stacey Cole Wilson
Baltimore-Washington Conference of The United Methodist Church

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COMMITTEE TO PROTECT HEALTH CARE

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

RE: Public Comment on Agenda Item V: Select Drug(s) for Cost Review Study

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff,

The Committee to Protect Health Care and Committee doctors practicing in Maryland appreciate the opportunity to provide comment on the selection of prescription drug products for your cost review study process. We applaud the work you do to help reduce the high costs of prescription drugs and are proud to support your efforts.

As physicians, we see firsthand how unaffordable prescription drugs force many patients to ration their medications to make their supplies last longer. We also hear all too often from our patients about their struggles to pay for their prescription drugs when the cost of everything, from their rent to gas and groceries, is rising faster than their wages. While some are fortunate to qualify for patient assistance programs, many are denied such benefits, and even those who do qualify may still struggle to pay their portion.

Many of our patients tell us heartbreaking stories of making the impossible decision to choose between putting food on the table to adequately feed their families, and paying high out-of-pocket costs for crucial medications that can improve and even save their lives.

For these reasons, we thank you for undertaking this first cost review process so you can provide more transparency and accountability in drug pricing, and ultimately help rein in high drug costs with upper payment limits.

Swift action now from the Board is essential as drug companies increased the costs for hundreds of medications this year, as they do every year. Big Pharma is raising the costs for medications at a faster rate than inflation, and charging more than what Marylanders can afford. To make ends meet even as drug companies hike costs and rake in profits, Marylanders are cutting their pills and skipping doses – a dangerous practice that contributes to poorer health outcomes, avoidable hospitalizations, and even preventable deaths.

Meanwhile, U.S. prices across all drugs (brands and generics) were more than 2.5 times more expensive than prices in other developed countries in 2022, with U.S. prices for brand drugs at least 3.22 times more expensive, even after adjustments for estimated U.S. rebates. Maryland's Prescription Drug Affordability Board is uniquely positioned to shine a hard light on these unfair and harmful pricing practices.

We also encourage you to consider other factors in your selection process that may influence affordability and access, such as Medicare's new authority to negotiate lower costs for high-priced medications. Among the drugs subject to negotiations for reduced costs under Medicare Part D are Farxiga and Jardiance, which are on the list of eight medications you are considering for review. To maximize efficiency and minimize delay, we encourage you to adopt the Medicare-negotiated costs for these two drugs, and remove them from your review list.

The cost review study process cannot begin soon enough. Out-of-pocket drug costs are trending upward, adding to the financial burdens our patients and their families face. A whopping 82% of people now say prescription drug costs are not only unaffordable, but unreasonable.

You have an opportunity to provide real relief to patients across our state, by increasing transparency in drug pricing, demanding accountability from pharmaceutical companies, and capping costs through an upper payment limit.

While we appreciate the work being done by this Board so far to address costs for state and local governments, we are acutely aware that more needs to be done for Marylanders. We thank you for your dedication to addressing this issue and urge you to act swiftly, so that Board authority expansion can be considered in the 2025 legislative session.

Thank you for your commitment to the health and wellbeing of all Marylanders.

Sincerely,

Rob Davidson, MD, MPH
Executive Director

Delaware-Maryland Synod
Evangelical Lutheran Church in America
God's work. Our hands.

TO: Mr. Van Mitchell, Chair, and members of the Maryland PDASC
FROM: Lee Hudson, assistant for public policy to the DE-MD Synod bishop
DATE: May 14, 2024
RE: Stakeholders Council public comment on drug price review

The Delaware-Maryland Synod of the Evangelical Lutheran Church in America is a faith community with a demographically diverse Maryland constituency extending from Red House to Ocean City. Our community has advocated for access to appropriate, adequate, and affordable health care for all people in the United States since 2003 (*Caring for Health*, ELCA). We include medical treatment in "appropriate and adequate care," and therefore in any measure of "affordable."

We were among advocates for the passage of the 2019 bill establishing a Maryland Prescription Drug Affordability Board to monitor and address pharmaceuticals covered in State health care programs. We also supported SB202/HB279 of 2023 extending authority for PDAB to establish drug upper payment limits in certain indicated circumstances. We genuinely appreciate, then, this opportunity to submit comment in the first round of PDASC cost review.

Our essential position is that price can affect any medical client by affecting the efficacy of medical care. The experience of our community in contexts with elderly and/or disadvantaged citizens is that expensive treatment courses equal health disparities; and higher medical cost distributed onto other care interventions.

When price is influenced chiefly by demand, as in a standard business model, "most expensive" can mean "most needed." The medications PDASC has selected for cost review are frequently prescribed for medical management of well understood health conditions. (I happen to take one myself but am fortunate to be adequately insured.) Our understanding of access to care informs us that pricing can affect medical benefit.

Our advocacy for more access to better care for more people in Maryland is familiar with the identification of pharmaceuticals as publicly authorized monopolies. Medicines go to market with FDA approval, typically granted as a product of federally funded research and assessment. Therefore, a publicly financed interest in efficacious medicine exists. That interest ought not be captured for private profit absent that public health benefit. The experiences of inadequate health care in our parishes duplicates what is the national health care crisis best summarized as, *we pay the most, get the least, and have the worst outcomes* among peer nation health projects. That is true for almost any clinical and pharmaceutical medicine.

Clearly, better is possible; for all of us, which is the sphere our community seeks to influence with its witness. We encourage the PDASC to look thoroughly into cost and pricing for medicines available in Maryland health commerce with particular attention to availability, necessity, and equity of outcomes. (And we join others in encouraging PDASC to adopt the part D Medicare Maximum Fair Price for any drugs in a review cycle.) *Appropriate, adequate, affordable health care for all people* is our goal.

Thank you for your attention, Lee Hudson, A2B, DE/MD

5699 Meridale Rd. Baltimore, MD 21228 410-230-2860 800-869-5492 fax 410-230-2871

Amit “Mickey” Dhir
Baltimore, MD 21202

May 15th, 2024
Maryland Prescription Drug Affordability Board (PDAB)
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Board,

I am writing to you today as an HIV clinician who has worked in the trenches for over 8 years, serving the most underserved populations in Baltimore City. I see the daily struggles my patients face, and I am deeply concerned about the potential impact of restricting access to Biktarvy.

Biktarvy is a single-tablet regimen (STR) that is highly effective, well-tolerated, and has a high barrier to resistance. It combines bictegravir, emtricitabine, and tenofovir alafenamide, three active drugs, into one pill, simplifying daily intake and improving adherence. This reduces the risk of resistance development and treatment failure, which are critical concerns in HIV management as highlighted in the Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV.[1] Biktarvy's high barrier to resistance, demonstrated in studies like the GS-US-380-1489[2] makes it less likely to fail due to missed doses, addressing a significant challenge for vulnerable populations facing issues like homelessness and substance abuse. Additionally, Biktarvy has minimal drug interactions, making it a favorable choice for individuals with comorbidities and polypharmacy, a common scenario among people living with HIV. These qualities align with the DHHS guidelines' recommendations for initial regimens, prioritizing efficacy, tolerability, and resistance barriers.[1]

The proposed therapeutic alternatives to Biktarvy listed by the board fall short in comparison. Triumeq, while an STR, carries the risk of severe hypersensitivity reactions (up to 5% of patients[3]) and increased cardiovascular risks due to the inclusion of abacavir.[4] Genvoya, another STR, has a lower barrier to resistance compared to bictegravir and numerous drug interactions due to its boosting agent, cobicistat, making it less effective and potentially harmful for patients taking other medications.[1] Stribild, similar to Genvoya, also contains cobicistat, complicating its use and lowering its barrier to resistance.[1] Descovy, although a component of Biktarvy, is not a complete regimen and would need to be combined with other medications like Tivicay, increasing pill burden and complexity.[1] Isentress, Reyataz, and Prezista are older medications that require combination therapy or boosting agents, leading to increased pill burden and potential drug interactions.[1] Efavirenz, while cheaper, has a high rate (over 50%) of intolerable side effects, including neuropsychiatric changes, and a very low barrier to resistance, making it a less desirable option.[1,5] Pifeltro, like Descovy, is not a complete regimen and requires additional medications.[1]

Restricting access to Biktarvy would not only harm my patients but could also lead to increased healthcare costs. If patients are forced to switch to less effective or less tolerable medications, they are more likely to develop resistance, experience treatment failure, and require more

complex and expensive regimens. Additionally, the increased risk of side effects and drug interactions with alternative medications could lead to hospitalizations and other costly interventions. According to a study published in the Journal of Acquired Immune Deficiency Syndromes, treatment failure due to resistance can increase the lifetime cost of HIV care by over $200,000.[6]

I understand the board's concern about the cost of Biktarvy, but I urge you to consider the broader picture. Lowering the price of a medication does not automatically translate to increased affordability and access, as evidenced by the limited impact of Truvada becoming generic on PrEP coverage in Maryland, which remains below 20%, far from the national EHE goal of 50% by 2025. Instead of focusing solely on price, I urge the board to adopt an equity-based approach to access. This means considering the unique needs and challenges of different patient populations, including those who have been historically marginalized and ignored. I would like to see more transparency from the board on what equity-based framework is being used to inform this work. What does equity mean to PDAB? What are the specific metrics and goals being used to assess equity in access to HIV medications?

Furthermore, I would like to have more information on the modeling that has been done to show that lowering the price of Biktarvy will increase access and viral suppression. If there is one, what are the assumptions behind this modeling? How does it account for the complexities of HIV care and the barriers faced by different patient populations? It's crucial to understand the potential unintended consequences of reducing access to a preferred regimen like Biktarvy, such as increased transmission rates due to treatment failure and the emergence of drug-resistant strains.

As an HIV clinician working directly with patients, I see firsthand the impact of decisions made by stakeholders who may not fully understand the complexities of our communities. When we make decisions without considering the lived experiences of our patients, we fail them. We become the barriers to their care.

In conclusion, I urge the board to carefully consider the potential consequences of restricting access to Biktarvy. This decision could have a devastating impact on the lives of my patients and the broader HIV community in Maryland.

Thank you for your time and consideration.

Sincerely,

Mickey Dhir (He/Him/His), MSN, MBA, AGPCNP-C, AAHIVS
HIV Specialist
Baltimore, MD

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FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff,

We appreciate the opportunity to provide public comment and thank the Maryland Prescription Drug Affordability Board (the Board) for the work done to determine the prescription drug selection and cost review processes to date. Families USA is a nonprofit consumer advocacy organization who, for more than 40 years, has been working towards achieving a health care system where everyone has equitable access to high quality health care and good overall health. Central to this mission is the ability for people to access and afford their lifesaving and life-sustaining medications.

States play a critical role in reining in prescription drug costs for individuals and families, and Families USA is grateful that through your work on the Board, Maryland is taking important steps to address the prescription drug affordability crisis those in the state are grappling with today.

Medication unaffordability is at a critical level, driven by high and rising prices when a drug is initially put on the market, combined with year over year increases at rates far outpacing inflation.[1] And now, nearly half of all Marylanders report being worried about the cost of prescription drugs, and nearly 1 in 4 report being forced to not fill a prescription or ration medication due to cost.[2] The ability to identify which drugs are having the biggest financial impact on families – at the pharmacy counter and beyond – and to ensure better reimbursement rates through an upper payment limit (UPL) are essential steps to providing families needed relief from high and rising drug costs.

As the Board continues its crucial work for the remainder of the year and beyond, we offer the following recommendations to ensure these efforts ultimately achieve lower prescription drug prices for families, including:

1. Taking a broad look at factors beyond pharmacy-specific costs, such as impact on health insurance premiums, into account in assessing affordability of drugs in the state.
2. Applying Medicare's negotiated rate (when applicable) to help set UPLs.

Considering Affordability Implications Beyond Pharmacy Costs

The Board is committed to evaluating and understanding the cost of prescription drugs to families, individuals, and the state, but the cost of drugs can have an impact far beyond the price someone pays at the pharmacy counter. The Board already considers critical factors such as the wholesale acquisition cost, rebates, net prices, and patient copay, when

conducting their affordability review – all of which are important aspects of how the total cost of a medication affects the consumer and how the system experiences drug prices.[3]

But as high and rising drug prices drive up health care costs for people at the pharmacy counter, they also drive up health care premiums and deductibles, and are often experienced in the form of reduced wages. For example, for people with employer-sponsored health insurance, increased prices charged by drug companies for their drugs become part of the costs analyzed by actuaries to establish updated health insurance premiums. Those premiums accrue to *all* people within an insurance pool, regardless of whether those enrollees take prescription drugs. Currently, around 20% of insurance premiums are driven by prescription drug prices.[4]

Put simply, we all end up paying the price for drug manufacturer greed, whether or not we take a prescription drug.[5] And those of us who do rely on prescription medication for our health get hit in multiple ways, first at the pharmacy counter and then again through the broader impact of drug prices on health care costs and affordability of health care coverage.

Families USA therefore encourages the Board to thoroughly and consistently consider the impact of high drug costs beyond the bounds of pharmacy costs alone. Elements such as the drug price's impact on premiums, deductibles, and total cost to the state should all be included in the cost review and affordability determination to truly reflect the impact of prescription drug prices on Maryland's families and individuals.

Applying Medicare Negotiated Rates

Following the affordability review, the Board has the vital role of establishing UPLs – limiting the amount some plans will reimburse for drugs that the Board has determined to be unaffordable.[6] Earlier this year, the Board named eight drugs for consideration in a cost review, many of which are used to treat ongoing or chronic conditions. Medicare is currently conducting their own reviews of certain prescription drug prices as part of the Medicare negotiation process. Two of the drugs the Maryland PDAB is reviewing, Farxiga and Jardiance, are among the first 10 drugs named by the Center for Medicare and Medicaid Services (CMS) that Medicare will negotiate the cost of. The final negotiated rate that Medicare will pay will be announced by September 1, 2024 and go into effect in 2026.

Families USA believes that the Board should utilize these final Medicare negotiated rates when determining a UPL for these two medications, as well as for medications in future years that are identified for Medicare negotiation. When CMS announces the final negotiated rate, they will include justification for the price determination. This information should also be helpful to the Board in evaluating and justifying their UPLs. Minnesota has

written this practice into their PDAB authorizing legislation, requiring that their Board use the Medicare maximum fair price as the state's UPL when the drugs overlap.[7]

Families USA believes the work done by CMS to evaluate drug prices and set a fair rate will be helpful to the Board in their work considering reasonable and affordable costs and the Board should take advantage of their mutual interest with CMS in lowering drug prices for people and the health care system whenever possible.

Conclusion

Families USA believes that it is critical the Board continue their work as efficiently and effectively as possible. The Board is undertaking a key role to reduce the cost of drugs for millions of Marylanders and continues to be a leader among states working to find their own solutions. Families all across Maryland are counting on this work to make their health care more affordable, and policymakers throughout the state legislature are looking to the Board to complete its work in a timely manner so they can build upon the program to help even more families afford lifesaving medications.

Thank you for the opportunity to comment and for the important steps the Board continues to take for Maryland families and individuals. If there are any questions about Families USA's work to reduce prescription drug prices or our recommendations submitted today, please contact Bailey Reavis (Breavis@familiesusa.org).

Sincerely,

Yael Lehmann

Interim Executive Director

---

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May 10, 2024

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

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

Re: Reasons Biktarvy Should Not Be Selected for a Cost Review

Dear Members of the Prescription Drug Affordability Board:

I am writing on behalf of Gilead Sciences, Inc. ("Gilead"), in response to the Prescription Drug Affordability Board's ("PDAB") recent referral of Biktarvy® to the Stakeholder Council for input into whether Biktarvy should be selected to undergo a cost review and identification of proposed therapeutic alternatives for Biktarvy®, as well as to comment on unintended consequences of a UPL, and provide process recommendations.[1] 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.

Gilead previously submitted letters to the Maryland PDAB and Stakeholder Council explaining that Biktarvy should not be selected for cost review because Biktarvy is already affordable and accessible for Marylanders with HIV. These letters also addressed that imposing a UPL on Biktarvy could result in treatment delays and interruptions, which could also result in an increase in the amount of HIV virus in the blood, leading to worse clinical outcomes and development of resistant forms of the virus. A UPL on Biktarvy would thus not only be unnecessary in light of Biktarvy's affordability but could also result in Maryland facing increased healthcare costs and would undermine efforts to end the HIV epidemic, pose an undue risk to public health, and disproportionately affect vulnerable populations. These effects conflict with the Moore Administration's goal of ensuring health equity in Maryland.

This letter builds on the points made in Gilead's prior letters by providing additional information on:

<u>Reasons that Biktarvy is clearly differentiated from other HIV medicines:</u>

- HIV drugs have unique clinical and pharmacological qualities that need to be considered when selecting the most appropriate regimen for a person with HIV, in order to support better medication adherence, improve viral suppression, and reduce the risk of transmitting HIV.
- There is longstanding recognition in public programs that patients need access to the particular HIV medication that was prescribed for them, and that one HIV product cannot simply stand in for another.

- Biktarvy offers a single-tablet regimen that is highly effective, supports rapid start, provides a high barrier to drug resistance, and demonstrates exceptional tolerability and safety; therefore, other HIV drugs are not appropriate comparators for the cost-review process.

Reasons Biktarvy should not be selected for a cost review:

- Biktarvy is affordable and accessible to people with HIV in Maryland.
- The State is overestimating its spending on Biktarvy.
- Maryland's Medicaid program has access to unique lower drug pricing, specially determined for its low-income and disability-eligible enrollees. Policies that would disrupt Medicaid's exclusive access to protected pricing would also disrupt the stability of Maryland's Medicaid program for its most vulnerable patients.

In addition, the process of selecting drugs and conducting cost reviews should be fair, reasoned, and transparent while allowing for meaningful engagement from Gilead and other stakeholders.

***

I. HIV drugs have unique clinical and pharmacological qualities that need to be considered when selecting the most appropriate regimen for a person with HIV in order to support better patient medication adherence, improve viral suppression, and reduce the risk of transmitting HIV.

HIV is a uniquely challenging virus to treat, making HIV medicines especially poor candidates for the cost-review process. HIV aggressively replicates at a rate of one billion new viral particles per day, overwhelming and simultaneously destroying the immune system by targeting the $CD4^+$ T cells needed for a proper immune response.[2] Effectively targeting viral replication requires combining multiple drugs with different mechanisms of action, and this highly individualized approach has been critical to transforming a once-deadly disease into a manageable, chronic condition with minimal impact on life expectancy.[3]

Because of the complexity of treatment, antiretroviral therapy (ART) must be selected taking into consideration both clinical considerations and the ability of a treatment regimen to fit into an individual's overall healthcare experience and effectively support their adherence. For this reason, the U.S. Department of Health and Human Services (DHHS) *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV* states that "selection of a regimen should be individualized" for a particular patient based on factors such as virologic efficacy, toxicity, potential adverse effects, pill burden, dosing frequency, drug–drug interaction potential, resistance-test results, comorbid conditions, and childbearing potential."[4] In addition, studies show that, as people with HIV age, they are more likely to develop additional health issues and tend to develop them earlier than people who do not have HIV.[5,6] This often means they must take multiple medications and may be more prone to drug-drug interactions from medications for different conditions, particularly when their HIV medication includes certain components. When individuals take their medication as prescribed, such adherence prevents HIV from multiplying, which suppresses the HIV virus.[7] Viral suppression stops HIV infection from progressing,

helping people living with HIV stay healthy and live longer, and maintaining an undetectable viral load also effectively eliminates the risk of sexually transmitting the virus to an HIV-negative partner.[8]

Effectively managing HIV infection requires vigilance to avoid creating treatment resistant mutations, which reduce the efficacy of ART. Mutations are more likely to develop in patients with suboptimal adherence to treatment regimen and in patients who are given a regimen with a lower genetic barrier to resistance, including patients whose access to treatment is disrupted by policy interventions. Specific resistance mutations may create the need for varied combinations of medications, which may require taking more pills or otherwise be more inconvenient to take. Thus, given the possibility that resistance could develop to any single drug, it is essential to have a diverse artillery of ARTs available for all patients. The ARTs recommended by DHHS for most patients are those that effectively suppress the virus, have a high barrier to resistance, have minimal adverse events, and are simple to take. The importance of adherence, risk of transmission and HIV drug resistance means that the HIV landscape thus poses unique challenges that make the cost-review and UPL approach particularly inapt.

II. There is longstanding recognition in public programs that patients need access to the particular HIV medication that was prescribed for them, and that one HIV product cannot simply stand in for another.

The Centers for Medicare & Medicaid Services (CMS) recognizes the need for individual treatment in the context of Medicare Part D. With respect to antiretrovirals, CMS has stated there are a "number of multiple drug combinations and adjunctive therapies involved," drug protocols are subject to change, and changing drug resistance plays a role "in determining the selection of among the different antiretroviral drugs."[9] Moreover, CMS has acknowledged that "[t]he need to adjust specific combination antiretroviral therapy in real time is complex and must consider, among other things, viral sensitivity to the drugs, drug interactions, pregnancy status (if applicable), and potentially the patient's pharmacogenomic profile of the cytochrome P450 system."[10] For these reasons, CMS does not allow plans to implement any form of utilization management for antiretrovirals in Medicare Part D.

At the state level, Maryland's Integrated HIV Prevention and Care Plan for 2022-2026 identifies statewide needs to increase both community knowledge and provider education regarding treatment options (always mentioned in plural) and the benefits of ongoing HIV treatment.[11] Simply put, effective treatment regimens must take into account and be formulated according to patient-specific factors.

III. Biktarvy offers a single-tablet regimen that is highly effective, supports rapid start, provides a high barrier to drug resistance, and demonstrates exceptional tolerability and safety; therefore, other HIV drugs are not appropriate comparators for the cost-review process.

Biktarvy, a single-tablet regimen ("STR"), is an "AI" recommended treatment for most people to start on for treatment of HIV under the U.S. Department of Health and Human Services (DHHS) guidelines. Recommendations in DHHS guidelines are based on scientific evidence and expert opinion. Each recommendation statement includes a letter (A, B, or C) that represents the strength of the recommendation and a Roman numeral (I, II, or III) that represents the quality of the evidence that supports the recommendation.[12] The DHHS recommendation means that Biktarvy has demonstrated durable virologic efficacy, a favorable tolerability and toxicity profile, and is easy to use.[13] There are only three other regimens that received a "AI" recommendation for initiating HIV treatment in these guidelines, and Biktarvy has been shown to have specific advantages over each. While Maryland's PDAB statute and regulations state that certain factors regarding "therapeutic alternatives" should be considered "to the extent practicable," the proposed "therapeutic alternatives" list that the Board has identified as potential cost-comparators for Biktarvy contains regimens requiring multiple pills, medications that are not guideline-recommended, and medications that undervalue the clinical value that Biktarvy offers compared to previous generations of treatments. If the Board must use comparators for Biktarvy in the context of the State PDAB cost review, it should only focus on single-tablet regimens. Even focusing on these, Biktarvy is clearly differentiated as outlined below.

<u>Biktarvy offers a complete regimen in a single tablet</u>

In order to suppress the HIV virus, multiple antiretrovirals with different mechanisms of action must be combined to make what is considered a complete regimen. A single-tablet regimen (STR) includes multiple agents to treat HIV in one tablet and is approved as a complete regimen to treat HIV. A multi-tablet regimen, on the other hand, is one that combines multiple different medications across multiple pills taken separately, sometimes with different dosing intervals. Patients on STRs like Biktarvy have higher rates of adherence to HIV treatment and, subsequently, higher rates of achieving undetectable levels of virus in the body compared to patients on multi-tablet regimens ("MTRs").[14,15,16] This is because some patients may have difficulty adhering to complex treatment regimens due to factors such as the number of pills, dosing schedule, and dietary restrictions. As such, though MTR therapeutic alternatives may exist for a specific patient, this does not mean such alternatives represent the best choice to assure meaningful personal and public health outcomes for that patient. By improving treatment adherence and persistence, patients on STRs like Biktarvy are expected to better control their HIV, resulting in decreased rates of hospitalization and lower overall healthcare costs.[17,18,19,20,21] The majority of drugs identified by Maryland as potential alternatives for Biktarvy are not complete single tablet regimens for the treatment of HIV and therefore are inappropriate comparators.

Biktarvy supports rapid start

Biktarvy can be started immediately after HIV diagnosis— known as "rapid start" of HIV treatment—before results of recommended resistance testing or baseline laboratory testing are available.[22] Rapid start is not only associated with rapid suppression of the virus, but is also linked to individual receiving ongoing treatment for their HIV at higher rates.[23,24,25,26,27,28] Biktarvy is the only unboosted single-tablet option that is recommended by the DHHS for rapid start.[29]

Biktarvy has a high barrier to resistance

HIV can develop resistance to certain medications if they are not taken consistently and correctly, particularly with medications with a lower barrier to resistance. Once resistance develops, certain medications may no longer be effective against the resistant strain, leading to treatment failure and reduced treatment options. Biktarvy has a high barrier to resistance due to its unique pharmacokinetic and pharmacodynamic properties. For example, it is the only unboosted STR label-indicated and DHHS-recommended for patients with pre-existing M184V/I, an HIV resistance mutation seen in a large share of viruses tested for resistance in persons who have been on HIV treatment.[30]

Biktarvy is approved across broad populations

Furthermore, unlike other guideline-recommended STRs for treatment initiation, the efficacy and safety profile of Biktarvy have been evaluated in people living with HIV who have hepatitis B virus (HBV) coinfection, an infection which is 10-20 times more prevalent in the HIV population, and disproportionately prevalent in select subpopulations, such as persons who inject drugs.[31,32,33] Biktarvy is approved for individuals with end stage renal disease on chronic hemodialysis with history of treatment and pregnant women switching treatments, differentiating it from other STRs considered as potential therapeutic alternatives by the Board.[34]

For these reasons and many others, there are no true therapeutic alternatives for Biktarvy, which is uniquely proven to work across many diverse populations, with a high barrier to resistance and lower risk of producing viral resistance, and recommended for rapid start. The proposed therapeutic alternatives do not provide appropriate cost comparators for Biktarvy, as summarized in Table 1.

Finally, although the PDAB has posted a list of proposed therapeutic alternatives for Biktarvy on its website, the PDAB has not identified the criteria for selecting them. Accordingly, the basis for the identification of these drugs as therapeutic alternatives for Biktarvy is unclear. Further, because no UPL Action Plan has been published, it is unknown how the PDAB will use or consider any data concerning the proposed therapeutic alternatives. This lack of clarity limits stakeholders' ability to offer meaningful guidance.

Table 1: Biktarvy and Therapeutic Alternatives Proposed by the Board

Biktarvy and Proposed Therapeutic Alternatives	DHHS AI Recommended as Initial Regimen for Most People with HIV	DHHS Recommended Single Tablet Regimen for Rapid Start	Reported Treatment-Emergent Resistance in Clinical Trials**	DHHS Recommended for HIV & HBV coinfection
Biktarvy	Yes	Yes	None	Yes
Triumeq	Yes	No	Yes	No
Genvoya	No	No	Yes	Yes
Stribild	No	No	Yes	Yes
Dovato	Only in individuals with HIV RNA <500,000 copies/mL, with no HBV coinfection	No	Yes	No
Descovy*	Only in combination with another agent	N/A	Yes	In combination with a 3rd agent
Tivicay *	Only in combination with 2 other agents	N/A	Yes	Only if combined with tenofovir + a 3rd agent
Isentress *	No	N/A	Yes	No
Reyatz *	No	N/A	Yes	No
Prezista *	No	N/A	Yes	No
Pifeltro *	No	N/A	Yes	No
Sustiva *	No	N/A	Yes	No

*Incomplete regimens. Cells shaded in gray are NOT complete regimens and must be combined with other agents. A complete antiretroviral therapy regimen combines two to three antiretrovirals with different mechanisms of action to suppress the virus. The first five drugs on this table are combination products made up of multiple agents with different mechanisms.
** Based on Gilead studies

IV. Biktarvy is affordable and accessible to people with HIV

The PDAB's current UPL authority extends to drugs that are "[p]urchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government," "[p]aid for through a health benefit plan on behalf of a unit of State or local government," and "[p]urchased for or paid for by the Maryland State Medical Assistance Program."[35] Below we address affordability and access in each of these market segments.

- Maryland Medicaid: Enrollees in Maryland's Medicaid program who rely on Biktarvy fill their prescriptions for no more than $1. Furthermore, Maryland Medicaid does not generally currently require a prior authorization, in which a provider must provide documentation about why a medicine is needed, before patients are able to receive medicine to treat HIV. This means that people with HIV can obtain treatment in a timely way based solely on the recommendation of their doctor and without bureaucratic hurdles.

- State or local government health benefit plan: The vast majority of 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 with HIV can receive Biktarvy at the lowest cost-sharing amount for a branded drug. For instance, the State of Maryland prescription benefits administered through CVS Caremark have between $15-$25 copayment for preferred brand drugs for a 45-day supply.[36] If these individuals nonetheless face challenges affording their medicines, Gilead's Advancing Access® program may be available to reduce or eliminate out-of-pocket costs.[37]

On top of these programs, Marylanders with HIV can benefit from additional assistance through the Ryan White HIV/AIDS program (Ryan White) administered by the Health Resources and Services Administration (HRSA). Ryan White helps low-income people with HIV access medicines, medical care, and support services by providing grants to cities, states, counties, and community organizations. Ryan White has five parts, and Part B includes the AIDS Drug Assistance Program (ADAP), which supports access to medicines.[38] Maryland's AIDS Drug Assistance Program, or "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. [39,40] 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. These affordability protections are unique to HIV treatments, which makes the cost-review process uniquely unnecessary for Biktarvy and other HIV medicines.

The Maryland PDAB was set up to protect Marylanders from the high costs of prescription drugs. Based on the information presented, selecting Biktarvy for cost review would be an ineffective use of the Board's resources and time as it is already affordable for Marylanders.

V. 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 as candidates for potential cost-reviews.[41] Because the public has neither access to the data or full dashboard supporting this database nor 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 lack of disclosure of the information on which the PDAB is relying is particularly concerning because of several inconsistencies between "sample database" data and Gilead's data for Biktarvy.

- Maryland's "sample database" grossly overestimates total spend in Commercial and Medicare compared Gilead's own sales data. This is concerning because one of the selection criteria, which resulted in Biktarvy's consideration for potential cost review, is "highest total spend in the most recent available calendar year."
- Maryland did not publish Medicaid data, one of the main populations of interest for the UPL, leaving open the question of whether data being used to assess Biktarvy's affordability in this segment is also inaccurate.
- Gilead compared Biktarvy's patient out-of-pocket (OOP) costs in the "sample database" with IQVIA's Longitudinal Access and Adjudication Data (LAAD), an industry gold standard dataset for patient claims data.[42] The All-Payer Claims Database (APCD), which the Board relied on in identifying drugs for as cost review candidates, significantly overestimates final patient OOP costs. The APCD does not take accurate account of secondary benefits, such as manufacturer cost-sharing assistance, Medicare payments for dual-eligible patients, and MADAP payments that offset a portion of the patient's costs. As a result of the Board's reliance on the APCD, the Board's dashboard overestimates the patient OOP costs for Biktarvy by approximately 8 times for the commercial segment and by approximately 3 times for the Medicare Part D segment when compared to IQVIA's LAAD. Continuing to rely on the APCD in making affordability determinations would be a profound mistake, resulting in erroneous determinations.
- The "sample database" lacks consistency as the data years for each market segment is different (2022 for commercial and 2020 for Medicare). Moreover, the "sample database" does not include all data reportedly included in the non-public version of the dashboard, which purportedly included 2021 data for Medicaid.[43] This raises questions about how the board is considering "the most recent available calendar year" and weighting data from different sources and years.

These inconsistencies, lack of transparency, and inaccuracies in the "sample database" create doubt about whether Biktarvy should have been selected for potential cost review.

VI. Maryland's Medicaid program has access to unique lower drug pricing, specially determined for its low-income and disability-eligible enrollees. Policies that would disrupt Medicaid's exclusive access to protected pricing would also disrupt the stability of Maryland's Medicaid program for its most vulnerable patients.

Medicaid programs currently pay no more than the "best price" for which Biktarvy is sold to most purchasers in the United States, consistent with federal law. Under the Medicaid Drug Rebate Program, Gilead and other manufacturers enter into national rebate agreements with the federal Secretary of Health and Human Services in exchange for Medicaid coverage of their prescription drugs. Under these agreements, manufacturers provide a mandatory rebate that results in Medicaid programs receiving a net price that is no more than the lowest price at which a manufacturer sells its product in the commercial market. Certain providers that serve uninsured or underinsured people living with HIV – including Ryan White HIV/AIDS Program grantees and federally qualified health centers – also can access HIV drugs through the 340B drug discount program at a price that reflects the Medicaid "best price."

Such pricing guardrails, specific to the Medicaid program, ensure that eligible patients with low incomes have access to care. Special considerations that are unique to the Medicaid program and its enrollees inform pricing policies in this specific context. These considerations are not appropriately extended to other purchasers or payer types covering different populations, such as commercially sponsored or employer-sponsored health benefits. For example, HIV products such as Biktarvy are disproportionately provided at the Medicaid "best price" compared with other prescription drugs because HIV is more prevalent among low-income, historically marginalized, and minority populations – who are also more likely to be covered by Medicaid or receive their medicines from 340B providers. To illustrate, forty percent of nonelderly adults with HIV are covered by Medicaid, compared to only fifteen percent of nonelderly adults overall.[44] Similarly, IQVIA found that the share of sales accounted for by 340B were twice as high for antivirals as for drugs overall.[45]

If Maryland were to impose a UPL on an HIV medicine that would change the dynamics around Medicaid's access to a unique "best price," such changes would impact and potentially disrupt drug access not only for Medicaid enrollees in Maryland but possibly other patients in Maryland with different coverage as well. The impact of such changes in public policy could be particularly harmful for patients enrolled in Medicaid, in addition to being economically unsustainable for pharmacies, providers, or manufacturers, resulting in disruptions to patient access—as can be seen in other countries where government price setting has resulted in reduced patient access and comments submitted by pharmacies and community health centers.[46] And this disruption would occur without improving affordability for Marylanders with HIV because Biktarvy is already affordable to those insured by Medicaid or other populations where the UPL would apply.

Given the potential for perverse consequences, Gilead urges the PDAB to take caution and avoid disrupting care for people living with HIV by declining to select Biktarvy for cost review. Additionally, the Board should finalize and approve its UPL Action Plan as required in statute

before drugs are selected for cost reviews. This will help ensure that unintended consequences of a UPL can be further assessed.

VII. The process of selecting drugs and conducting cost reviews should be fair, reasoned, and transparent while allowing for meaningful engagement from Gilead and other stakeholders.

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 public stigma often associated with HIV and the socioeconomic barriers that confront many people living with HIV. In addition, a 90-second speaking allotment for live public testimony during meetings is not enough time for stakeholders to offer substantive comments.

Moreover, the Board's opportunities for public comment arise arbitrarily and unpredictably, with comment windows often opening upon the Board's taking of certain actions (such as posting particular information on the website) that are not scheduled or announced in advance. That was the case with respect to the comment windows for letters responding to the list of proposed therapeutic alternatives and the list of drugs referred to the Stakeholder Council for input. As a result, stakeholders do not know in advance when a comment window will be open, which makes planning challenging, particularly when the Board does not update its website regularly and uses the listserv only occasionally or belatedly. Any 30-day comment period is generally too short for most stakeholders to prepare and engage meaningfully, but the uncertainty of when the 30-day period will begin and close creates additional process concerns.

The PDAB and the Stakeholder Council must also provide manufacturers with a meaningful opportunity to weigh in before the PDAB makes decisions. Manufacturers can offer a unique and valuable perspective to the PDAB. They can correct or clarify outdated or incomplete data, explain technical details, and contextualize information about the drug at issue. In selecting eight drugs for potential cost reviews, the PDAB failed to provide manufacturers and other stakeholders with an opportunity to serve this critical role. Instead, the PDAB selected drugs for discussion in private, based on a vague and unpredictable methodology, and in reliance on data that it has not made available to the public and which appears to be inaccurate. In addition to potential concerns regarding Maryland's Open Meetings Act,[47] this approach deprives manufacturers of a meaningful opportunity to comment on the inclusion of their drugs on the initial drug list. The PDAB should address this issue and ensure that Gilead has an opportunity to meaningfully participate in the selection and (if necessary) the cost review process going forward.

Lastly, the PDAB has not made recordings of its meetings available to the public, despite multiple requests by members of the Stakeholder Council and concerns raised by the General

Assembly. Other State PDABs do provide this tool. Given these potential barriers, the PDAB's current process does not allow for meaningful patient and other stakeholder engagement in the process.

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Biktarvy is the only unboosted single tablet HIV regimen that is recommended by DHHS guidelines for use in rapid start. It better supports adherence and persistence than other HIV drugs.[48,49,50] It is also the only STR FDA-approved and DHHS-recommended for patients with pre-existing M184V/I, a common resistant mutation, in people who have been taking HIV medicines. And, unlike other guideline recommended STRs for starting treatment, Biktarvy has been studied in people living with HIV who have hepatitis B virus coinfection and pregnant women. To give people with HIV in Maryland confidence that they will be able to continue accessing Biktarvy, Gilead urges the PDAB not to select Biktarvy for a cost review.

Sincerely,

DocuSigned by:
Kristie Banks
3B4BECBA5AB74F3...

Kristie Banks
Vice President, Managed Markets
Gilead Sciences, Inc.

DocuSigned by:
Betty Chiang
DE32260A4A3E4AA...

Betty Chiang, M.D.
Vice President, Medical Affairs
Gilead Sciences, Inc.

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prolonging their presence in the body. Unboosted regimens tend to have fewer drug interactions due to the fact that boosters affect not only the metabolism of HIV drugs but other medications as well.

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[40] https://alivemaryland.org/wp-content/uploads/2022/08/MADAP-FAQ-082922A.pdf

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HIV + HEP
POLICY INSTITUTE

May 14, 2024

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

Dear Prescription Drug Affordability Board 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, we have long advocated for affordable access to prescription medications.

While we are supportive of the Maryland Prescription Drug Affordability Board (PDAB) goal of improving treatment affordability, we urge PDAB members and staff to address concerns surrounding access to provider-recommended HIV treatments at the individual level and the impact on broader public health goals and provide clarity around the affordability review process to enable meaningful community input.

We appreciate the opportunity to provide further comments to the Board as you carry out your work (see our letter of April 2024 and testimony of March 2024). As the Board considers the affordability of an initial list of eight prescription drugs, including a treatment for HIV, we urge Board members to consider the unique needs of the patient populations impacted by each treatment and the specific public health implications of interruptions to treatment. In addition, the PDAB must carefully consider the ramifications of recommending therapeutic alternatives for HIV treatments and the unique impact of such decisions on those living with HIV and broader public health.

Address Access Concerns
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 cases of HIV in the state. Along with diagnoses being concentrated by

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

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]

During a recent stakeholder meeting, PDAB staff suggested that concerns around access to HIV treatments would be addressed throughout the Board's process. However, an upper payment limit action plan has not been released so we cannot review it to determine any potential impact on the treatment and care of HIV/AIDS.

As the PDAB continues to develop the process for conducting affordability reviews and potentially setting a UPL on selected drugs, patient perspectives must be kept central to the conversation to ensure that access barriers are avoided and do not negatively impact the health of individuals and the broader public.

Support Access to Provider-Recommended Treatments

Patients work closely with their healthcare providers to identify the best course of treatment for them based on their unique individual circumstances. Treatments other than those recommended by a provider may not be as effective for a patient 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.

As the PDAB considers therapeutic alternatives for the HIV treatment selected for review, it is critical to recognize the unique nature and complexity of HIV compared to other therapeutic areas. People living with HIV are at greater risk of developing additional health issues and co-morbidities than those with other complex conditions. Individuals with HIV often must take multiple medications and may be more prone to side effects and drug-drug interactions from medications for different conditions, making therapeutic alternatives to the treatment their doctor prescribed not always effective within the broader context of their healthcare needs.

Moreover, threats to timely access to recommended treatments for HIV can enable resistant viruses to progress and complicate ongoing care for those living with HIV and co-morbidities—leading to greater strain on Maryland's healthcare system. Consistent access and adherence to HIV treatment and care can result in lower rates of hospitalization and system-wide costs.

Recognize the Current Affordability of Treatments for HIV/AIDS

The Board must acknowledge that drug affordability is also directly related to existing assistance programs by both the federal and Maryland state governments and drug companies. For example, the federal Ryan White AIDS Drug Assistance Program currently provides medications or purchases insurance for nearly 6,000 people living with HIV in the State.

In March 2024, the Maryland Department of Health provided updated guidance to Medicaid managed care organizations (MCOs) around pharmacy copayments and cost-sharing for HIV medications. The guidance requires Maryland HealthChoice MCOs to charge a low and affordable copayment of $1.00 for

[3] Maryland HIV County Overview Dashboard

HIV/AIDS drugs.[4] This updated guidance builds upon previous actions taken at the state and national levels, as well as from manufacturers, that help keep treatments for HIV/AIDS affordable for Marylanders. 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.[5] Additional patient assistance programs are administered by individual drug companies provide financial support around the costs of HIV treatment to those who qualify.

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. As the Maryland PDAB looks to finalize the list of drugs selected for affordability review, we urge the Board not to include treatments for HIV given the unique nature of the therapeutic area and the risk of significant individual and public health implications should treatments be interrupted.

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

[4] Maryland Medical Assistance Program MCO Transmittal No. 205

[5] 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

Imran Chowdhury, M.D. | Kody Modjtabai, M.D. | Ali Amjadi, M.D.

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CARE CENTER

10802 HICKORY RIDGE RD.
COLUMBIA, MD 21044

P: 410-997-7677 | F: 410-997-1636 | W: www.idcarecenter.net

May 13, 2024

RE: May Board Meeting Comments

To whom It May Concern,

As the Prescription Drug Affordability Board continues its consideration of Biktarvy its important to remember why this medication is the cornerstone of most of the HIV care in the state and the country.

I feel restricting Biktarvy use in favor of other agents that are not as effective or well tolerated is depriving certain Maryland residents of the best possible care and introducing secondary and inferior choices.

The reason Biktarvy is the leading medication on the market is because this one pill is comprehensive and can be given to all patients, is effective in almost all cases of HIV as well as very well tolerated.

Most of the medications that can be substituted for Biktarvy are deficient in one or more ways, whether in effectiveness, tolerability, or convenience (multiple pills a day).

I urge you to allow all Maryland residents access to the best HIV care and not just any HIV care.

Sincerely yours,

Kody Modjtabai, MD
Infectious Disease

May 13, 2024

Dear members of the Maryland Prescription Drug Affordability Board:

We are writing to address our concerns regarding the potentially significant negative impact of putting an upper payment limit on medications on people living with HIV in Maryland.

Biktarvy is the most prescribed medication for treatment of HIV in the United States. This is because it is a highly effective medication that combines 3 drugs into one tablet that is taken one time a day, an easy regimen to follow. Even with 3 drugs combined in one single tablet, it is a small pill that is easy to swallow, unlike some of the alternative drugs available. It has very few side effects compared to other HIV medications and very few drug interactions with other medications. Biktarvy also has a high barrier to resistance compared to other HIV medications, meaning patients who don't take their medication daily due to other life stressors (homelessness, mental health issues, drug use, etc.) are less likely to develop resistance to it.

The HIV medication alternatives are not equivalent to Biktarvy. Switching to a different drug may involve taking a bigger tablet, more than once a day, which is a harder regimen to follow. Some of the alternatives also have potentially serious side effects and the possibility of long-term negative effects. Many of the alternatives are also single drugs that require the patient to take at least one or more other drugs with them, increasing the pill burden and in turn increases the risk of poor adherence to medication. Pharmacies sometimes don't have all the medications in stock and will dispense just one of the drugs at a time and if they are not taken together, resistance may occur. Requiring a switch to alternative medications could also cause delays or interruptions in treatment.

HIV disproportionally impacts communities that are economically disadvantaged thus limiting their access to life saving resources. These health disparities compounded with the continued stigma surrounding a HIV diagnosis continues to isolate patients and further deter them from seeking care and support, which only continues to increase HIV transmission. A simple, single tablet, highly effective regimen help with adherence.

Biktarvy is also the only HIV medication that has indications for both pregnancy and pediatrics. A smaller dosage form was developed specifically for pediatric patients, and is once a day, which makes it easier for parents to give to children. It has been found safe to use during pregnancy as well.

We understand the council's intent to make medications more affordable, but also feel that by putting a cap on certain medications, without looking at the alternatives, could potentially cause increased costs in the long run. We hope you will carefully consider what negative impact changing access to Biktarvy could have on people living with HIV in Maryland.

Sincerely,

Susan Lovelace, MS, CRNP
Adolescent and Young Adult Center
University of Maryland
120 Penn Street
Baltimore, MD 21201
410-706-8732

UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE

PIPC Partnership to Improve Patient Care

May 13, 2024

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

Dear Mr. York:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Maryland Prescription Drug Affordability Board's ongoing Cost Review Study process. Our comments follow letters sent to the Board urging it to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment.[1] We are writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations.

On May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, protecting the rights of people with disabilities in programs and activities receiving federal financial assistance.[2] In response to the proposed rule last year, the Partnership to Improve Patient Care (PIPC) joined 100 organizations and individuals on a letter supporting agency rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care.[3]

The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG). The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating, "The Department interprets recipient obligations under the current language of § 84.57 to be broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to qualified individuals

[1] https://valueourhealth.org/wp-content/uploads/2021/08/MD-Letter-Final.pdf
[2] https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov
[3] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf

with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment." As you may be aware, section 1182 of the ACA bars Medicare's use of QALYs and similar measures that that discount the value of a life because of an individual's disability. PIPC was pleased that the final rules governing Section 504 would be interpreted as broader than the section 1182 statute.

The agency referenced both § 84.56 and § 84.57 as relevant to entities receiving federal financial assistance, which includes state Medicaid programs. For example, the agency stated, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability, among others." Therefore, it will be critical for compliance with these rules that the Board understand the methods for generating the utility weights in any clinical and cost effectiveness studies that it may be using to make decisions to ensure they do not devalue people with disabilities. As PIPC and others noted in its comments to HHS, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives that people with disabilities have a low quality of life.[4] Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

Alternatively, we would encourage the Board to engage directly with patients and people with disabilities to learn about their real-world experiences, consistent with recommendations from experts in the patient and disability communities.[5,6,7,8] We are also concerned about the transparency of the decision-making process by the Board and hope that the evidentiary basis for its decisions will be made public in a manner that is accessible and clear.

Thank you for your consideration of our comments.

[4] Ne'eman Et. Al, "Identifying and Exploring Bias in Public Opinion on Scarce Resource Allocation During the COVID-19 Pandemic," October 2022, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00504.
[5] https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf
[6] https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf
[7] https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf
[8] https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

Progressive Maryland's Impacted Members Urge You to Proceed!

1 message

Patty Snee <patty@progressivemaryland.org> Wed, May 15, 2024 at 4:46 PM
To: comments.pdab@maryland.gov

Dear Prescription Drug Affordability Board Members,

I write on behalf of our Executive Director, Larry Stafford, Jr. our grassroots members and leaders across the state, and our organizational affiliates who represent labor, community and social justice groups, to urge you to move forward with the cost review of the eight selected prescription drugs.

Marylanders from all walks of life and geographic regions are struggling with high-cost prescription drugs. Attached are the results of a recent survey we did with our members. In just a week's time fifteen of our foks shared with us how expensive drug prices are hurting their health and their family finances. Many more of our supporters have been in touch with us this year to express their outrage about the greed and price gouging of drug companies. They feel strongly as does our organization, that people, not profits, must be the priority in our healthcare system.

The stories of people cutting doses in half, waiting to get their prescriptions filled or leaving their medicines at the pharmacy because they cost
more than they can possibly afford are heartbreaking. We should not tolerate corporate practices that result in people not being able to get the treatment they need.

The Board can take significant steps to end the heartbreak by conducting the cost review and finalizing the Action Plan to implement UPLs for our state and local governments. Please make this happen! Time is of the essence.

Thank you for your consideration.

Sincerely,
Patty Snee

--
Patty Snee, she/her/hers
Lead, Statewide Healthcare Issues Campaigns
patty@progressivemaryland.org
[redacted]

5.15 Progressive Maryland's Prescription Dug High Cost Impact Survey 5.9-5.15 2024 final - Sheet1.pdf
135K

[redacted]

Progressive Maryland's High Cost Drug Survey		
Survey Results tracked from May 9th - May 15th, 2024 and submitted to PDAB on May 15th		
15 Member Stories		
PDAB List of Proposed 8 Drugs for Cost Review		
Biktarvy, Dupixent, Farxiga, Jardiance, Ozempic, Skyrizi, Trulicity Vyvanse		
Responses		
8 members who use or know someone who uses 5 of the 8 up for review:		
Ozempic, Vyvanse, Dupixent, Skyrizi, Jardiance		
7 Members mentioned other drugs:		
Restoril, Myrbetriq, Icosapent, Amlopidine, Actimmune, Bexarothene, Repatha		
Zip Codes of Survey Takers	21228, 21206, 21045, 21136, 21236, 21014, 21601, 21817, 21093, 20639, 21215, 21211, 20904, 20906	
Drug	**Impact**	
Ozempic	1. Very difficut to manage my A1C	
	2. Can't get it, insurance doesn't cover, too expensive to buy	
	3. Taking it as alternative to an even more expensive med to treat atheroclersis	
Vyvanse	1. Cost for 1 month is $380, more than 1/4 of my SSDI monthly check	
	this person's son takes it, too, but dose is 10 mg higher than insurance covers	
	so can't get it.	
	2. Unable to get generic brand due to shortage, brand-name is expensive	
	3. Switched to another prescription medicine due to costs and insurance not covering it	
Dupixent	4. Very hard to get the assitance program renewed, so it's hard to come up with the co-pay so the time lag means skipping doses	
Jardiance, Dupixent, Ozempic	In addition to my personal experience with Dupixent (see above) I'm family physician and have had patients stop some of these medicines b	
Skyrizi	Impact on Medicare Part D and supplemental	
Other:		
Actimmune, Bexarotene, Repatha	He takes all 3 and it has two main negative impacts: First, I spend between $4,000 and $5,000 a year on prescription co-pays. The co-pay f	
Amlodipine	Not impacted yet but concerned about future	
Icosapent	Very hard to manage when on a fixed income	
Myrbetriq	Challenging to budget for this	
Restoril	Very big impact on finances	
Skyrizi	Impact on Medicare Part D and supplemental	

REGENERON

May 15, 2024

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

RE: May Board Meeting Comments

Dear Members of the Maryland Prescription Drug Affordability Board,

Regeneron Pharmaceuticals Inc. ("Regeneron") appreciates the opportunity to submit comments to the Maryland Prescription Drug Affordability Board ("Board") regarding agenda item V "Select Drugs for Cost Review Study". Regeneron is the scientific force behind the development of Dupixent® (dupilumab), which gives us a unique perspective on the immense value it provides for patients and the significant investment that went into the research and development of the product. For the reasons we lay out below, we respectfully ask that the Board not conduct any cost review of Dupixent.

Regeneron is an American Company Dedicated to Bringing New Medicines to Patients in Need

Regeneron is a leading U.S.-based biotechnology company that invents, develops, and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

For more than 35 years, Regeneron's goal has been to use the power of science to bring new medicines to patients over and over again. We have fostered and maintained a long-term focus on bringing innovation to patients by investing our resources back into research and development of new technologies and therapies, and by pricing our products responsibly and ethically.

Regeneron Invests Significant Revenue into Research and Development of Innovative Therapies

We take a value-based approach to pricing our medicines that reflects their benefit to patients, society, and the healthcare system. We consider the long-term investment and risk inherent in science and technology innovation, which is required to bring novel medicines to patients. Regeneron has been committed to making substantial investments in research and development (R&D) to support the invention of needed new medicines for years to come.

In 2023, we invested approximately 34% of our revenue into R&D, amounting to $4.4 billion. Our support for patients extends beyond the lab to disease education and awareness efforts, product support services, and our commitment to access and responsible pricing. Dupixent, like all our medicines, is priced to reflect our medicines' value, and our commitment to patient access while minimizing our contribution to health care inflation.

REGENERON

Dupixent Treats Conditions with Significant Unmet Medical Need, Including for Certain Pediatric Patients

Invented by scientists at Regeneron, who partnered with Sanofi to develop the medicine, Dupixent is approved in the U.S. to treat five conditions associated with significant unmet medical need: eczema/atopic dermatitis, asthma, nasal polyps, eosinophilic esophagitis, and prurigo nodularis (PN). PN, for example, is a chronic inflammatory skin disorder resulting in intense itching and painful lesions on the extensor surfaces of the limbs and trunk. While there are several off-label treatments, there are no other FDA-approved systemic therapies for the treatment of PN. Dupilumab was approved by the US FDA in 2022 for treatment of adults with PN and remains the only FDA-approved treatment for the condition.

Another such condition is eosinophilic esophagitis, an orphan disease for which there were significant unmet medical needs, including for young patients. Despite existing treatment options, 40% of children with the condition in the U.S. under the age of 12 continue to experience symptoms of this disease. Dupixent is approved to treat eosinophilic esophagitis in many patients aged one year or older. It is also approved to treat atopic dermatitis and asthma in certain children. Dupixent has a demonstrated unprecedented safety profile in children as young as 6 months of age. Regeneron is bringing therapies to patients, especially young children, with unmet needs.

Dupixent Has Been Evaluated by an Independent Organization That Concluded Dupixent is Reasonably Priced

At its initial approval in 2017, Dupixent was evaluated as part of the drug class used to treat atopic dermatitis by the Institute for Clinical and Economic Review (ICER). At that time, ICER found the Dupixent net price to be "well-aligned with the added benefit it provides to patients. Dupilumab represents a good value for money." Since Dupixent launched, it has undergone reasonable and predictable price increases. Notably, ICER has never included Dupixent in their annual "Unsupported Price Increase Report." This ICER determination of value at launch, coupled with responsible price increases leads to the conclusion that Dupixent remains a good value to patients in need and to the system.

Regeneron Agrees with The Arguments Previously Presented by Sanofi for Why Dupixent Should Not Be Subject to a Cost Review, Including:

- **Dupixent is affordable for Maryland patients.** Although pharmaceutical manufacturers do not determine the amount that patients pay out of pocket at the pharmacy counter for their medication, most manufacturers, including Regeneron and Sanofi, provide significant copay assistance to help offset the costs Maryland patients pay for treatments. According to Sanofi, the average cost of Dupixent was $38.53 per script, with many patients paying as little as $0 copay per fill of Dupixent**.** The benefits of Dupixent – and the "good value for money" that ICER found – are not only realized by Maryland patients, but also by state health plans and Maryland Medicaid, which covers about 1.8 million people. Atopic dermatitis, for example, affects 13% of children and 7% of adults in the U.S.[1] Children and adults with atopic dermatitis experience more outpatient visits, emergency visits, and hospital admissions with prolonged hospitalizations

[1] See, e.g., Hua T, Silverberg JI. Atopic dermatitis in US adults: epidemiology, association with marital status, and atopy. Ann Allergy Asthma Immunol 2018;121(5):622–624.

compared to those without atopic dermatitis.[2] Successful treatment can help the system avoid some of the estimated direct and indirect costs associated with atopic dermatitis, which the National Eczema Association estimated to be greater than $5 billion annually.[3]

- **Over-emphasizing a medicine's list price will not improve patient affordability and will likely impede patient access.** 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 and pharmacy benefit manager (PBM), not the manufacturer of the medicine(s) their doctors prescribe for them. A focus on list price that results in a price control would not only likely impede access to medication but would also do nothing to improve patient affordability.

- **Dupixent represents exactly the type of innovation that public policy should protect.** Dupixent received an Orphan Drug designation from the U.S. FDA for eosinophilic esophagitis, which means that it was being studied and is now approved to treat a rare disease impacting 200,000 patients or less in the United States. There are more than 7,000 rare diseases that affect roughly 30 million Americans, or 1 in 10 of all Americans,[4] more than half of whom are children.[5] Congress passed the Orphan Drug Act in 1983 to incentivize investment in the development of treatments for rare conditions,[6] recognizing that "Some promising orphan drugs will not be developed unless changes are made…to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs."[7] The Orphan Drug Act has given millions of Americans with rare diseases hope for cures. Prior to passage of the Act, there were only 38 FDA-approved treatments for all rare diseases. After the Orphan Drug Act, the number of federally approved orphan drugs surged to more than 550 drugs that treat more than 1,000 rare disorders.[8] Still, only about 5% of rare disease have an FDA-approved treatment,[9] and the FDA has recognized that we need "significantly more drug development, not less," to find treatments for all rare diseases.[10] A price control on an orphan drug could have a chilling impact on rare disease innovation, as it would disincentivize other companies from taking the financial risks of orphan drug development. Additionally, Dupixent is still being studied in other indications that have no currently approved advanced therapies.

- **The Board has provided insufficient data for a complete response and has failed to follow a reasonable process.** The Board recently posted incomplete data on the eight selected drugs that is simply described as a "sample database that includes non-proprietary data and data that has been approved for public display." The data that the Board has provided does not address the

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[2] See, e.g., Silverberg JI Gelfand JM Margolis DJ, et al.. Atopic dermatitis in US adults: from population to health care utilization. J Allergy Clin Immunol Pract 2019;7(5):1524–1532.e2.
[3] Se, e.g., Drucker AM Wang AR Li W-Q, et al.. The burden of atopic dermatitis: summary of a report for the National Eczema Association. J Invest Dermatol 2017;137(1):26–30.
[4] See, e.g., FDA, "Rare Diseases at FDA," 2022
[5] See, e.g., FDA, "FDA is Working to Bridge Gaps and Meet Needs for Rare Disease Product Development," 2019
[6] See, e.g., U.S. Department of Health and Human Services, Office of Inspector General, "The Orphan Drug Act Implementation and Impact," 2001.
[7] Federal Drug Administration, "Orphan Drug Act - Relevant Excerpts," March 09, 2018.
[8] See, e.g., Rare Disease Company Coalition, "Recognizing the 40th Anniversary of the Orphan Drug Act," 2023
[9] See, e.g., Chan Zuckerberg Initiative, "Rare as One Project," 2023.
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10290406/

REGENERON

Board's methodology, list its sources for the data it includes, nor describe how the Board identified the eight drugs for referral to the Stakeholder Council.

We appreciate the opportunity to provide additional comments and concerns. **We urge the Board to safeguard robust research and development of innovative therapies by not conducting a drug cost review of Dupixent.** A cost review on Dupixent could have an impact on patient access to this important medicine and devastating consequences on the development of therapies and cures in the long term.

Sincerely,

Maya Bermingham

Maya Bermingham
Senior Vice President, Public Policy & Government Affairs

Jack Quinn

Jack Quinn
Director Government Affairs

Value of Care Coalition

May 15, 2024

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

RE: ACCESS CONCERNS RESULTING FROM UPPER PAYMENT LIMITS

Dear Members of the Board,

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 board considers drugs for cost reviews and the potential actions resulting from those reviews, 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 recently 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 moving forward with cost reviews and upper payment limit planning.

AfPA Alliance for Patient Access

American College of Allergy, Asthma & Immunology Advocacy Council

AWIR Association of Women in Rheumatology

CSRO Coalition of State Rheumatology Organizations

Lupus and Allied Diseases Association, Inc.

Patients Rising

Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

RE: May Board Meeting Comments

1 message

Chikoti M. Wheat <[redacted]> Mon, May 13, 2024 at 9:53 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

7671 Quarterfield Road
Suite 200
Glen Burnie, MD 21061

May 13th, 2024

To Whom It May Concern

I am writing to express my concern regarding the newly proposed list of drugs being reviewed for their affordability to patients in Maryland. The list has a total of 8 brands including Dupixent. Dupixent is a commonly prescribed drug that is FDA approved to treat Atopic Dermatitis and Prurigo Nodularis in ages 6 months and above. I treat a number of my patients with these conditions and love the safety, accessibility and efficacy of Dupixent. As a result, I do want this drug to be affordable to my patients at a low cost.

However, I also need to be critical of the consequences of placing a cap on the price of a widely used drug. I worry that pharmaceutical companies that make the drug will no longer allow for it to be available to my patients. Regeneron currently provides patients the opportunity to enroll in Patient Assistance in situations where the patient is denied the drug or has the inability to afford the co-pay. They will often cover the full cost of the drug making it available to as many as 40% of my patients. The access to a life changing drug allows my patients a chance to live a “normal” life and taking away this chance at life will negatively impact my patients.

Let us not forget that placing a price limit will not change whether or not insurance companies cover the drug. But it will certainly change how Regeneron will allocate funds to help patients in need. As a physician who has patients relying on Regeneron for this life-altering drug, I urge you to reconsider this decision that will impact a significant number of my patients.

Sincerely,
Chikoti M. Wheat, M.D., F.A.A.D

May 15, 2024

Dear Prescription Drug Affordability Board,

I am an AAHIV (American Academy of HIV Medicine) certified physician assistant providing specialized care to over 250 persons living with HIV on the Eastern Shore of Maryland. I am also a member of the Speaker Bureau for Biktarvy as well as Cabenuva, a long-acting injectable HIV medication. These two positions offer me the opportunity to be exposed to a large amount of efficacy and safety data regarding antiretroviral therapy as well as comparisons between different agents.

I urge you to be very cautious with your evaluation and suggestions for modification for use of Biktarvy within the state of Maryland. As with all specialties, HIV has much nuance and recommendations should be made with consultation of those with expertise in the area.

Biktarvy is a versatile, well-tolerated medication that provides a tremendous resource to the patients whom I care for on the Eastern Shore. There are many reasons why Biktarvy is the number one single tablet regimen prescribed for people living with HIV in the United States. First, it is indicated for rapid start, meaning that once a person is diagnosed with HIV, he or she can be immediately started on this medication without waiting for baseline laboratory evaluations. This plays a *huge* role in my office as I have many patients who present without any insurance or records and need immediate start of antiretroviral therapy. No other medication has this indication to use without baseline laboratory evaluations. If it weren't for Biktarvy, many of my patients would not be on therapy today.

Secondly, Biktarvy has recently been listed as an alternative recommendation for use in women who are pregnant. With the large influx of immigrants from Haiti in our area, I have seen a drastic increase in the number of pregnant women living with HIV. If it weren't for Biktarvy, many of these women would likely not be on therapy and we would risk seeing an increase in the rates of mother-to-child transmission.

Lastly, Biktarvy has proven clinical data in persons with common antiretroviral resistance, especially in persons who have been living with HIV for many years and who have histories of multiple prior regimens. In fact, it is the only antiretroviral regimen with a label indication for use in persons with documented or suspected M184V/I resistance. It is well documented that the number of persons living with HIV over 50 continues to grow and therefore, the risk of resistance interfering with virologic suppression will continue to grow. Biktarvy has been shown in multiple clinical trials to demonstrate continued virologic suppression in these patients.

I am very fearful for my patients' future should the option of Biktarvy be removed for treatment in the state of Maryland. I imagine having to tell someone that I don't have an option for them when they come into my office fearful, tearful, and hoping I have an answer. For many years, Biktarvy has been that answer. Please make this decision wisely and understand the many lives that will be affected by this potential change.

Sincerely,

Brittany Yerkes, MS PA-C, AAHIVM

Physician Assistant, Chesapeake Health Care