Testimony

Maryland Prescription Drug Advisory Board
Re: Drugs Referred to the Stakeholder Council
Sent Via Email comments.pdab@maryland.gov

Dear PDAB Board Members and Staff,

Boehringer Ingelheim submits this testimony in response to the Prescription Drug Advisory Board's Meeting from March 25th, specifically Attachment A "March 25 Preliminary Identification of Potential Drugs for Referral to the Stakeholder Council".

Founded in 1885 and independently owned ever since, Boehringer Ingelheim is a research-driven company with 53,000 employees around the world dedicated to the discovery and development of breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, we create value through innovation in areas of high unmet medical need focused on breakthrough therapies and first in-class innovations.

Boehringer understands the scrutiny over prescription drug prices. The U.S. healthcare system is complex and often does not work for patients, especially the most vulnerable. In many cases patients face prices at the pharmacy counter that are out of reach. Policy reforms are needed that will address the root of the problem. While we understand that there is a need to find ways to concurrently reduce state budget expenditures and reduce patient out of pocket costs, we feel compelled to show our five areas of concern about using an Upper Payment Limit (UPL) as a solution.

1. A UPL Unlikely to Reduce Cost for Patients:

Simply capping the price of a prescription drug for the payor or pharmacy benefit manager (PBM) with an upper payment limit (UPL) will not directly help people at the pharmacy counter. Pharmacy counter prices are controlled by the patient's insurance plan.

Boehringer currently provides significant discounts and rebates off the list price of its medicines to insurers, pharmacy benefits managers and other parties. Unfortunately, these discounts are not always passed on to patients. As a result, patients often face high out-of-pocket costs at the pharmacy counter.

Prescription drugs subject to an UPL will likely have less ability to offer the rebates necessary to negotiate with PBMs to guarantee preferred tier access to patients. PBMs and other middlemen seek larger and larger rebates from manufacturers that rarely reach

patients while claiming they are providing cost savings to their customers. Their goal is not to ensure the best patient outcome but to continue to extract rebates for formulary access. This perverse incentive means that although Jardiance® has proven its value to patients and health systems patients may not have access due to PBM decisions.

2. A UPL is Likely to Hurt Patient Access:

Boehringer shares your goal of ensuring patients have access to the medicines we develop. However, instituting an UPL may further restrict access for some patients. Patient access may decrease for drugs subject to an UPL because they may be placed on a less preferred tier, and this is all due to the financial incentives of the PBM and health plans. The health care system – including how payors purchase drugs – drives the misaligned incentives. Manufacturers negotiate rebates with PBMs for preferential formulary placement on tiers that provide patients with low-cost sharing. If a PBM/Payor is not satisfied with rebate negotiations, they may choose another prescription drug that is not therapeutically equivalent to the preferred drug for a given condition and put the low-rebate drug on a tier that limits patient access and is more expensive for patients or sometimes remove the drug from their formulary altogether.

3. Jardiance® Data Proves Its Value:

Boehringer Ingelheim's focus has always been helping to improve outcomes for adults living with a range of cardio-renal-metabolic conditions. We are confident in the value that Jardiance® brings to patients and the healthcare system.

Jardiance® is a highly utilized drug since it treats interconnected co-morbid conditions referred to as Cardio-Renal-Metabolic diseases. It is an SGLT2 inhibitor approved for Type II diabetes and three additional indications including cardiovascular disease associated with Type II diabetes, chronic heart failure, and chronic kidney disease (CKD).

Almost 60% of U.S. adults aged 65 years and older – more than 33.5 million Americans - have at least one cardio-renal-metabolic condition, driving significant disease burden, mortality and total overall healthcare spend.

Jardiance® is the number one prescribed SGLT2 inhibitor with 59 million prescriptions. Boehringer is committed to our patients and approximately 88% of Jardiance patients pay no more than $50 for their prescriptions due to our multiple assistance programs.

The American Rescue Plan Act removed the statutory cap on rebates resulting in some pharmaceutical manufacturers paying more than 100% in rebates on some products to Medicaid.

Peer-reviewed, published economic assessments using real-world data consistently demonstrate that Jardiance® lowers the total cost of care. Studies show Jardiance® is cost-effective in treating CKD. For commercial payers, the increased effectiveness of treating CKD with Jardiance® resulted in a lower cost of approximately $16,363 per patient per year for payers.[1]

Another specific example of Jardiance's® value is demonstrated through Outcome Based Agreements with large health systems. For example, Boehringer entered into an Outcomes-Based Agreement with Highmark in Pennsylvania to demonstrate the value of Jardiance®. The results showed that Jardiance® reduced the total cost of care by 20%. Specifically, the cost of care savings was driven by a 30% reduction in the total annual medical spend for adults with type 2 diabetes and cardiovascular disease who took Jardiance compared to other anti-glycemic medications. This is just one example – there are more.

By putting a UPL in place, fewer patients will have access to Jardiance® due to the complexity of our healthcare system leading to higher total costs of care and patient disruption. Jardiance® has already proven its value by leading to better health outcomes for patients and by demonstrating overall cost savings to the healthcare system and state.

In 2015, a Jardiance® landmark clinical trial became one of the most significant breakthroughs in the field of diabetes care and the first ever trial for any diabetes medication to show statistically significant reduction of adverse cardiovascular outcomes in people with type 2 diabetes and established cardiovascular disease. This trial forever changed the way healthcare providers treat adults with type 2 diabetes and led to change in the professional diabetes treatment guidelines in the United States and worldwide. In 2016, FDA relied on this landmark clinical trial to approve Jardiance® "to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease."[2]

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[1] National Institute of Diabetes and Digestive and Kidney Disorders. Kidney disease statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease. Updated September 2021. Accessed January 18, 2023

[2] Jardiance® (empagliflozin tablets) Prescribing Information at 1 (Dec. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf.

We have continued to invest significantly in research and development that has extended the impact of Jardiance® to expand its use with additional patient populations. The CKD indication was the result of this continued investment.

This is a critical point because investment in drugs does not end once it is approved for one condition, research, and development (R & D) investments continue. Price control policy would negatively impact decisions to continue investing in R&D for such drugs.

4. <u>Jardiance's Focus on Health Equity</u>:

Cardiovascular Disease is the leading cause of death in the US; and Diabetes is the eighth leading cause of death in the US. These diseases are more common among people who are members of some racial and ethnic minority groups and groups with lower socioeconomic status. [3] By enacting UPLs on drugs that treat these diseases, patients may be disadvantaged by access restrictions and changes in formulary coverage.

CKD is more common among Black and Hispanic adults, compared to White adults.[4] Additionally, health disparities in CKD are exacerbated when there is poor access to health care and health insurance. Certain racial and ethnic groups have an increased risk of type 2 diabetes and hypertension which could lead to a faster onset and progression of CKD.

Increased awareness of the importance of screening and early detection of CKD would benefit patients. In its initial stages as many as 9 in 10 adults with CKD are not aware they have the disease.[5] If left untreated CKD may progress into end-stage renal disease (ESRD) requiring dialysis or kidney transplant.[6] Those options impact quality of life and add cost to the health care system.

[3]CDC.gov. Advancing Health Equity | Diabetes | CDC; Accessed April 12, 2024.
[4] National Institute of Diabetes and Digestive and Kidney Disorders. Kidney disease statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease. Updated September 2021. Accessed January 18, 2023
[5] National Institute of Diabetes and Digestive and Kidney Disorders. Kidney disease statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease. Updated September 2021. Accessed January 18, 2023
[6] National Institute of Diabetes and Digestive and Kidney Disorders. Kidney disease statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease. Updated September 2021. Accessed January 18, 2023

5. Costs and Data Analysis Transparency

Per the state statute, the purpose of the Board is to protect state residents, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system from the high costs of prescription drugs.[7] Implementation of this misguided law in FY 2023 expended $1.4M in operational costs with another estimated $1.4M in FY 2024 for almost $3M in total costs derived from fees on manufacturers without achieving any cost savings for patients.[8] Also, these budget allocations do not include the extra costs incurred by the Maryland Health Care Commission since the law's initial inception.

These operational costs, including the data analysis to set a UPL does not solve for the stated goals of the Board, but increases the cost to manufacturers and does nothing to reduce the out-of-pocket costs for the patients or to reduce the overall healthcare costs to the state.

The lack of transparency in the data methodology calls conclusions into question since the analysis and results cannot be independently verified.

Conclusion

Boehringer opposes government price setting programs at the federal and state level as they do not ensure lower prices for people at the pharmacy counter.

In addition, these policies can also jeopardize patient access and the ability for manufacturers to invest in future innovations.

We respectfully request you remove Jardiance® from further review.

Regards,

Bridget Walsh
VP, Government Affairs and Public Policy
Boehringer Ingelheim Pharmaceuticals, Inc.

[7] Pena-Melnyk, D. et al., Maryland House Bill 769; 2019 Regular Session - House Bill 768 Enrolled (maryland.gov). Accessed April 12, 2024.
[8] Fiscal Digest FY 2023 (maryland.gov); Accessed April 12, 2024