AARP Maryland

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July 1, 2025

To the Members of the Maryland Prescription Drug Affordability Board:

AARP Maryland, on behalf of its more than 850,000 members in the state, urges the Maryland Prescription Drug Affordability Board (PDAB) to move rapidly to adopt Upper Payment Limits (UPLs) on Jardiance and Farxiga. The cost savings that will result from the first two UPLs adopted by the board are both critically needed and clearly warranted, as the PDAB's own research has found. These two drugs are very widely used for treating diabetes, heart failure and chronic kidney disease, and their lofty and rising prices are major cost drivers for state and local government entities that would benefit from these UPLs.

Putting these UPLs into effect sooner rather than later is important for multiple reasons. First of all, the savings involved are large and will aid both the state and local government agencies at a time when they are severely challenged financially, as are their employees and dependents who also will benefit. Second, these two drugs not only are very high priced and show a history of recent significant price increases, but they also are critically needed by patients. It is with such factors in mind that the federal government chose these two Rx drugs as among the first batch for Medicare's own negotiated drug prices.

AARP Maryland also urges the PDAB to be wary of comments from entities, purportedly representing patient organizations, urging delays in the UPL process. Some of these groups draw their principal financial backing from pharmaceutical producers and other entities in the Rx drug industry. And they are acting in the interests of their sponsors rather than of patients themselves. This has become apparent in comments submitted to, or presented at, meetings of the PDAB's Stakeholder Council, of which I am a member. For instance, one recent comment urged the PDAB to work with the Maryland legislature to put in place unspecified "safeguards for patients" prior to moving forward with UPL policies. This comment fails to recognize everything the PDAB already has done to ensure that UPLs are applied in the right way.

It has been more than six years since the law establishing the PDAB was enacted. During that time, the board has been meticulously preparing for the start of UPLs, keeping all stakeholders informed in the process. It very carefully selected the initial drugs for UPLs, using the federal government's research as well as its own to decide that Farxiga and Jardiance are the right products to start with. And it has kept all stakeholders informed throughout the process of what it plans to do and why. AARP Maryland commends the PDAB for all these steps and urges it to go forward with the initial UPLs now.

Sincerely,

James Gutman
AARP Maryland Health Care Advocacy Volunteer Lead
and PDAB Stakeholder Council Member

Boehringer Ingelheim

July 09, 2025

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

Dear PDAB Board Members and Staff,

Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer) is sending this letter in response to the cost dossier published by the Maryland Prescription Drug Affordability Board (PDAB) for Jardiance (empagliflozin). Boehringer is a research driven company with approximately 53,500 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 for the patients we serve. We share a common goal with Maryland PDAB to ensure affordability and access for patients to medicines. Given our limited time to respond, enclosed is high level feedback we strongly encourage Maryland PDAB to consider in order to develop meaningful reform. We remain committed to working with the Board and its staff to develop solutions that help patients better afford their medicines.

Price-setting tactics do not consider the complexity of US drug pricing and do not address individual patient out-of-pocket (OOP) costs or affordability.

Evaluating cost impact of Jardiance to the state of Maryland by looking at "total gross spending" in Section 4 of the dossier is an inaccurate and misleading metric to assess pricing and patient affordability because it does not reflect actual spend or patient OOP costs. Gross sales do not reflect the substantial rebates and discounts, which may be both mandatory (such as to Medicare and Medicaid programs) and discretionary (such as rebates to commercial health plans), and to various stakeholders involved in the supply chain. These rebates and discounts are a competitive market requirement to ensure formulary coverage and access to Jardiance and may be used by payers to subsidize benefit costs across members, but do not directly benefit the individual patient taking Jardiance. Price-setting approaches, like imposition of an "upper payment limit," could further exacerbate, not alleviate, access barriers for patients and impede Boehringer's R&D investments into treatments for unmet needs.

Furthermore, evaluating "total number of patients in the State using [Jardiance]" reflects a *system* level budget impact of drug cost, whereas patient affordability assesses *individual patient* OOP burden and access to therapy. Conflating the two can lead to conflicting conclusions and undermine the transparency and predictability necessary to complete an analysis. For example, Factor 7.7 attempts to project gross spending for Jardiance "if all patients used a full year of treatment" based on the annual WAC cost. Even if this analysis included the more accurate actual cost of Jardiance to Maryland after discounts and rebates were applied and real-world adherence patterns, the output would still be wholly irrelevant to what individual patient OOP costs are for Jardiance and overall patient affordability.

Inconsistent and missing information suggest additional time and resources are needed to conduct an accurate assessment of Jardiance.

Boehringer recognizes the challenges to appropriately evaluate a product like Jardiance with four FDA-approved indications, extensive and comprehensive clinical and real-world evidence data, and a broad Cardiovascular Renal Metabolic (CRM)–eligible patient population that is often comorbid and

complex. However, given the significant implications of any price-setting measures to patients and access, it is imperative that resources and attention to detail in the materials used in this decision-making process, including the development of a publicly available dossier, be commensurate to the task.

In Section 2.2 of the dossier outlining the "disease burden of the condition that is treated by the prescription drug product," Boehringer observes that only 3 of the 4 indications for Jardiance are mentioned: Type 2 Diabetes Mellitus (DM), Heart Failure (HF), and Chronic Kidney Disease (CKD).[1] The use of Jardiance to reduce risk of cardiovascular death in DM patients with established cardiovascular disease (eCVD) is absent despite eCVD being the most prevalent of the 4 CRM diseases in Maryland (41.3%, compared to 13.4% with HF, 28.4% with DM, and 6.4% with CKD).[1,2]

Similarly, there is inconsistent reporting of information across the 4 indications further suggesting that any analyses or conclusions made from the information in the dossier would be incomplete. The dossier includes that the "diabetes-attributable total and per-person productivity losses due to morbidity were $3.4B and $6,224, respectively" in 2021 in Maryland. However, no similar figures are reported in the HF and CKD sections, and eCVD is absent entirely.

Boehringer must also note that "dapagliflozin", rather than "empagliflozin", the correct chemical name for Jardiance, was listed on page 64 as the search term used by staff to search for relevant articles in the dossier. This, along with numerous other misspellings throughout the document, raises concerns of invalid word searches and review. Several links that are referenced in support of the dossier are also missing or invalid (please see appendix for full list). These inaccuracies may lead reviewers to incorrect or incomplete conclusions.

There are limited conclusions that can be drawn from claims and pricing analyses with redacted or incomplete source information.

As stated above, drug pricing in the US is multifaceted and involves several interrelated factors across a variety of stakeholders, including, but not limited to, manufacturers, payers, distributors, wholesalers, pharmacies, and patients. While Boehringer appreciates the attempt to consider some of these factors in the dossier, there are inherent limitations with prescription claims data as well as the sources Maryland PDAB cited for its pricing assumptions.

Claims data, even if complete, is most appropriate to evaluate specific moments in time or *trends* in drug utilization. On its own, however, claims data cannot inform what the specific cause or drivers are for any observed trends. For example, the analyses in Factor 7.1 to estimate the "impact on patient access resulting from the cost of [Jardiance] relative to insurance benefit design" attempts to compare reported patient OOP costs to the change in utilization or "number of prescriptions a patient has in a year." Regardless of the results, a *causal* relationship cannot be confirmed. Changes in an individual patient's utilization may or may not be related to OOP cost or more plainly, patient OOP cost is only one of many factors that may influence utilization.

It's also critical to note that final patient OOP costs in claims data are rarely accurate, especially in the commercial channel, because secondary insurance or manufacturer copay programs that further reduce patient responsibility are not included. For Jardiance, 47% of Commercial *claims*, not patients, in Maryland utilized the copay program as of June 2024,[3] which means the OOP spend of nearly half of all Commercial claims included in the analysis would be overestimated.

Lastly, Boehringer strongly cautions that any assumptions related to commercial or Medicare rebates and net pricing from SSR health may not be accurate and should not be uniformly assumed across all payer channels or calendar years. For example, in Factor 5.2, Maryland PDAB attempts to estimate "net sales amounts of [Jardiance]" by applying the most recently available SSR rebate estimate (2024 Q2) to 2023 Commercial and 2022 Medicare gross sales.

The dossier does not recognize the transformative value of Jardiance across 4 CRM conditions.

Jardiance is a transformative medication that addresses multiple interconnected diseases with a single once-a-day oral[1] treatment. The well-established safety profile and holistic approach to treatment offered by Jardiance has led to a paradigm shift in the management of CKD, HF, and DM, as recognized by professional guidelines and FDA Fast-Track designations. Despite this, Factor 2.1 "clinical information" and 2.2 "disease burden of the condition that is treated" does not mention this overlap of CRM conditions that Jardiance treats, nor the significant economic and clinical value of a single oral treatment across these comorbid conditions. Traditional claims data, which are cited in the dossier, often fails to capture the full spectrum of cost savings from improved patient outcomes, such as reduced hospitalizations, fewer ER visits, enhanced productivity, and lower mortality rates, thereby underrepresenting Jardiance's true value. Jardiance provides substantial cost savings across its CRM indications by lowering healthcare expenses. For patients with T2, Jardiance results in annual savings of $13,704 per patient per year compared to other antidiabetic medications, including an approximate 50% reduction in medical costs.[4] This includes a 60% reduction in emergency room (ER) costs, a 37% reduction in outpatient costs, and a 62% reduction in inpatient costs.[4] Heart failure patients, with or without type 2 diabetes, experience annual savings of $14,271 per patient per year and a 53% reduction in medical costs with Jardiance.[4] For chronic kidney disease patients, annual expenses range from $8,700 to $144,000 for those 65 and under, with medical costs comprising 93.6% and prescription drug costs 7.4% of all costs.[5,6]

Jardiance is already affordable for Maryland patients.

Boehringer remains committed to ensuring Jardiance remains accessible and affordable for all patients in Maryland. In 2024, the average commercial OOP cost for State of Maryland employees (net manufacturer assistance and copay card support) was $32.40 for both 30-day and 90-day prescriptions.[7] This amount is lower than the average commercial OOP cost of Jardiance for the State of Maryland, which was $44.13, and the national commercial average OOP cost of Jardiance which is $44.41.[7] Additionally, the copay for Jardiance, as a preferred formulary product, is $25 for patients enrolled in the Maryland Commercial and Employer Group Waiver Plans (EGWP) and $15 for Maryland State Law Enforcement Labor Alliance (SLEOLA) employees.[8] The lower copay for State of Maryland Employees and 47% commercial utilization rate of Boehringer's copay assistance program mentioned above highlight Jardiance as an accessible, affordable, and highly efficacious treatment option for a wide range of patients in Maryland.

Boehringer works collaboratively with partners to help patients afford their medications by enrolling in programs that also help them stay compliant and adherent to their therapy. Our goal behind our efforts working across the healthcare ecosystem is to improve patient outcomes and minimize the need for additional healthcare services like routine lab visits or expensive hospitalizations, or search for other affordable options for their medications.

Boehringer respectfully urges the Board to consider the above information and the implications of price setting tactics—like imposing an "upper payment limit"—due to the complexities of the prescription drug supply chain. Jardiance is a transformative therapy for patients in Maryland with serious, costly, and inter-related CRM conditions. Jardiance provides clinical and economic value for these patients via broad access, highly discounted pricing and low OOP cost that already benefits patients.

APPENDIX

The following links do not lead to a valid webpage:

a. Page 2: https://pdab.maryland.gov/index.html
b. Page 22 – reference 45: https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/summarysupplemental-applications-proposing-labeling-changes-approved-drugs-and-biologicalproducts
c. Page 23 – reference 53: https://www.fda.gov/advisory-committees/endocrinologic-and-metabolicdrugs-advisory-committee/june-28-2016-meeting-endocrinologic-and-metabolic-drugsadvisory-committee
d. Page 65 – reference 66: https://www.cms.gov/priorities/medicare-prescription-drugaffordability/overview/medicare-drug-price-negotiation-program/selected-drugs-andnegotiated-prices

REFERENCES:

1. JARDIANCE® (empagliflozin tablets), for oral use. Prescribing Information. Boehringer Ingelheim; 2023.
2. Torch Insight - Analysis of 2021 Medicare Claims limited data sets, 2017. Salt Lake City, UT. Data retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets
3. RelayHealth Pharmacy Solutions. Data run September 2024.
4. Data on File. Boehringer Ingelheim Pharmaceuticals, Inc. 2024
5. Golestaneh L, Alvarez PJ, Reaven NL, et al. All-cause costs increase exponentially with increased chronic kidney disease stage. *Am J Manag Care*. 2017;23(10 Suppl):S163-S172.
6. U.S. Bureau of Labor Statistics. CPI for All Urban Consumers (CPI-U): Medical care in U.S. city average, all urban consumers, not seasonally adjusted. January 2022-December 2022.
7. IQVIA Longitudinal Access and Adjudication Data (LAAD). Data run September 2024.
8. MedImpact Healthcare Systems, Inc. MedImpact Prescription Handbook. Maryland Department of Budget and Management. 2023. Accessed July 1, 2025. https://dbm.maryland.gov/benefits/Documents/CY25%20Medimpact%20Prescription%20Handbook.pdf

EACH PIC COALITION

July 3, 2025

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

RE: Public Comments on Jardiance Dossier

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

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

On behalf of our national network of patient organizations, we appreciate the opportunity to provide comments to the board on Jardiance. We continue to urge the board to carefully evaluate the impact implementing UPLs could have on patients in the state and to consider the concerns of patient organizations as they proceed with cost reviews and consideration of UPLs.

Comment Deadlines and Complexity of Process

While we appreciate the board's continued effort to implement a transparent and thorough cost review process, we again must emphasize that Maryland has established an incredibly complex process with multiple and overlapping deadlines for comment. Further, providing only a 15 day comment period on the dossiers for Farxiga and Jardiance is inadequate to allow for substantive analysis and response.

We again urge the board and staff to provide greater clarity around the cost-review process as a whole and provide a minimum 60-day comment period on data related to cost reviews and UPL implementation.

Centering the Process on Patient Burdens and Affordability

We continue to encourage the board to center cost reviews around the lived experiences of patients and the real-world affordability challenges they face. A review that focuses solely on systemic or payer-level costs risks overlooking the most meaningful aspect of affordability: the context behind affordability concerns, including the impact on people's ability to access and adhere to their prescribed medications.

We urge the board to make good on its commitment to consider multiple policy interventions, by utilizing the cost review process to clearly identify the root causes of affordability and access challenges for patients for each drug under review.

Therapeutic Alternatives Are Not Interchangeable

The course of treatment for each patient is as unique as the individual and their disease. Once diagnosed with a chronic condition, each patient starts an often life-long journey to identify the correct treatments and regimen to successfully manage their symptoms and improve their

health. Many will also face multiple chronic conditions or need medications to treat specific symptoms or even side effects of their preferred treatment. Patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered.

For these patients, therapeutic alternatives may not be alternatives at all. Very often drug interactions or other health conditions would prevent individual patients from being able to switch to an alternative medication that, on paper, seems like it would be an appropriate treatment. Further, patients with chronic conditions can build up a tolerance to medications over time, so they must retain access to all treatments in a class of drugs to prolong their treatment.

Therefore, we urge the board to carefully evaluate the needs of all patients. Failure to do so can result in limiting options within a therapeutic class to only one option - which might not be the right option for many patients.

Protect Patient Access to Care

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.

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.

We encourage the board to take the necessary time and care to ensure this process supports, not disrupts, continuity of care. Patients must not face unintended consequences from policy decisions that limit treatment options or impose additional burdens.

To that end, we strongly urge the board and staff to utilize the authority of the board to fully explore with all healthcare stakeholders how they will implement UPLs to identify in advance any potential adverse impact to patients.

Finally, we invite the board to utilize this organization and its EACH and PIC members as a direct conduit to understanding and incorporating patient and caregiver perspectives, as we have the best understanding of the life cycle of disease from the lens of prevention, diagnosis, and disease management.

We appreciate your commitment to this work and offer our coalition as a continued resource in elevating patient voices and informing thoughtful, patient-centered policymaking.

Sincerely,

Tiffany Westrich-Robertson
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

EACH PIC COALITION

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

Maryland

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

DOSSIER COMMENT - Jardiance

1 message

Joan Leahy [redacted] > Thu, Jun 19, 2025 at 8:18 AM
To: comments.pdab@maryland.gov

Affordability problem - with Part D, this medication costs us approximately $400/month until we reach the $2000 cap set by Medicare this year. Already taking much less expensive medication Metformin, so not an alternative choice.

Sent from Yahoo Mail for iPhone

July 2, 2025

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

The Maryland Health Care for All Coalition (HCFA) is pleased to offer our support for the work the Prescription Drug Affordability Board (PDAB) and its staff are doing to complete the Cost Review Study for Jardiance, including the published dossier.

Jardiance is widely used for treating diabetes, heart failure, and chronic kidney disease, and we know from the Board's work and previous public comment that its high cost has harmed Maryland patients and is a direct contributor to the immense strain that expensive prescription drugs place on our state and local government budgets. Comment submitted by Public Citizen for the January 2025 Board meeting indicated that Jardiance has generated more than $28 billion in revenue for AstraZeneca, largely from charging patients in the United States over eleven times more than in comparable countries. Predatory patenting tactics have extended the monopoly on this product, keeping costs to patients and our health care system higher for longer.

We have held forums across the state in past years, and routinely heard from patients about their struggle to afford Jardiance. One patient wrote, "I'm on Medicaid and if I ever make just enough to not be on Medicaid I won't be able to afford this medication [Jardiance] which works tremendously well for me. I forgot to take it for about 3 or 4 days a few months ago and my blood sugar went up, I started having neuropathy in my feet, I felt constantly tired, and that's what made me look to see if I had the Jardiance in my 'pill minder' and I didn't. **Within a day back on the Jardiance I was feeling better. It is a serious worry for me – not being able to afford the drug that is keeping me health and functional so I can still work.**"

We know this issue extends beyond the pharmacy counter for patients, as anti-diabetics are the single biggest expenditure for the state health plan, meaning our state and local governments are burdened by the skyrocketing costs of these medications. It is important that the Board acts quickly to establish an upper payment limit for this prescription drug, along with Farxiga, so that taxpayers can begin to save millions of dollars that are essential for other critical services.

Importantly, since Jardiance is on the CMS list of Medicare Maximum Fair Price negotiated products, the Maryland PDAB could utilize this negotiated cost as an upper payment limit for our state. An estimated 19,000 state residents on Medicare use Jardiance, and we look forward to the savings these Marylanders will see come January 1, 2026 when the negotiated price is utilized. We encourage the PDAB to build on this progress to generate real savings to the state.

2600 St. Paul Street Baltimore, MD 21218
www.healthcareforall.com
Phone (410)235-9000 Fax (410)235-9000

Our coalition thanks the PDAB for its great work so far and encourages thoughtful, swift action on this matter. Should the Board and Staff wish to speak to Maryland patients regarding their experiences with Jardiance, we would be happy to connect you with consumers willing to provide feedback.

2600 St. Paul Street Baltimore, MD 21218
www.healthcareforall.com
Phone (410)235-9000 Fax (410)235-9000

July 3, 2025

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

Re: FARXIGA AND JARDIANCE COST REVIEW DOSSIERS

Dear Members of the Board,

As a broad network of patient, caregiver, and health care provider advocacy organizations, the Value of Care Coalition (VCC) writes to share concerns regarding the recently published cost review dossiers on Farxiga and Jardiance. We appreciate the Board's commitment to reviewing one aspect of health care affordability in Maryland and value the opportunity to submit these comments.

VCC's July 2024 comments, which can be found within Exhibit 4A of each dossier, emphasize the belief that no discussion of prescription drug affordability is complete without consideration of value. We believe value is best defined by patients who receive the life-changing benefit of these treatments and by clinicians who weigh individual risks, comorbidities, and long-term outcomes of these treatments.

The current dossiers for Farxiga and Jardiance reflect great effort to compile certain data points but ignore others through their omission. The only instances highlighting the perspectives of stakeholders closest to the drugs being reviewed are relegated to exhibits containing a handful of written comments regarding each drug.

The dossiers lack any data on why clinicians prescribe these specific drugs, why patients choose these drugs, or how health outcomes would be impacted without these drugs. Data is not included regarding the value to the society that these drugs provide – whether it be direct savings from additional health care services that are no longer needed thanks to the slowed disease progression or prevention these treatments provide, or the economic benefit received through the increased productivity of patients whose conditions are now stable.

The dossiers, as they stand, reflect little effort to understand the value these treatments provide to health care providers and the patients they serve.

The Value of Care Coalition urges a focus on thorough, complete processes and re-refers the Board to its previous comments dated July 22, 2024, informed by prescribers of each treatment, for a brief summary of the value they and their patients perceive in these innovative, life-changing medications. As we wrote nearly a year ago:

"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."

Thank you for your willingness to consider stakeholders' perspectives of value. Each affordability review will benefit from the input of the full range of stakeholders, particularly patients and healthcare providers.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition