July 22, 2024

VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Comments on SKYRIZI®'s Referral to the Stakeholder Council

Executive Summary

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

Setting an upper payment limit (UPL) would not set a drug's price but would cap reimbursement for certain stakeholders who purchase the drug (i.e., pharmacists) and create access and affordability challenges for patients, including SKYRIZI® patients, as a result. It is crucial that the Board have a fulsome understanding of these issues before making decisions on the cost review process, and AbbVie urges the Maryland Prescription Drug Affordability Board (PDAB) to follow the Oregon PDAB's lead in voting to hold moving forward with affordability reviews at their last meeting on June 26, 2024.[1]

Within its therapeutic class, SKYRIZI offers clinical and economic advantages over alternatives, as shown by higher rates of remission and fewer hospitalizations in Crohn's Disease (CD) and lower rates of dose escalation and medicine switching in psoriasis. Treating advanced disease patterns early and with effective therapies is crucial for preventing costly complications and improving patient outcomes. In fact, for every 100 patients treated with SKYRIZI instead of another medicine for CD, a payor could save nearly $230,000 annually because of improved patient outcomes.[2] Further, AbbVie's industry-leading patient assistance programs significantly reduce true patient out-of-pocket costs in many cases to $0, filling gaps left by eroding health coverage.

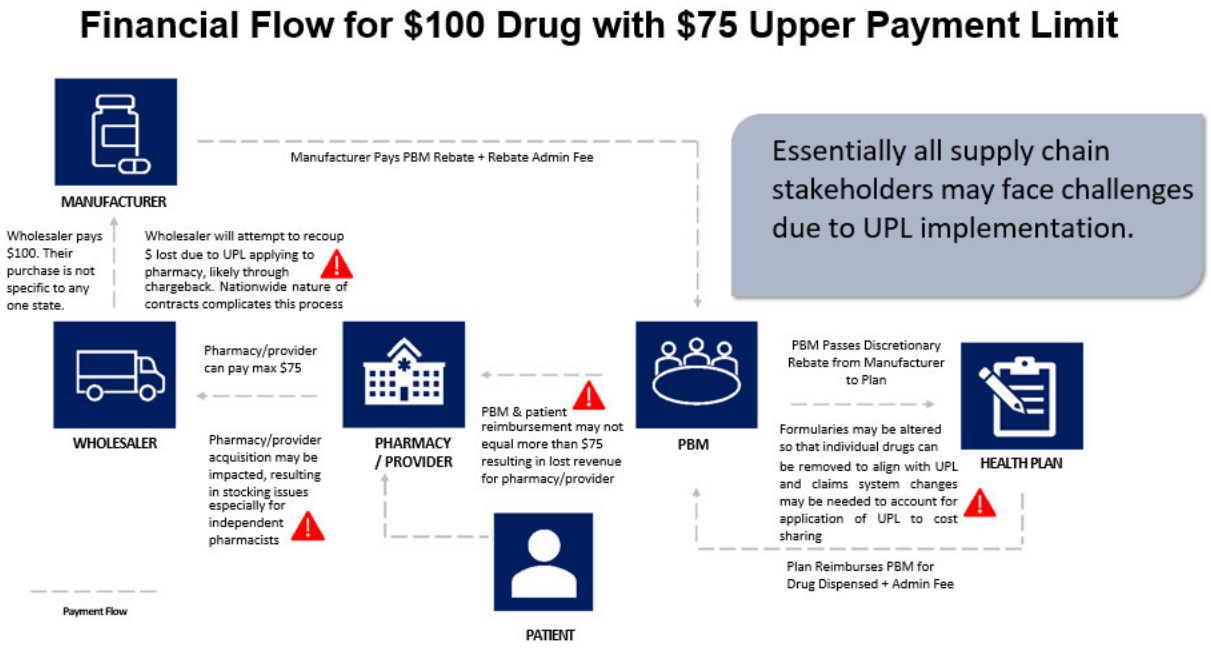
Setting a UPL Will Harm Patient Access Without Lowering Their Costs

Some members of the PDAB have expressed confusion regarding the negative access impacts that come with setting a UPL. Likewise, many proponents of setting a UPL have failed to acknowledge the access harms that will follow UPL setting. Perhaps those proponents do not fully appreciate the national nature of the drug supply chain.

The reality is that setting a UPL does not set the price of a drug in the state. It sets a reimbursement cap for stakeholders like pharmacies, providers, and hospitals, and can result in those stakeholders not being made whole for medicines with a UPL. If pharmacies and others cannot be made whole, they will not keep those medicines in stock and patients will lose

[1] Chair Shelley Bailey shared the following in her motion to consider pausing affordability reviews: "…We've needed to create a structure for the Board to learn about the supply chain… While we have made needed process improvements, we are still short of building a systematic approach for our affordability reviews that can be applied consistently to all drugs under review."
[2] Chapman CJ, Sharma D, Griffth J, Theigs C, Fang S. Evaluation of quality-of-care indicators among patients with Crohn's disease and ulcerative colitis in the United States: 2019-2020. Poster presented at: American College of Gastroenterology (ACG 2022); October 21-26, 2022; Charlotte, NC.

access. The graphic below illustrates the transaction points that will be negatively impacted by a UPL and can result in access harms.



- Further, **health insurers have said that a UPL on medicines will not lower patient cost sharing** and could actually make it more difficult for patients to access their medicines. In a series of interviews conducted by Avalere,[3] health plan executives provided two pieces of insight that should give any PDAB pause:
    - "The five interviewees did not anticipate changes to benefit parameters that apply broadly to medical and prescription benefits, such as changes to deductibles or out-of-pocket maximums." More plainly, **a UPL will not lower the price that health plans force patients to pay**.
    - **"[A]ll interviewees agreed that UPL-affected drugs or their competitors in the therapeutic class could see greater utilization management (e.g., step therapy, prior authorization)**..."
    - Greater utilization management means more hoops for patients to jump through to access their medicines, and impeding access is the antithesis of what the PDAB has set as its goal.

SKYRIZI Saves: Fewer Hospitalizations and Treatment Changes Result in Significant Cost Reductions

Reducing the need for medical services or additional treatment is key to reducing health care costs. Medicines that reduce the need for other interventions offer a significant return on investment for payors and, importantly, ensure that patients can live healthier, more fulfilling lives.

- Clinical studies show that patients treated with SKYRIZI have reduced hospitalization rates[4], and that translates into tangible savings for payors. **At least one study has shown that SKYRIZI is the most cost-effective treatment among commonly used CD treatments**.[5]

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[3] Avalere, Research Explores Health Plan Perceptions of PDABs and UPLs, https://avalere.com/insights/research-explores-health-plan-perceptions-of-pdabs-and-upls. April 2024.
[4] D'Haens G, Panaccione R, Baert F, et al. Risankizumab-rzaa as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. Lancet. 2022a;399:2015-2030.
[5] Bayesian network meta-analysis (NMA) (Section 4.1.2.3: Efficacy) of phase 3 randomized controlled trials was conducted to assess the rates of clinical response (≥100-point change in the Crohn's disease activity index [CDAI] from baseline) at end of induction (4 to 12 weeks) and clinical remission (CDAI <150) at end of maintenance (20 to 52 weeks from maintenance baseline). Effectiveness was assessed separately in populations with and without prior biologic failure when feasible. To simulate treatment effectiveness in a treat-through/intent-to-treat (ITT) population, Markov Chain Monte Carlo (MCMC) chains of induction response rates were multiplied with those of maintenance remission rates

- When compared to at least one other medicine, the **reduced hospitalization rate means payors could save nearly $230,000 annually in medical costs associated with CD-related hospitalizations for every 100 patients treated with SKYRIZI instead**.[6] One reason for these savings is that in the first year of treatment, patients on SKYRIZI only experience CD-related hospitalizations at a rate of 4.5 per 100 patients.[7] Patients on another common CD medicine experience CD-related hospitalizations, at a rate of 12.9 per 100 patients.[8] That's a difference of 8.4 hospitalizations per 100 patients.
- For psoriasis patients, use of SKYRIZI drastically reduces the need for costly changes to dosage and the need to switch medicines. Compared to other medicines commonly used to treat psoriasis, **SKYRIZI results in ~$600 to ~$6,000 less in spending for dose escalation**.[9]
- Understanding these economic impacts is essential to the Board's processes, but members must also understand that SKYRIZI's cost-effectiveness is directly related to the improved outcomes experienced by patients, and patients must be at the center of any discussion that could decide their access to medicines.
- This Board's process attempts to supplant the expertise of physicians and other providers for their own, not least in its decision to create "therapeutic alternatives" that include medicines contraindicated for the conditions SKYRIZI treats. Payors often require multiple steps or medicine failures before a patient can get approval to use a medicine as effective as SKYRIZI. Those delays drive up costs throughout the health system, impede patient access, and worsen patient outcomes. To date the Board has not considered these negative impacts and the reimbursement caps it is considering implementing would exacerbate such harmful consequences.

AbbVie provides Significant Assistance that Lowers Patient Costs & Improves Access When Insurance Fails

AbbVie recognizes that health insurance coverage has severely eroded[10], and the PDAB has heard the impacts of this erosion in public comments that highlight insured patients' difficulty accessing their medicines. AbbVie is committed to patient access and has stepped up to provide assistance where insurance fails to protect patients. Unfortunately, when choosing to review SKYRIZI, the PDAB relied on incomplete and inaccurate information about patient cost. The data relied upon by the PDAB included only the amounts that insurers force patients to pay and did not account for the incredible amount and quality of assistance that AbbVie provides to the patients that rely on AbbVie's medicines.

- Most commercially insured patients qualify for SKYRIZI Complete, which offers a Savings Card that **reduces patient cost sharing to as little as $5 per dose, and in many cases it lowers patient costs to $0**. Some insurers prevent patients from benefiting from patient assistance by circumventing the Affordable Care Act and siphoning the assistance for themselves, and AbbVie strongly encourages the PDAB to consider patient protections to prevent such benefit designs as at least 21 other states have done.[11]
- Additionally, under myAbbVie Assist, **low-income patients who are uninsured, unemployed, or have recently lost insurance coverage may be eligible to receive SKYRIZI at no cost**.

to obtain ITT effectiveness rates for biologic-naïve and biologic-failure populations. These effectiveness estimates were then weighted to estimate the effectiveness in a total population of moderate-to-severe CD patients. This was done using an analysis from the IBM® MarketScan® Commercial and Medicare Supplemental database that showed the proportion of biologic-naïve and biologic-experienced TIM initiations as being 50.1% and 49.9%, respectively (Data on File, AbbVie Inc. H22.DoF.015).

[6] Chapman CJ, Sharma D, Griffth J, Theigs C, Fang S. Evaluation of quality-of-care indicators among patients with Crohn's disease and ulcerative colitis in the United States: 2019-2020. Poster presented at: American College of Gastroenterology (ACG 2022); October 21-26, 2022; Charlotte, NC.

[7] Peyrin-Biroulet L, Chapman JC, Colombel J-F, et al. Risankizumab versus ustekinumab for patients with moderate to severe Crohn's disease: Results from the phase 3b SEQUENCE study. Presented at the United European Gastroenterology Week (UEGW 2023), October 14-17, 2023. Copenhagen, Denmark, OP# LB01.

[8] Peyrin-Biroulet L, Chapman JC, Colombel J-F, et al. Risankizumab versus ustekinumab for patients with moderate to severe Crohn's disease: Results from the phase 3b SEQUENCE study. Presented at the United European Gastroenterology Week (UEGW 2023), October 14-17, 2023. Copenhagen, Denmark, OP# LB01

[9] DoF H21.DoF.98 v2, HEOR Feb 2022

[10] *See* Kaiser Family Foundation Health System Tracker at https://www.healthsystemtracker.org/brief/many-households-do-not-have-enough-money-to-pay-cost-sharing-in-typical-private-health-plans/.

[11] https://www.the-rheumatologist.org/article/state-copay-accumulator-legislation-an-overview/

The above is all consistent with AbbVie's commitment to patient access and our aim to make SKYRIZI affordable for patients, including patients in Maryland. **AbbVie's patient support programs set a new industry standard for patient service by focusing on a high-touch, highly personal, human health care experience** delivered through a combination of personal interactions, digital solutions, and sophisticated data management.

Conclusion: The Maryland PDAB Should Not Continue with Review of SKYRIZI and Should Not Move Forward with the UPL Process

Thank you for the opportunity to provide comments on the selection of SKYRIZI for cost review. It is critical to understand the health system savings and true patient out-of-pocket costs for each medicine the PDAB has identified for review. If the PDAB had been provided with complete and accurate data during the selection process, members would have been shown that

- SKYRIZI results in overall savings compared to other medicines and greatly improves patient outcomes.
- The vast majority of patients – insured and uninsured – can access SKYRIZI for little or no cost.

By the PDAB's standards SKYRIZI exceeds the thresholds for affordability because it could save payors – including the state of Maryland – significant costs, and AbbVie's assistance programs greatly reduce or eliminate true out-of-pocket costs for patients. AbbVie therefore urges the PDAB to remove SKYRIZI from the cost review process.

Setting a reimbursement cap – a UPL – for any medicine would reverberate throughout the medicine supply chain and negatively impact patients. Payors, according to their executives, would likely change their formularies and impose further utilization management hoops for patients to jump through. Providers and pharmacists would be at risk of the reimbursement cap leaving them partially paid and place them in an untenable position at the expense of their patients' access to the medicines they need. Yet, a reimbursement cap would not lower deductibles and out-of-pocket maximums for patients, leaving their total costs unchanged or pushed higher.

Finally, conducting a review on SKYRIZI, which data shows has enormous patient and financial benefits, would be a waste of the State's resources. If the PDAB wants to stay true to its mission, AbbVie encourages the Board to follow the lead of the Oregon PDAB and pause its proceedings. Such an action would afford the Maryland PDAB members the ability to better understand true impediments to patient and health system affordability and take a course of action that can address rather than exacerbate them.

Please reach out to Emily Donaldson at emily.donaldson@abbvie.com with any questions.

Sincerely,

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

Maryland

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

Board Selected Drugs: Jardiance, Ozempic, Trulicity and Farxiga

1 message

Patrick Mutch <pmutch@chasebrexton.org> Fri, Jul 19, 2024 at 6:37 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>
Cc: [redacted]

Dear Members of PDAB,

As President and Chief Executive Officer of Chase Brexton Health Care, I am expressing our concerns focused on the several of latest diabetes medications under review, Jardiance, Ozempic, Trulicity and Farxiga. We rely on these medications to manage the complex healthcare needs of the over 4,700 diabetic patients, most of whom are underserved patients from marginalized communities.

Chase Brexton Health Care is a Federally Qualified Health Center (FQHC) non-profit organization with five centers in Baltimore City, Columbia, Glen Burnie, Woodlawn (Security Square) and Easton. We serve more than 45,000 unique patients annually, most of whom are underserved and would not have any other access to health care. Of the 45,000+ patients, 45% are insured by Medicaid, and 26% are uninsured.. As a safety net provider, Chase Brexton relies on the 340b margins from these diabetic medications to provide comprehensive outpatient services to care for our patients and sustain our mission.. Our chief medical officer, Dr. Sebastian Ruhs has submitted a separate letter to comment on the clinical benefits of these medications and potential negative effects if an upper payment limit negatively impacts the ability of patients to receive these medications.

Once again, we would like to bring to your attention that Federally Qualified Health Centers such as Chase Brexton Health Care have a dedicated mission to serve impoverished communities “regardless of ability to pay”. Chase Brexton Health Care and other FQHCs utilize their 340B savings to provide the array of integrated care that includes, but not limited to, adult and pediatric primary care, behavioral health, substance use, psychiatry, ob/gyn services, dental services, pharmacy, social services, LQBTQ affirming care, food assistance, transportation, and housing. The 340B savings are essential to safety-net providers in reducing health care disparities, increasing access to comprehensive services, and ensuring patients have access to life saving medications. Indeed, FQHCs are some of the best stewards of the program and any reduction in the 340B savings reduces those entities’ ability to serve the most marginalized of Marylanders. **We respectfully ask the Board to review the potentially negative impacts to 340B covered entities before implementing any actions. Thank you for the opportunity to comment.**

Patrick F. Mutch

Patrick F. Mutch
President & Chief Executive Officer

Pronouns (he/him)

Chase Brexton Health Care
Because everyone’s health matters.

Chase Brexton Health Care

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July 19, 2024

Submitted for Public Comment: Maryland Prescription Drug Affordability Board

Dear Members of the Maryland Prescription Drug Affordability Board,

As Chief Medical Officer, I write on behalf of the medical and pharmaceutical team at Chase Brexton Health Care which foresees a potentially significant negative impact on the health outcomes of Diabetes Mellitus (DM) patients should an upper payment limit on vital, preferred medications, such as Ozempic, Trulicity, Farxiga, and Jardiance, be established and restrict these medications from use. Cost increases may be seen should providers have to switch patients to non-preferred drug options. I will not address the other issue which is the significant 340b margins from these medications which are totally reinvested in caring for the vast majority of our patients who have complex healthcare needs and are underserved and often uninsured.

I can attest to both the importance and complexity of treating this chronic disease which has been diagnosed in nearly 500,000 (1 in 10) Marylanders and remains undiagnosed in an estimated 140,000 Marylanders. This number of patients and potential patients in need of effective and accessible treatment options should lead the Prescription Drug Affordability Board (PDAB) to reduce restrictions to ensure positive and cost-effective health outcomes for every community member in our state.

Patient outcomes and cost effective, accessible treatment for this complex disease is a priority. As providers and pharmacists, we must consider many factors in creating our treatment plan including adherence, identified comorbid conditions, and risks of developing comorbid conditions.

Treatment of DM is a complex matter and when prescribing medications, many factors must be considered:

> **1) Adherence**: Complex regimens, such as insulin injections multiple times a day, are less likely to be taken as prescribed than simple regimens. Trulicity and Ozempic, which are once weekly injections, have shown to greatly improve adherence, which leads to better controlled sugar levels. **Optimized blood glucose control decreases the risk of developing costly complications from DM, such as renal failure, heart attacks, and strokes.**
>
> **2) Comorbid conditions:** People with DM are more likely to have other comorbid conditions, such obesity, hypertension, kidney disease, and cardiovascular disease. Some of those conditions are strongly associated with DM and a result of poorly treated or untreated DM. Some medications treating DM can

Chase Brexton Health Care

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improve clinical outcomes in patients with existing renal or cardiovascular disease. Farxiga and Jardiance belong to the class of sodium-glucose co-transporter-2 (SGLT2) inhibitors. SGLT2 inhibitors have shown to improve clinical outcome in patients with preexisting congestive heart failure and preexisting renal disease. **SGLT2s, like Farxiga and Jardiance, can improve overall mortality and decrease hospital admissions in patients with those conditions.** Not having the option to choose from such DM regimens can lead to further exacerbation of such preexisting conditions, such as renal failure leading to dialysis and congestive heart failure with increases in hospital admissions and worsening overall mortality.

3) Risk of developing new cardiovascular disease in patients at risk: Some DM drugs decrease the risk for developing new cardiovascular disease, such as heart attacks and strokes. Ozempic and Trulicity belong to the class of glucagon-like-peptide-1 (GLP-1) agonists. In addition to improving blood glucose levels, those GLP-1s promote weight loss, which is an important factor in treatment of DM, and they decrease the risk of heart attacks and strokes in at risk patients. **Being able to choose from Ozempic and Trulicity to treat DM minimizes the risk of developing cardiovascular complications which can lead to poor clinical outcomes and increase in cost.**

To treat DM, we need to be able to choose from options that improve adherence, and which can be tailored to the individual needs of the patient, depending on their pre-existing comorbid conditions, or their risk of developing such. **Limiting access to Farxiga, Jardiance, Ozempic, and Trulicity and aswitching patients to non-preferred, less effective medications, will put multitudes of patients at risk of reduced adherence, poor control of blood sugar level, and increases in complications from comorbid conditions all of** which then further increases the risk of developing complications from DM. These factors will ultimately lead to an increase in new drugs prescribed and an increase in hospital admissions, and therefore an increase in overall cost.

Sincerely,

Sebastian Ruhs, MD, PhD
Infectious Disease Physician
Chief Medical Officer

CC: Patrick Mutch, CEO, Chase Brexton Health Care
Mahro Ershadi, Chief Pharmacy and Strategy Officer, Chase Brexton Health Care
Jeff Cywinski, Director of Pharmacy, Chase Brexton Health Care

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

July 22, 2024

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

RE: Public Comments on Board Selected Drug for Cost Reviews

Dear Members and Staff of the Maryland Prescription Drug Affordability Board and Stakeholder Council:

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first.

Once diagnosed with a chronic condition, each patient starts an often life-long journey to identify the correct treatments to successfully manage their symptoms and improve their health. Many chronic disease patients will ultimately rely on multiple medications to their condition. Some will face multiple chronic conditions or even need additional medications to treat the side effects of either their condition or the medication that keeps their condition manageable. For these reasons, patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered.

We respectfully urge the board to consider the concerns of patient organizations outlined in this letter. We offer our organization as a resource to board members seeking to connect with patient organizations and patients.

Cost Reviews and UPLs Could Compromise Patient Access to Medications

While we applaud the board's commitment to supporting patients and lowering the costs of prescription medications, we are concerned that cost reviews and upper payment limits (UPLs) can further complicate an already complex healthcare marketplace and result in worse outcomes for patients.

At their core, cost reviews necessitate selecting individual drugs for review and implementing market interventions for the selected drugs. This alone puts PDABs in a position of picking winners and losers between drugs and within the broader population of Maryland patients. Individual drug reviews unnecessarily create inequities between patient populations and can pit disease states against each other.

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies. This eventuality was outlined by the Centers for Medicare and Medicaid Services in their May 3, 2024 Guidance on Medicare Drug Price Negotiation, "CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."

Additionally, many of the drugs under cost review are administered directly by physicians under a “buy and bill” model. Physician reimbursement rates are already being squeezed, and UPLs could additionally lower opportunities for treatment costs to be recouped. As a result, it is likely that physicians would adjust treatment recommendations to avoid facing financial deficits, leaving patients with fewer treatment options.

Finally, creating a unique pricing structure in Maryland will create state-specific conditions for coverage. We don’t know yet how either insurers or manufacturers will react to state-by-state exceptions, but this has potential to cause either of these stakeholders to limit availability in the state and could cause confusion for patients and providers in the state.

Upper Payment Limits Don’t Necessarily Translate to Patient Savings

Assuming that UPLs directly translate to lowered costs for patients ignores the complicated nature of our healthcare system. In our system, patients are not responsible for paying the full cost of their prescription medications nor are they allowed to freely select from the full range of treatments medically approved for their condition. Instead, these decisions are determined by their insurance company and pharmacy benefit manager (PBM). It is also these stakeholders that determine if cost-savings realized by the payer are subsequently shared with patients. Unfortunately, in most cases, they are not.

Payers in our health marketplace do not necessarily derive the most value from the lowest cost drugs. According to reporting on PBMs by the New York Times, “Even when an inexpensive generic version of a drug is available, P.B.M.s sometimes have a financial reason to push patients to take a brand-name product that will cost them much more. For example, Express Scripts typically urges employers to cover brand-name versions of several hepatitis C drugs and not the cheaper generic versions. The higher the original sticker price, the larger the discounts the P.B.M.s can finagle, the fatter their profits — even if the ultimate discounted price of the brand-name drug remains higher than the cost of the generic.”

Ultimately, this could mean insurers and PBMs place drugs subject to UPLs on higher tiers of the formulary. This could ultimately lead to higher out-of-pocket costs for patients who could face higher copay or coinsurance rates to retain access to that drug or alternatively be forced to switch to a more expensive drug that results in higher profits to their PBM. This is also supported by the concern raised by CMS above.

Additionally, non-medical switches in medication can cause unnecessary complications for patients. At a minimum, a switch in medication will require more doctor visits to monitor the efficacy of a new medication. Further, if the switch results in side effects or worsened outcomes, patients could face medical interventions or hospitalization and the additional costs borne out by both.

Patient Access Cannot Be Compromised

Ultimately, chronic conditions are incredibly complex to treat. Each patient will face a unique experience and should be able to work with their doctor to identify the treatment that works best for them. Substituting or requiring patients to change drugs based on cost considerations instead of medical needs can disrupt continuity of care and result in complications and higher overall medical costs.

We urge this board to seriously consider the unique circumstances faced by these patients and work diligently to ensure that access to all treatments is protected. We strongly urge the board and staff to utilize the authority of the board to fully explore with all healthcare stakeholders how UPLs will be implemented and identify in advance any adverse impact to patients.

Identify and Resolve Patient-Reported Obstacles to Care

As we have outlined, while well-intentioned, UPLs fail to address many of the underlying causes and complicated factors that result in higher prescription drug costs for patients. Therefore, we urge the board to focus its time on identifying and addressing patient-reported obstacles to drug affordability.

Failing to resolve the underlying factors that lead to higher costs for patients can result in short-term relief and uneven benefits – aiding some but potentially leaving others with higher costs and drug accessibility challenges. Additionally, regulators should clearly define cost-saving targets, including what percentage will be patients and what will be the state or the broader healthcare system.

We acknowledge that this is a substantial undertaking in its own right, and urge the board to proceed with the care and humility that it requires. As recently as last month, the Oregon PDAB acknowledged the significance of their directive when they voted to halt drug reviews for 2024 to allow adequate time to improve their process, design, and definitions. We urge Maryland and other states to follow their lead in an effort to ensure patient benefit.

Sound Health Policy is Founded on Patient Perspectives

Finally, while our health system and the policies that impact it are complicated, one principle is simple: every change that we make and policy we implement should ultimately benefit patients. We urge the board to keep this principle as a singular focus as it evaluates the impact of its cost reviews and UPLs.

We urge the board to utilize this organization and its members as a direct conduit to understanding and incorporating patient and caregiver perspectives, as well as those of patient organizations who have an understanding of the life cycle of disease from the lens of prevention, diagnosis, and disease management.

We appreciate your laudable efforts to improve our health system and your steadfast commitment to protecting patients. We look forward to working together to achieve these goals.

Sincerely,

Ensuring Access through Collaborative Health (EACH) Coalition

Eli Lilly and Company

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July 17, 2024

By Electronic Submission

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

Re: Board Selected Drugs

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

Eli Lilly and Company ("Lilly") is the manufacturer of Trulicity® and submits these written comments to the Board in response to Trulicity's inclusion on the list of selected drugs from the May 20, 2024, PDAB meeting and cost review study process (collectively, the "Selected Drug List"). Lilly urges the Board to consider the following before proceeding any further with its cost reviews.

Price controls may limit patient access

The arbitrary capping of prices or profits within the drug supply chain could restrict patients' access to life-saving therapies in Maryland. Access may suffer if an intermediary or dispenser cannot obtain or stock the drug because the cost to acquire or dispense exceeds an Upper Payment Limit ("UPL").

Many entities play a role in determining the net cost of pharmaceuticals, and a UPL fails to address cost concerns at the pharmacy counter for patients as patients should, but do not, have information about how payors and PBMs limit access to prescriptions medicines, such as formulary and utilization management techniques. Setting a UPL could cause formularies to move affected drugs into non-preferred or higher cost tiers, resulting in increased out-of-pocket for patients. Some plans may choose to eliminate coverage for the drug entirely, or severely reduce the options available to patients within a therapeutic class. This could hamstring important facets of managing patient healthcare such as individual patient experiences, health care providers' expertise and the importance of patient-centered care.

Price controls also may jeopardize the development of new medicines available to patients. Investments may shift away from research, development and exploration of post-approval uses if such investment is not financially viable.

The data review and drug selection process should be more transparent

Lilly is concerned about the lack of transparency and data review process that led to the selection of Trulicity for cost review. We appreciate that the Board's compilation of the Selected Drug List required the aggregation of large sets of data from multiple sources; however, stakeholders did not get the opportunity to validate or provide feedback or additional context to any data utilized in the selection. Data sources reviewed by the Board may be incomplete or inaccurate for this purpose. For example, the Maryland All Payer Claims Database ("APCD") excludes self-insured ERISA health plans, as well as other plans that do not report. In addition, aggregated and spending data at the highest total gross spending does not reflect the nature of the industry, the pricing by intermediaries (wholesalers, pharmacies) and the negotiation of net cost by pharmacy benefit managers or health plans. Using this data as an initial source for cost review selection is flawed, and at least one state has chosen to "pause affordability reviews . . . so the board can review, assess and possibly improve the criteria and methods used to assess and select drugs for potential affordability reviews in 2025, using a refreshed data set."[1]

The cost review process for Trulicity is unnecessary

As stated in Lilly's previous letter to the Board and Prescription Drug Affordability Stakeholder Council on May 10, 2024, Trulicity is affordable. Patients in Maryland paid an average of $2 to $39 per month for their therapy, which equates to only 0.2% to 4% of the list price.[2] This affordability stems from exceptional access provided by payers within the state, as well as affordability programs provided by Lilly: Trulicity is available on over 80% of formularies across segments (including healthcare marketplace, Medicaid and Medicare)[3]. Lilly

[1] https://dfr.oregon.gov/pdab/pages/affordability-review.aspx#:~:text=UPDATE%3A%20At%20the%20June%2026,using%20a%20refreshed%20data%20set.
[2] Based on information licensed from IQVIA: IQVIA™, Real-World Evidence Claims Data for the period March 2023 - Feb 2024 reflecting estimates of real-world activity. All rights reserved. Accessed on April 23, 2024.
[3] Ibid.

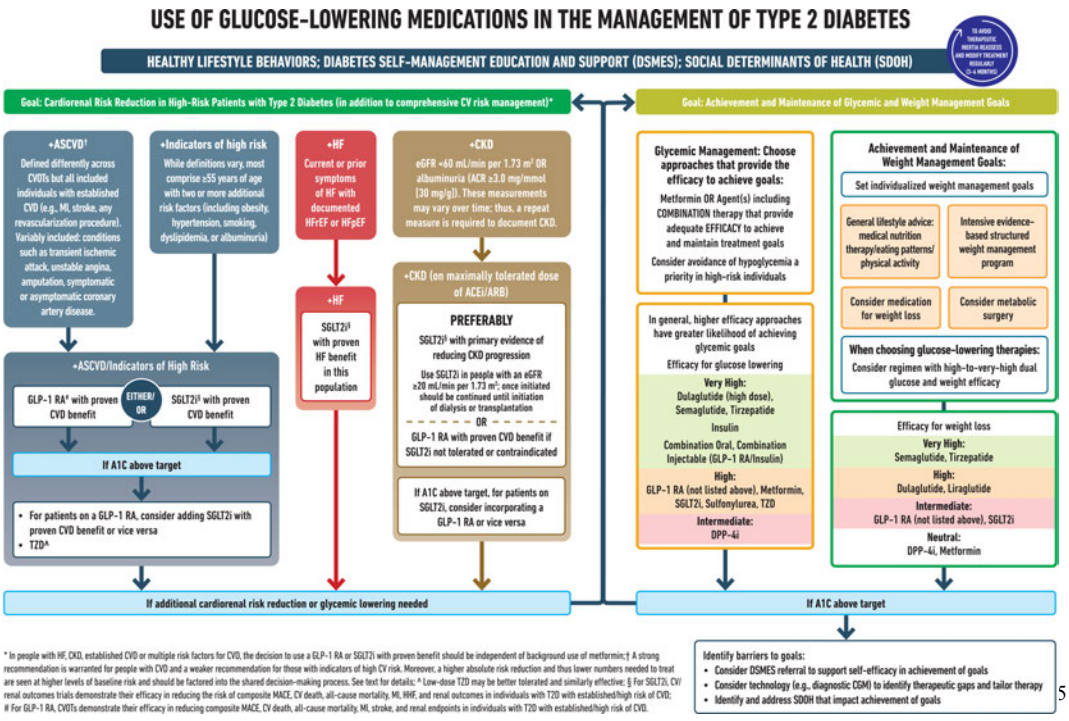
continues to advocate for patient choice, with most patients having the ability to choose the incretin therapy that is appropriate for them with the help of their healthcare provider. This choice has maintained healthy competition in the broader incretin therapy market.

The Board's selection of therapeutic alternatives is inconsistent with clinical guidelines

As part of the Cost Review Study Process, the Board published "Trulicity Proposed Therapeutic Alternatives." Lilly believes a number of drugs contained on this listing are not necessarily valid alternatives for therapy with Trulicity. Semaglutide (Ozempic), liraglutide (Victoza), exenatide (Byetta), lixisenatide (Adlyxin), exenatide-extended release (Bydureon), semaglutide (Rybelsus), tirzepatide (Mounjaro) are valid alternatives that should remain on the listing. All other products, which are not glucose-dependent insulinotropic polypeptide (GIP) receptor or glucagon-like peptide-1 (GLP-1) receptor agonist products, should be removed prior to any further price comparisons in products potentially subject to a cost review.

The American Diabetes Association ("ADA") publishes annually The Standards of Care in Diabetes ("Standards of Care").[4] It includes the current clinical practice recommendations of the ADA and is intended to provide clinicians, researchers, policy makers, and other individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care. Lilly urges the Board to review these guidelines, as therapies are not interchangeable in Type II diabetic patients:

[4] https://professional.diabetes.org/standards-of-care (accessed July 17, 2024)



[5]

***Trulicity provides value to patients*[6]**

Trulicity is for adults and children 10 years of age and older with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose). Trulicity is also used in adults with type 2 diabetes to reduce the risk of major cardiovascular (CV) events (problems having to do with the heart and blood vessels) such as death, heart attack, or stroke in people who have heart disease or multiple cardiovascular risk factors. Trulicity is the only GLP-1 RA that provides this combination of benefits: powerful A1C reduction across 4 doses, proven CV benefit in both primary and secondary prevention patients, simply delivered.[7] In fact, in AWARD-11, Trulicity provided sustained A1C reduction at 1 year of <7%.[8] Trulicity acts like the natural human hormone, GLP-1, helping the body do what it's supposed to do naturally:

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[5] Use of glucose-lowering medications in the management of type 2 diabetes. ACEi, ACE inhibitor; ACR, albumin-to-creatinine ratio; CVOT, cardiovascular outcomes trial; DPP-4i, dipeptidyl peptidase 4 inhibitor; GLP-1 RA, glucagon-like peptide 1 receptor agonist; HHF, hospitalization for heart failure; SGLT2i, sodium-glucose cotransporter 2 inhibitor; T2D, type 2 diabetes. Adapted from Davies MJ, Aroda VR, Collins BS, et al. Diabetes Care 2022;45:2753–2786.

[6] See full Prescribing Information for Trulicity at https://uspl.lilly.com/trulicity/trulicity.html#pi

[7] Treating Adults with Type 2 Diabetes | HCP | Trulicity (dulaglutide)

[8] Clinical Trials: Lowering A1C, Weight Change & CV Data | HCP | Trulicity (dulaglutide)

reduces hepatic glucose production by decreasing glucagon secretion, slows gastric emptying and releasing glucose-dependent insulin. Reductions in fasting and postprandial serum glucose were observed as quickly as 48 hours after the first dose of Trulicity.[9]

* * *

We appreciate that the Board shares our commitment to prescription drug affordability; however, the cost review for Trulicity is unnecessary and, if performed, may be wrought with inaccurate conclusions based on incomplete or missing data. Patients and their caregivers count on access to pharmaceutical products and the imposition of any type of price control may put this access at risk. We remain committed to work with the state of Maryland to find alternative common-sense solutions to safeguard patient access and the affordability of medicines. Please reach out with any questions or clarifications.

Sincerely,

Cynthia Ransom
Sr. Director, Government Strategy

[9] How Trulicity Works, MOA & FPG and PPG Reductions | HCP | Trulicity (dulaglutide)

July 22, 2024

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

RE: Board Selected Drugs (Skyrizi & Dupixent).

Dear Maryland Prescription Drug Affordability Members and Staff,

On behalf of the National Psoriasis Foundation, and the more than 8 million individuals living with psoriatic disease, we thank you for the opportunity to provide comment on the Cost Review Study Process for the Board Selected Drugs presented on May 20, 2024. We write to convey our concerns with the inclusion of Skyrizi (risankizumab) and Dupixent (dupilumab) on the referred list.

Psoriasis is an immune-mediated disease that causes inflammation in the body. There may be visible signs of inflammation such as raised plaques and scales on the skin, which may look different for different skin types. The symptoms associated with psoriasis, including itch, pain, and flaking skin, can directly impact patient wellbeing, patient sleep, and ability to complete activities of daily living. Psoriasis is also well known to have systemic medical associations including metabolic syndrome, cardiovascular disease, metal health conditions like depression and anxiety, and psoriatic arthritis (PsA), a potentially debilitating inflammatory arthritis. In fact, one in three people with psoriasis may develop psoriatic arthritis.[1] Signs of PsA include swelling, stiffness, and pain in the joints and areas surrounding the joints. Scientific research on PsA progression has demonstrated that it is important for patients with PsA to begin treatment for PsA shortly after the onset of symptoms to avoid (or at least minimize) permanent joint damage.

The National Psoriasis Foundation (NPF) is a non-profit, 501 (c)(3) organization that works to drive efforts to cure psoriatic disease and improve the lives of the over 8 million Americans affected by psoriatic disease. As part of that second mission the NPF advocates for access to care reforms that will benefit people living with psoriasis, and it's in this capacity that we reach out to the PDAB Board today with our concerns about the consequences of implementing a UPL on drugs used to treat psoriatic disease. Below we have outlined two priorities that we urge the Maryland PDAB to consider when assessing these medications:

Priority 1: Protecting a diverse range of treatment options for patients with psoriatic disease

The introduction of biologic products for the treatment of psoriasis and psoriatic arthritis has allowed many in our community to achieve a level of clearance never before possible. New systemic treatments, including biologics, have provided many patients with an effective therapy for the first time in their lives. Biologics have also opened a new world of combination therapies, being used alongside other systemic treatments, phototherapy, and/or topical treatments. Each patient is

[1] Mease PJ, Gladman DD, Papp KA, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. J Am Acad Dermatol. 2013;69(5):729-735. doi:10.1016/j.jaad.2013.07.023

unique in the way they respond to various therapies, however, and there is no 'one size fits all' approach to managing psoriasis.

Although recent research has shed some light on the underlying factors that determine whether or not any given drug will effectively treat a patient's specific presentation of psoriatic disease (for instance, psoriatic arthritis patients with enthesitis seem to do better with IL-23 inhibitors, while those with axial involvement seem to do better with IL-17 inhibitors),[2] there is still no universal heuristic for matching a patient to the most effective treatment for their psoriatic disease. Physicians often prescribe one or more ineffective treatments for patients with psoriatic disease before identifying an approach that works, and the immunological nature of psoriatic disease means that patients may even have to cycle off previously effective treatments if they build up immune tolerance.

The extreme heterogeneity of both psoriatic disease and treatments for psoriatic disease make physician and patient access to the full range of therapies particularly important. Because of this unique set of considerations, we caution the PDAB to be on guard against creating scenarios in which UPLs incentivize insurers to re-tier, restrict access to, or even eliminate certain drugs from their formularies. Given the diversity of drugs that could plausibly treat one patient's psoriatic disease but not another's, any incentive structure that makes it more difficult for psoriatic disease patients to access a full range of treatment options through Maryland's state-regulated plans would create major access barriers for people living with the condition.

UPLs are a new enough policy tool that our team has struggled to predict or model the potential impacts of a UPL on insurers, PBMs, hospitals, pharmacies, and providers. That said, we have seen some analyses of the likely impacts of a UPL that echo our concerns of increased utilization management. For instance, a recent Avalere report summarized their findings into a March 2024 report that warned "All payers interviewed noted that UPL drugs and competitors in the therapeutic class are likely to see increased utilization management (e.g., step therapy, prior authorization) should the UPL restructure new benefit designs. Additionally, five of six payers cited in their interviews that UPL implementation would result in changes to formulary designs, such as movement up or down tiers for UPL drugs."[3] We urge the Maryland PDAB to think seriously about these effects and consult outside stakeholders with expertise in healthcare economics before making decisions which could create unintended consequences that ultimately restrict access.

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[2] Kamata M, Tada Y. Efficacy and Safety of Biologics for Psoriasis and Psoriatic Arthritis and Their Impact on Comorbidities: A Literature Review. Int J Mol Sci. 2020;21(5):1690. Published 2020 Mar 1. doi:10.3390/ijms21051690

[3] Avalere, Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs, https://www.fightchronicdisease.org/sites/default/files/FINAL%20PFCD%20Avalere%20PDAB%20Insurer%20Research.pdf.

Priority 2: Distinguish between affordability to the patient and affordability to the state

In the Maryland Legislature's instruction to the PDAB for conducting a cost review found in HB 768, the legislature instructs the Board to consider whether "use of the prescription drug product that is fully consistent with the labeling approved by the united states food and drug administration or standard medical practice has led or will lead to affordability challenges for the state health care system or high out–of–pocket costs for patients."[4]

As an organization focused squarely on advancing patient access, NPF wants to reiterate and emphasize the already-noted distinction between "affordability challenges for the state health care system" and "high out-of-pocket costs for patients." Under current law the Maryland PDAB can only create UPLs for state and local government plans, and this limitation dramatically constrains the possibilities for reducing out-of-pocket costs for patients via an UPL. Maryland PDAB Executive Director Dr. York noted these shortcomings to the current system in his testimony to the Maryland Senate Finance Committee on SB 3088, a bill that would (among other things) task the PDAB with writing a report on whether their power to implement UPLs should be expanded, when he said that "most of the savings [created under the current law] will be to the state and local government, because Medicaid has a nominal copayment and then our employee health plan has a very generous copay as well."[5]

Although the PDAB's own website states that the Board has been "tasked with protecting Marylanders and the Maryland health care system from the high costs of prescription drug products," Dr. York's comments indicate that this current version of the PDAB has very little power to reduce out of pocket costs for patients. Given these facts, NPF is concerned that any UPLs implemented under the current law would do very little to reduce costs for HealthChoice users or Maryland state employees while simultaneously creating potential unintended consequences that restrict available treatment diversity for all the reasons laid out in Priority 1. Avalere once again agrees with our analysis in their study on UPLs, writing that of the health plan representatives they interviewed "Most payers (five of six) did not anticipate that UPL-related savings would be passed on to patients in the form of lower premiums, deductibles, or cost sharing."[6]

Reducing the state's expenditure on prescription drug use is obviously an important policy goal in its own right, but we believe that any cost review report examining whether a drug's use creates "affordability challenges for the state health care system or high out–of–pocket costs for patients" should clarify that these high out-of-pocket costs are likely to remain unchanged *unless* the report also contains clear guidance on how the state can implement a UPL that ensures savings will be passed on to patients using these drugs. Absent this sort of guarantee, our fear is that the cost review process will overstate the need for a UPL by considering patient affordability issues that the

[4] https://mgaleg.maryland.gov/2019RS/Chapters_noln/CH_692_hb0768e.pdf.
[5] https://mgaleg.maryland.gov/mgawebsite/Committees/Media/false?cmte=fin&ys=2024RS&clip=FIN_2_7_2024_meeting_1&billNumber=sb0388, timestamp 21:53.
[6] Avalere, Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs.

PDAB is not actually equipped to meaningfully address with its current toolkit. Implementing a UPL that saves the state money without doing the same for patients would practically be a cost-cutting measure like state Medicaid cuts, something that drives down state budgets while potentially reducing access for end healthcare users. For these reasons, NPF urges the PDAB Board to remain cautious in its cost-benefit analysis of UPLs for Skyrizi (risankizumab) and Dupixent (dupilumab).

On behalf of National Psoriasis Foundation, thank you for your consideration of these comments which we hope will positively inform this review. We again invite you to call upon us, our Medical Board, and our patient community as you move forward. Please contact Will Hubbert, State Government Relations Manager, East at whubbert@psoriasis.org with any questions.

Sincerely,

Jason Harris Vice President, Government Relations and Advocacy

July 22, 2024

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

VIA EMAIL TO: comments.pdab@maryland.gov

RE: Board Selected Drugs – Ozempic®

Dear Members of the Maryland Prescription Drug Affordability Board:

Novo Nordisk appreciates the opportunity to submit written comments to the Maryland Prescription Drug Affordability Board (Board) regarding the Board's cost review of Ozempic®. Novo Nordisk is a global healthcare company committed to improving the lives of those living with serious chronic conditions, including diabetes, hemophilia, growth disorders, and obesity. The Novo Nordisk Foundation, our majority shareholder, is among the top five largest charitable foundations in the world. Accordingly, our company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and the sustainability of society.

As we have expressed in our previous comments to the Board, we share the Board's interest in making prescription medications affordable to patients. **We believe, however, that any efforts by the Board to pursue an upper payment limit (UPL) are misguided and will ultimately harm Marylanders' ability to access prescribed medications and disrupt their clinical care.** For these reasons, we are providing the following information to not only reaffirm the cost-effectiveness of Ozempic®, but to also urge the Board to reconsider its decision to subject Ozempic® to a cost review.

Diabetes is a devastating disease.

Type 2 diabetes is a chronic disease that places an enormous strain on patients suffering from it; families across America; the entire U.S. healthcare system, including the Maryland healthcare system; and the economy as a whole. To fully understand the impact that GLP-1 medications like Ozempic® can have, it is important to understand the toll that metabolic chronic disease has on society. The CDC estimates that 36 million Americans are living with type 2 diabetes today, and an additional 98 million Americans are prediabetic and at risk for developing the disease.[1]

[1] *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States*, CDC (accessed May 22, 2024), https://www.cdc.gov/diabetes/php/data-research/index.html; *Statistics About Diabetes*, Am. Diabetes Ass'n (accessed May 22, 2024), https://diabetes.org/about-diabetes/statistics/about-diabetes.

In Maryland 537,000 adults (11.1% of the adult population) are living with diagnosed diabetes. [2] These numbers are only projected to increase, and by 2045 it is expected that 783 million adults will be living with type 2 diabetes,[3] with one third of that population experiencing cardiovascular disease, and two fifths facing chronic kidney diseases.[4] [5] Patients living with type 2 diabetes often face a significant disease burden that impacts their quality of life and overall health. This chronic condition is a progressive and insidious disease that worsens over time and requires continuous management. [6] Many patients living with diabetes suffer from debilitating symptoms that include exhaustion, depression, and damage to their eyes, nerves, kidneys, and limbs. [7] Without proper and stable treatment, these symptoms can quickly advance to even more serious complications.

Diabetes is a costly chronic condition.

The state of Maryland allocates significant resources to managing diabetes, including substantial healthcare expenditures for treatment, hospitalization, and management of complications associated with the disease. These costs are driven by the high prevalence of the disease. However, Ozempic® and other GLP-1 therapies pioneered by Novo Nordisk have the potential to transform patients' lives and to drive hundreds of billions of dollars in long-term savings for the state. [8] [9] By effectively managing blood sugar levels, Ozempic® helps reduce the risk of type 2 diabetes complications such as cardiovascular disease, kidney damage, and neuropathy. Studies showed that patients with HbA1c below the ADA target for glycemic control (HbA1c<7%) incur substantially lower diabetes-related annual costs compared to patients with insufficient glycemic control.[10] In addition to reducing direct medical costs, lower HbA1c is also associated with statistically significant lower diabetes-related outpatient costs, acute care costs, and drug costs. Fewer complications mean fewer hospital visits, medical procedures, and long-term care needs. Any drug therapy able to reduce the prevalence of these expensive and deadly diseases will provide enormous personal, economic, and societal value to individuals, families, and communities across the country, including those in Maryland.

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[2] The American Diabetes Association. The Disease Burden of Diabetes in Maryland. adv_2024_state_fact_maryland.pdf (diabetes.org)
[3] International Diabetes Federation. IDF Diabetes Atlas. 10th edn. 2021. https://www.diabetesatlas.org/ (accessed December 2023); IDF 2021 report;
[4] *Murphy D et al. Ann Intern Med 2016; 165(7):473-481*
[5] *Saran R et al. Am J Kidney Dis 2019; S0272-6386(19)31008-X*
[6] Vivian A. Fonseca, Defining and Characterizing the Progression of Type 2 Diabetes, Diabetes Care (Nov. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811457/.
[7] *E.g.*, Divya Gopisetty et al.*, How Does Diabetes Affect Daily Life? A Beyond-A1C Perspective on Unmet Needs*, Clinical Diabetes (April 1, 2018), https://diabetesjournals.org/clinical/article/36/2/133/32827/How-Does-Diabetes-Affect-Daily-Life-A-Beyond-A1C; Christopher J. Bulpitt et al., *Association of Symptoms of Type 2 Diabetic Patients With Severity of Disease, Obesity, and Blood Pressure*, Diabetes Care (Jan. 1, 1998), https://diabetesjournals.org/care/article/21/1/111/19852/Association-of-Symptoms-of-Type-2-Diabetic; Matt Reynolds, *What the Scientists Who Pioneered Weight-Loss Drugs Want You to Know*, Wired (June 12, 2023), https://www.wired.com/story/obesity-drugs-researcher-interview-ozempic-wegovy/.
[8] Financial Times Editorial Board, *The promise of anti-obesity drugs*, Financial Times (Sept. 6, 2023), https://www.ft.com/content/a6e0ccbd-66b4-4e5d-9a9a-002b95b0d19f.
[9] Gina Kolata, We Know Where New Weight Loss Drugs Come From, But Not Why They Work, N.Y. Times (Aug. 17, 2023), https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.
[10] Boye KS, Lage MJ, Thieu VT. The Association Between HbA1c and 1-Year Diabetes-Related Medical Costs: A Retrospective Claims Database Analysis. Diabetes Ther. 2022;13(2):367-377. doi:10.1007/s13300-022-01212-4

Novo Nordisk is committed to curing diabetes.

We are the largest private investor in diabetes research and development in the world**.** We are not only further investing in innovation to enhance diabetes treatment but are also striving to cure it. GLP-1-based therapies represent a significant advance in the treatment of type 2 diabetes, and Ozempic® reduces the risk of all-cause mortality, major adverse cardiovascular events, and stroke among people with type 2 diabetes. The development of semaglutide, the active ingredient in Ozempic®, spanned over a decade. This long and rigorous process reflects the complexity and precision required to bring a new therapeutic molecule from concept to market. The work of the scientists, researchers, and personnel not only made Novo Nordisk the industry leader in treating diabetes, but it also radically altered the medical management of this complicated and devastating chronic disease and opened the door to new possibilities and avenues of inquiry for other serious chronic diseases—including heart, kidney, liver, and Alzheimer's diseases.

Ozempic® was approved by the Food and Drug Administration ("FDA") in 2017 for the treatment of type 2 diabetes. It increases the body's production of insulin, a hormone that lowers blood sugar levels, and reduces production of glucagon, which increases blood sugar levels. As the New York Times recently reported, Ozempic® is "changing diabetes treatment," as many patients "have been able to lower their insulin doses after starting Ozempic [®], and some have been able to go off insulin entirely." [11] Ozempic® is a once weekly GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events (MACE) (Cardiovascular death, non-fatal myocardial infarction (MI) or non-fatal stroke) in adults with type 2 diabetes and established cardiovascular disease.[12] Research and clinical trials demonstrate the superiority of GLP-1 receptor agonist to other antihyperglycemic drugs in improving glycemic efficacy, reducing weight and blood pressure, and having a cardioprotective effect, all without the risk of hypoglycemia.[13] These drugs have transformed the guidelines for the management of patients with diabetes.[14] All told, Ozempic has revolutionized the management of diabetes and related comorbidities – providing unsurpassed value to the healthcare system.

Novo Nordisk works to make our medicines accessible.

Novo Nordisk devotes significant resources, like rebates to insurers and pharmacy benefit managers (PBMs) for formulary placement, to make its medicines accessible and we will continue to collaborate with policymakers to expand access for patients. However, gaps will remain as long as the U.S. healthcare system allows intermediaries, such as PBMs, to stand between innovators and patients. The complexities of the system unfortunately reduce access and affordability for many Americans. At Novo Nordisk, we are driven by our commitment to

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[11] Dani Blum, How Ozempic Is Changing Diabetes Treatment, N.Y. Times (May 13, 2024), https://www.nytimes.com/2024/05/13/well/live/insulin-ozempic-diabetes.html; see also Paresh Dandona, Ajay Chaudhuri, and Husam Ghanim, Semaglutide in Early Type 1 Diabetes, N. Engl. J. Med. (2023) https://www.nejm.org/doi/full/10.1056/NEJMc2302677.
[12] Ozempic® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. https://www.novo-pi.com/ozempic.pdf
[13] Latif W, Lambrinos KJ, Rodriguez R. Compare and Contrast the Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) [Updated 2023 Mar 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572151/
[14] American Diabetes Association. Standards of care in diabetes—2024. Diabetes Care. 2024;47(suppl 1):S1- S321.

improving the lives of those living with serious chronic conditions—a commitment we demonstrate through our efforts to promote access and affordability.

Notably, the price of Ozempic® has substantially declined every year since launch. Since Ozempic® was first introduced in 2018, the net price—the amount that is actually paid to Novo Nordisk for the medicine—has declined by roughly 40 percent in the U.S. The decrease in net price has been driven largely by the market dynamics that are common in highly competitive product classes, where health plans negotiate substantial price concessions from manufacturers in exchange for preferred formulary access. As more GLP-1 receptors enter the market, increased competition will continue to place downward pressure on net prices. Today, 80 percent of U.S. patients—and 82.5% percent of Maryland patients, specifically—with insurance coverage for Ozempic® are paying $25 or less for each prescription, and 90 percent —are paying $50 or less. Additionally, 99.6% of Medicaid patients pay less than $5 on average for Ozempic®.[15] Short-sighted price-setting policies advanced by state governments are likely to disrupt these competitive dynamics by discouraging additional manufacturers, including generic manufacturers, from entering the market.

For patients who continue to struggle to afford their medication, either due to inadequate plan benefit design or a lack of coverage altogether, Novo Nordisk provides additional financial support through our affordability programs. We also provide copay assistance for Ozempic® that reduces a commercially insured patient's out-of-pocket cost to as little as $25. As evidenced by our efforts, Novo Nordisk remains committed to ensuring access to our medications by reducing the out-of-pocket cost burden, helping to transform the complex pricing system, and fostering better pricing predictability.

The methodology used by the Board to select Ozempic® for a cost review is misguided.

The information underpinning the Board's decision to proceed with a cost review on Ozempic® is based on limited data that does not reflect the actual price that health care systems, plans, and PBMs pay. As noted previously, 80 percent of U.S. patients—and 82.5% percent of Maryland patients, specifically—with insurance coverage for Ozempic® are paying $25 or less for each prescription, and 90 percent— are paying $50 or less. While the process of conducting a cost review includes gathering additional information regarding a drug and its price, the Board's process so far has been opaque and uneven. For instance, it remains unclear how the Board assessed all drugs eligible for a cost review and ultimately selected the six drugs subject to review. Additionally, there is no clear process for manufacturers to dispute or correct inaccurate information received by the Board before it proceeds to vote on whether use of a drug "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients"; without transparency around the data the Board is using to assess Ozempic®, Novo Nordisk is unable to verify the accuracy of the information. Given current market dynamics, the risk of inaccuracy could have dire consequences for patient access. The PDAB's process of conducting cost reviews and potentially seeking to implement a UPL must be

[15] Novo Nordisk internal data on file.

fair, reasoned, and transparent. It must allow for meaningful engagement with manufacturers and other stakeholders.

A UPL would put Ozempic's® current access and affordability for the majority of Marylanders at risk.

Healthcare in America is complex - varying insurance plans with different formularies and coverage policies create inconsistencies in access and affordability for patients. To ensure that our patients can access our medications, we offer substantial price concessions to ensure patients can reasonably afford their medication. Novo Nordisk has worked to ensure Ozempic® is covered by 99% of commercial insurance plans in the United States.

An UPL could undermine this affordability picture, and potentially *raise* out-of-pocket costs for patients, as plans may prefer other medications not subject to an UPL that can continue to offer larger rebates to insurers and PBMs. As we have stated in our previous comments, research has consistently shown that plans tend to prefer highly rebated products over lower priced alternatives, given the impact of rebates on keeping plan liability and premium pressure low. A recent Government Accountability Office report highlighted that "Part D plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which generally had lower rebates."[16] Setting a UPL for drugs sold in the state of Maryland, could result in decreased access to those drugs as the dynamics in the current system favor drugs that have higher rebates. The impact of a UPL would undermine the PDABs goal of lowering costs and promoting affordable access for state and local governments and Medicaid.

A UPL that is too low could lead payors to disadvantage UPL-subjected drugs in favor of competitors with higher list prices/higher rebates. While the Board is looking at a select few medications used to treat diabetes, it is not looking at the drug class in totality. As the Board seeks to apply UPLs to select drugs, it is effectively putting its thumb on the scale and picking winners and losers within a crowded and highly competitive drug class. Recent history demonstrates that this not a purely theoretical concern. In 2020, the drugmaker Viatris launched the biosimilar Semglee® at a substantially lower wholesale acquisition cost (WAC) than its reference product, Lantus®. After realizing very modest formulary uptake, Viatris launched a higher priced version of Semglee®, with the flexibility to offer manufacturer rebates to plans and PBMs. The relaunch of Semglee® at a higher WAC resulted in greater formulary access and increased market volume.[17] Novo Nordisk observed similar trends with our own unbranded

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[16] Government Accountability Office. CMS Should Monitor Effects of Rebates on Drug Coverage and Spending: Statement of John E.
Dicken, Director, Health Care Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives [Internet]. 2023 Sep 19 [cited 2024 Jun 30]. Available from: https://www.gao.gov/assets/gao-23-107056.pdf

[17] Fein AJ. How Health Plans Profit—and Patients Lose—From Highly Rebated Brand-Name Drugs [Internet]. Philadelphia, PA: Drug
Channels Institute; 2019 Feb 20 [cited 2024 Jun 30]. Available from : https://www.drugchannels.net/2019/02/how-health-plansprofitand-patients.html

biologic for NovoLog®, which launched at a 50 percent reduction from the branded list price to address policymaker interest in lower list prices and to provide an additional option to lower out of pocket costs for some patients. Plan uptake of the unbranded version was tepid. In 2023, formulary access of the insulin aspart unbranded biologic stood at 4 percent, while it was 58 percent for branded NovoLog®.[18]

The prescription drug supply chain continues to be driven by misaligned incentives – where PBMs' horizontal and vertical integration has created and compounded financial conflicts of interest and incentives for their business practices that threaten to "lessen competition, disadvantage rivals, and inflate drug costs—all to the detriment of patients." [19] As a result of this consolidation, the largest PBMs in the U.S. exert significant control over the treatment options available to patients.[20] Through formulary designs, PBMs apply influence by directing patients to medications that can generate the highest rebates from manufacturers.[21] Loss of coverage can also be extremely disruptive for patients and clinicians. Patients that need a new prescription will require additional prescriber visits that could disrupt continuity of care and increase the likelihood of care delays, increasing the risk of hospitalizations and increased overall healthcare costs.

Given these complexities outlined above, we urge the Board to reconsider making any decision related to the proposed review of Ozempic®. Further, we urge the Board to refrain from seeking to impose a UPL, as it would ultimately undermine the Board's goals of promoting access and affordability.

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Maintaining access to Ozempic® is crucial for patients living with type 2 diabetes. With its proven effectiveness in lowering blood sugar levels and reducing the risk of cardiovascular events, Ozempic® represents a valuable treatment option for managing diabetes and improving overall health outcomes. Ensuring access to Ozempic® enables patients to realize its therapeutic benefits, which ultimately leads to better disease management, enhanced quality of life, and the potential for lower healthcare costs associated with diabetes-related complications.

Novo Nordisk is committed to working with patients and payers to ensure that those who benefit from our medications have access to them. Because Ozempic® is both highly effective and broadly affordable, we respectfully request that the Board decline to conduct a cost review for Ozempic®, and caution that the unintended consequences of pursing a UPL could upend care for thousands of Marylanders living with diabetes.

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[18] Novo Nordisk internal data on file.
[19] The Federal Trade Commission. Interim Staff Report. July 2024. "Pharmacy Benefit Mangers: Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacy." Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (ftc.gov)
[20] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022. https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html
[21] *Id. at 15*

Thank you for the opportunity to provide comments and for your consideration of the issues raised in this letter. Should you have any questions or concerns, please contact Ryan Urgo, Head of Policy, at RVUR@novonordisk.com for additional information.

July 22, 2024

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

RE: SIX DRUGS CHOSEN FOR COST REVIEW
(FARXIGA, JARDIANCE, OZEMPIC, TRULICITY, DUPIXENT, SKYRIZI)

Dear Members of the Board,

As a broad coalition of advocacy organizations representing patients, caregivers and health care providers, we write concerning the value of the six drugs chosen by the Prescription Drug Affordability Board for cost review and consideration of affordability. The Coalition has previously submitted comments expressing concern that methods available to the Board to lower health care spending – the setting of upper payment limits, in particular – may restrict patients' access to needed treatments. Therefore, we are hopeful that the Board will consider the value of access to these drugs when considering affordability.

The Value of Care Coalition believes that value is best determined by those who know – providers who prescribe medicines and patients who rely on the medicine to keep their medical conditions stable. Just as the term "affordability" has many different definitions and could be determined by a multitude of criteria, so does "value". Cost and value are not the same thing, but cost, or affordability, cannot be fully considered without accounting for value.

DIABETES TREATMENTS

At the May 20 meeting of the Prescription Drug Affordability Board, the Board voted to review four drugs with an indication for type 2 diabetes as a "class". It is not clear what this grouping means for how reviews are conducted, or the drugs are compared to each other or other treatments, and it is not clear if such a grouping is appropriate considering the different types of treatments within the group.

FARXIGA, JARDIANCE, OZEMPIC, TRULICITY

Two of these treatments, Farxiga and Jardiance, are SGLT-2 inhibitors. Two others, Ozempic and Trulicity, are GLP1 agonists. While each drug is used to treat type 2 diabetes, they are not all the same and physicians value each for their unique role in their toolbox of treatments.

For example, Farxiga and Jardiance both treat chronic kidney disease and heart failure independent of diabetes, but are commonly used for patients with both heart failure or chronic kidney disease and diabetes. Farxiga has also been shown to reduce cardiovascular death with certain kinds of heart failure, while Jardiance may be prescribed for people with diabetes and established cardiovascular disease or stroke. These two drugs are taken orally.

Ozempic and Trulicity are commonly prescribed for type 2 diabetes and weight loss. Ozempic has also been shown to reduce risk of cardiovascular hospitalizations and death. These two drugs are injected.

There is a well-established connection between diabetes and cardiovascular disease. People with diabetes are at a greater risk of heart failure.[1] In fact, according to the Partnership to Advance Cardiovascular Health, "people with type 2 diabetes are twice as likely to develop heart disease and if they struggle with obesity their risk is even higher."[2]

Cardiovascular disease was the cause of death for over 900,000 Americans in 2020 – more than all forms of cancer and Chronic Lower Respiratory Disease combined. Meanwhile, in 2020, heart attacks occurred approximately every 40 seconds, and someone died of stroke every 3 minutes 17 seconds in the United States. As of 2018, the prevalence of adult obesity stood at 43% of males and 41.9% of females in America with an upward trend over the previous twenty years.[3]

In the face of these statistics, physicians value treatments tailored to patients' unique needs and comorbidities. Additionally, loss of access to these medications could force doctors to veer from evidence-based guidelines.

At the same time, the value patients find in these treatments is immense. Without access to a treatment that works for them, that they're comfortable with and that keeps their condition stable, their diabetes may be less well controlled. This can lead to weight gain and higher risk for other complications such as eye disease, neuropathy, foot complications and limb loss, gum disease, hearing loss, and cardiovascular disease, chronic kidney disease, and stroke.[4] These comorbidities are each debilitating in their own way, causing patients pain, suffering and an inability to go about their day to day lives as they otherwise would.

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[1] CDC, *Your Heart and Diabetes,* https://www.cdc.gov/diabetes/diabetes-complications/diabetes-and-your-heart.html

[2] Partnership to Advance Cardiovascular Health, *The Diabetes-Cardiovascular Connection, https://www.youtube.com/watch?v=RshYNrftKwo*

[3] American Heart Association, *2023 Heart Disease and Stroke Statistics Updated Fact Sheet, https://professional.heart.org/en/science-news/-/media/453448D7D79948B39D5851D1FF2A0CFE.ashx*

[4] American Diabetes Association, *Diabetes Complications, https://diabetes.org/about-diabetes/complications*

Left untreated, the progression of chronic kidney disease can lead to cardiovascular complications, hospitalizations, dialysis and kidney transplant.

Likewise, the benefits of these treatments related to cardiovascular diseases are profound. Consider a patient who suffers a stroke. Lucky to be alive, they may face paralysis causing them to lose mobility, have speech and language problems, vision problems, trouble thinking and memory issues. They can no longer work or even hold their child or grandchild. The value of treatment proven to reduce stroke risk is extraordinary to this patient.

In addition to the value found in quality-of-life aspects provided by these treatments, a forced switch to another medication may result disease progression, symptoms re-emerge or new side effects surfacing, more doctor visits, hospitalizations, additional treatments, and lost economic output in terms of missed work. In fact, the American Heart Association estimates the indirect cost of cardiovascular disease alone to be "$155.9 billion in lost productivity/mortality" from 2018-2019.[5]

DUPIXENT

Dupixent is a biologic approved for several conditions, including eczema, asthma, nasal polyps and eosinophilic esophagitis, including approval for young children for many of those indications. Prescribers value Dupixent for its versatility as asthma and nasal polyps often coexist, as do asthma and eczema. Like other treatments being assessed, Dupixent treats multiple debilitating conditions at the same time.

From the patient perspective, consider a patient with severe asthma and nasal polyps. Symptoms of polyps can include runny nose or congestion, postnasal drip, loss of smell and taste, pain in the face and teeth, headache and snoring.[6] With proper treatment, polyps shrink. The patient no longer needs surgery to remove polyps. Their nose stops running and they can breathe again. They can smell again and taste food. And they may feel better than they have in decades.

In the short term, asthma patients can have trouble breathing, suffer from wheezing, coughing and tightness or pain in the chest. Symptoms can be exacerbated by simple changes in the weather, seasonal cycles, and many other common triggers. [7]

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[5] American Heart Association, *2023 Heart Disease and Stroke Statistics Updated Fact Sheet, https://professional.heart.org/en/science-news/-/media/453448D7D79948B39D5851D1FF2A0CFE.ashx*

[6] Mayo Clinic, *Nasal Polyps, https://www.mayoclinic.org/diseases-conditions/nasal-polyps/symptoms-causes/syc-20351888#:*

[7] Asthma and Allergy Foundation of America, *Asthma Facts, https://aafa.org/asthma/asthma-facts/*

Like many chronic conditions, uncontrolled asthma can lead to further complications. Damage to airways and lungs can occur, sleep can be disrupted, pregnancy complications can arise, patients face an increased risk of infection, gastroesophageal reflux disease and obesity.[8] On average, 10 Americans die from asthma each day and nearly all deaths are avoidable with proper treatment and care.[9]

Conversely, when not facing common asthma symptoms or reducing the impact of common triggers, patients value the ability to live their daily lives, missing fewer days of work, exercising, playing outdoors with their friends or their children.

For a patient with eczema, the impact of proper treatment can be equally valuable. According to the National Eczema Association (NEA), 10% of Americans have some form of eczema. Unbearable itching can occur, lasting 12 or more hours per day. Some patients have severe pain. About a third of patients face insomnia, shorter sleep time, daytime sleepiness and fatigue. NEA states that hospitalizations due to flares of atopic dermatitis "and related infections is associated with an 8.3-year reduction in lifespan compared to the general population."[10]

Without their condition controlled, sores emerge requiring regular antibiotics. Lifestyle impacts emerge. Patients report feeling angry or embarrassed about their appearance due to their disease, causing them to limit interactions with others. They turn down job or educational opportunities. Children and teens are bullied because of their disease. Mental health can suffer as feelings of isolation, frustration, helplessness and sadness set in. Economically speaking, NEA reports "nearly 5.9 million work days annually are lost due to eczema."[11]

SKYRIZI

Plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis are all treated with Skyrizi. The inflammatory bowel diseases can be life-threatening, while psoriatic arthritis can be debilitating, and plaque psoriasis can be associated with severe complications. Like other treatments chosen for assessment, prescribers value Skyrizi in their toolbox because of its versatility. It is not uncommon for psoriatic arthritis and inflammatory bowel disease to occur simultaneously, and Skyrizi is one of only two drugs in its class that are approved to treat the joint, skin and bowel conditions.

Clinicians also note that the medical benefits of this drug can be life-changing for patients, and switching to another drug on the PDAB's therapeutic alternative list may be inappropriate for

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[8] Asthma.com, *Uncontrolled Asthma's Effects Over Time,* https://www.asthma.com/treating-asthma/effects-of-asthma/

[9] Asthma and Allergy Foundation of America, *Asthma Facts, https://aafa.org/asthma/asthma-facts/*

[10] National Eczema Association, *Eczema Stats, https://nationaleczema.org/research/eczema-facts/*

[11] ibid

the patient's condition. Moreover, when talking about autoimmune diseases, it is important to understand that people sometimes have an initial response to a treatment followed by a change in their immune system which causes them to need a different treatment. Similarly, a patient switched to another drug followed by a return to the original drug may find that the original drug does not work anymore due to changes in the immune system. Therefore, prescribers value access to multiple treatments with a variety of mechanisms of action and the ability to maintain access to the treatment as long as it's working.

Among psoriasis patients, plaque psoriasis is the most common type of psoriasis and causes scaly, itchy, painful patches on skin.[12] If not controlled, this can lead to frequent complications such as infections, requiring additional doctor visits and treatments. Psoriatic skin disease can cause superinfections than can lead to life-threatening sepsis. Unfortunately, about one in three people with plaque psoriasis will develop psoriatic arthritis.[13]

For patients whose psoriatic arthritis is newly controlled by proper, effective treatment, the elimination of joint inflammation leads to incredible gains in quality of life. Where their disease can be deforming, debilitating and deadly due to an increased risk of early heart disease, and it had previously caused them to be unable to work or do hobbies, play with their kids or be active in their communities, effective treatment allows them to function, work, and go about their daily lives.

Meanwhile patients with inflammatory bowel disease face persistent diarrhea, abdominal pain, bleeding, weight loss and fatigue.[14] This disease puts patients at risk for gastrointestinal cancer and can lead to removal of portions of the gastrointestinal tract. If the disease is active, the patient may be bleeding and not absorbing food, which can be deadly. With proper treatment, symptoms can be managed, and disease progression can be slowed or stopped, preventing these outcomes.

Unfortunately, inflammation in the gut, skin and joints can flare relentlessly and simultaneously. Without proper treatment, this can lead to worse health outcomes and absorption of more medical resources, time and cost for the system and the patient.

CONCLUSION

Each treatment selected for review by the Maryland Prescription Drug Affordability Board provides unique value to prescribers and the patients they treat.

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[12] National Psoriasis Foundation, *Plaque Psoriasis,* https://www.psoriasis.org/plaque/
[13] National Psoriasis Foundation, *About Psoriasis,* https://www.psoriasis.org/about-psoriasis/
[14] CDC, *What is inflammatory bowel disease?,* https://www.cdc.gov/ibd/what-is-IBD.htm#

In each instance, prescribers value the ability to treat their patients more efficiently and holistically as the conditions the drugs treat often exist simultaneously (i.e. psoriatic arthritis and inflammatory bowel disease) or create greater risk for each other (i.e. diabetes and cardiovascular disease). To be able to effectively treat one condition while also lowering the risk of another with one medication is impactful to their practice of medicine. While there may be other treatments for each indication, each drug listed is a valuable tool in the toolbox for doctors as they assess the medical needs of each individual patient.

Patients value the ways these treatments change their lives for the better. What was once a deadly diagnosis is something that can now be managed. They now have the power to control their symptoms and do things many Americans may take for granted – work, play, interact with friends, family and colleagues in a meaningful, productive way, exercise, go outside, and even simply breathe normally.

While it may be difficult to properly quantify the value doctors find in these treatments or that patients receive in terms of quality of life, these benefits cannot be ignored when considering cost and affordability. The Value of Care Coalition asks that as the Board evaluates the affordability of the treatments its chosen, it considers the value these treatments provide to clinicians and patients in Maryland.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition