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

July 3, 2025

VIA ELECTRONIC MAIL

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

Re: Dossier Comment – FARXIGA® (dapagliflozin)

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care. AbbVie is using advanced technologies and data science to gain unprecedented insights that help us to target medicines more precisely, identify opportunities for combinations and provide patients and their physicians with actionable diagnostic tools, treat disease and to respond to unmet patient needs. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives. AbbVie manufactures and markets SKYRIZI®, one of the products selected by the Board for a "cost review" (or "affordability review").

AbbVie is submitting these comments in response to the Board's dossier for FARXIGA® to highlight a selection of a myriad of concerns regarding the Board's work product and how it was developed. Please note that the issues and flaws we have identified herein by no means represent the universe of objections we have to the dossier and the Board's development of it, or any other aspect of the Maryland PDAB statute and/or the Board's implementation or interpretation of the law (including, among other things, the Board's compliance with Maryland's Administrative Procedure Act ("APA") and other applicable legal authorities and its activities, policies, and processes). Also, our submission of these comments does not waive in any way future objections we may raise related to the same. We maintain and reiterate our serious concerns, as repeatedly detailed in the Company's prior comment submissions to the Board incorporated by reference herein,[1] regarding the Board's reliance on flawed data, policies, and procedures in connection with its decision-making and affordability review activities to date.

[1] *See, e.g.*, AbbVie's Comments on SKYRIZI®'s Selection for Cost Review (July 22, 2024), at https://pdab.maryland.gov/Documents/comments/Board%20selected%20Drugs%20Comments.pdf; AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024), at

***General Concerns*:**

As a threshold matter, in its haste to push through unsupported and ineffective policies, the Board continues to prioritize speed over substance, in the process failing to sufficiently weigh public feedback and depriving stakeholders of substantively meaningful opportunities for engagement. For example, the Board posted revised Version 1.1 of the FARIXA® dossier on June 18, 2025, giving stakeholders a mere 11 business days to comment on a more than 80 page document (which, notably, does not identify changes made by the Board to prior published iterations of the document — *e.g.*, on March 17, 2025, May 12, 2024, and May 19, 2024); in contrast, the Board has been developing this dossier for more than 18 months.

On this truncated timeline, the Board did not afford stakeholders adequate opportunity to validate or provide feedback or additional context to any data and/or data elements cited in the dossier. Data sources reviewed by the Board are likely incomplete or inaccurate even for the most basic elements, as exemplified by the flawed NDC-11 list for FARXIGA® discussed further below. Nonetheless, the Board is concurrently forging ahead with the RFI process for additional drugs before it even receives feedback on its first round of cost review data compilations, again begging the question of whether the Board is meaningfully considering any of the feedback it is receiving from stakeholders in this context as well as more broadly. Significantly, Maryland courts recognize "an implied limitation upon an administrative board's authority . . . that its decisions be supported by facts and that they be not arbitrary, capricious or unreasonable."[2] An agency's failure to consider a particular argument or information presented in public comments, or negative consequences of a policy enactment, can provide the basis for arbitrary and capricious review.[3]

The Board also continues to evidence what appears to be a lack of comprehension of basic pharmaceutical industry concepts, definitions, and information sources. For example, the first section of the FARXIGA® dossier includes "a list of all possible NDC-11 codes associated with Farxiga (proprietary name) and dapagliflozin (non-proprietary name)[,]" which the Board finalized

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https://pdab.maryland.gov/Documents/comments/AbbVie_MD%20PDAB%20Comment%20Letter_May%209%2024-FINAL.pdf; AbbVie's Comments on the Board's List of SKYRIZI® Therapeutic Alternatives (May 13, 2024), at https://pdab.maryland.gov/Documents/comments/MD%20PDAB%20Therapeutic%20Alternatives%20Comments%20-%20SKYRIZI.pdf; AbbVie's Comments on SKYRIZI®'s Selection and Referral to the Stakeholder Council (April 23, 2024), at https://pdab.maryland.gov/Documents/comments/4.29.2024%20PDASC%20Comments%20combined.pdf.

[2] *Heaps v. Cobbs*, 185 Md. 372, 380 (1945); *see also Reese v. Dep't of Health & Mental Hygiene*, 177 Md. App. 102, 144 n.21 (2007) (recognizing that "administrative mandamus . . . creates a right of judicial review of a quasi-judicial order or action of an administrative agency" because Maryland courts have "inherent power . . . to correct abuses of discretion and arbitrary, illegal, capricious[,] or unreasonable acts"). Maryland law defines a "[q]uasi-judicial function" to include "a proceeding before an administrative agency for which Title 7, Chapter 200 of the Maryland Rules would govern judicial review." Md. Code, Gen. § 3-101(i). The Maryland Rules provide for judicial review of "an order or action of an administrative judicial review is authorized by statute." Md. R. Jud. Rev. Cir. Ct. 7-201(a). The Maryland PDAB statute authorizes review of Board decisions. Md. Code, Health-Gen. § 21-2C-15. Thus, final decisions of the Board—such as affordability determinations and adoption of policy recommendations—must be supported by facts or otherwise risk invalidation.

[3] *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (describing one basis of arbitrary and capricious agency action as entirely "fail[ing] to consider an important aspect of the problem" intended to be addressed); Md. Bar Ass'n, Practice Manual for the Maryland Lawyer, ch. 3, Administrative Law § 5 (6th Ed. 2023) (Maryland courts generally "seek to harmonize Maryland common administrative law and Maryland APA interpretation with federal administrative law").

more than a year ago in May 2024. In this first section, the Board further surmises whether FARXIGA® authorized generic products exist, seemingly characterizing the issue as ambiguous when it is anything but.[4] Simple internet searches should have led Board Staff to delete close to half of the list of FARXIGA® NDCs and resolved any confusion as to whether authorized generic versions of FARXIGA® are currently marketed. For example, readily available public information indicates the following:

Table 1. NDC List

	National Drug Code	Proprietary Name	Non-Proprietary Name	Dosage-Strength	
✖	00003-1428-11	Farxiga	Dapagliflozin	10 MG	*Discontinued in 2017*
✖	00003-1428-12	Farxiga	Dapagliflozin	10 MG	*Discontinued in 2017*
✖	00003-1428-13	Farxiga	Dapagliflozin	10 MG	*Discontinued in 2017*
✖	00003-1428-14	Farxiga	Dapagliflozin	10 MG	*Discontinued in 2017*
✖	00003-1428-91	Farxiga	Dapagliflozin	10 MG	*Discontinued in 2017*
	00310-6210-90	Farxiga	Dapagliflozin	10 MG	
	00310-6210-30	Farxiga	Dapagliflozin	10 MG	
	00310-6210-39	Farxiga	Dapagliflozin	10 MG	
✖	00310-6210-95	Farxiga	Dapagliflozin	10 MG	*Sample (Non-Commercial) Product*
	50090-3481-00	Farxiga	Dapagliflozin	10 MG	
	50090-7057-00	Farxiga	Dapagliflozin	10 MG	*Authorized Generic per FDA NDC Directory*
	55154-6933-08	Farxiga	Dapagliflozin	10 MG	
	63629-3253-01	Farxiga	Dapagliflozin	10 MG	*Authorized Generic per FDA NDC Directory*
	66993-0457-30	Farxiga	Dapagliflozin	10 MG	*Authorized Generic per FDA NDC Directory*
✖	00003-1427-11	Farxiga	Dapagliflozin	5 MG	*Discontinued in 2017*
✖	00003-1427-12	Farxiga	Dapagliflozin	5 MG	*Discontinued in 2017*
✖	00003-1427-13	Farxiga	Dapagliflozin	5 MG	*Discontinued in 2017*
✖	00003-1427-14	Farxiga	Dapagliflozin	5 MG	*Discontinued in 2017*
✖	00003-1427-91	Farxiga	Dapagliflozin	5 MG	*Discontinued in 2017*
	00310-6205-90	Farxiga	Dapagliflozin	5 MG	
	00310-6205-30	Farxiga	Dapagliflozin	5 MG	
✖	00310-6205-95	Farxiga	Dapagliflozin	5 MG	*Sample (Non-Commercial) Product*
	50090-3482-00	Farxiga	Dapagliflozin	5 MG	*Authorized Generic per FDA NDC Directory*
	50090-7056-00	Farxiga	Dapagliflozin	5 MG/1	*Authorized Generic per FDA NDC Directory*
	55154-6932-08	Farxiga	Dapagliflozin	5 MG/1	
	66993-0456-30	Farxiga	Dapagliflozin	5 MG/1	*Authorized Generic per FDA NDC Directory*

The substantial problems associated with one of the most basic types of information in the FARXIGA® dossier – the NDC-11s in scope of the PDAB's cost review – hardly inspires confidence in the quality of the broader data set considered by the Board, particularly with respect to more nuanced data elements. Throughout its drug selection and cost review process, the Board has repeatedly failed to articulate how it will appropriately consider and weigh the accuracy, reliability, and validity of the data sources it references, and how the Board will limit its consideration of data and information from such sources to the factors listed in statute and implementing regulations. The PDAB's decision-making can be only as accurate as the data and

[4] *See* Maryland Prescription Drug Affordability Board, "Farxiga (dapagliflozin) Dossier (June 18, 2025, Version 1.1)," at 5 (stating that "Staff found conflicting information concerning the availability of authorized generics for Farxiga. The FDA's published list of authorized generics identifies no authorized generic for Farxiga. However, based on the labeler codes, a subset of the NDCs included in this dossier may be authorized generics.").

information upon which the Board relies, so we request that the Board identify with greater specificity the processes it will implement to help reduce the risk that the Board's analyses may rely on erroneous, incomplete, dated, or otherwise misleading and/or deficient datasets or analyses. The FARXIGA® NDC list alone is evidence as to why such vetting of the Board's work product is critical.

***Select Examples of Specific Concerns*:**

As we have explained in prior comment letters, the Board's actions have not served the public interest, including, prominently, the needs of patients: pointedly, we believe that the Board has yet to satisfy the statutory directive to consider, in conducting a cost review, patients' out-of-pocket costs—that is, "[t]he average patient copay or other cost–sharing for the prescription drug product in the State …."[5] For example, the FARXIGA® dossier provides no further clarity on how, if at all, the Board will consider patient out-of-pocket costs. We identify and outline below additional examples of factors included in the FARXIGA® dossier that, if further applied by the Board to other drugs for which it conducts cost reviews, require clarification and reconsideration:

- **Scope of Data Considered:** The Board must determine "affordability" solely as to state and local government entities to which a UPL would apply and should not consider "affordability" as to commercial payors and other entities to which a UPL would not apply. A substantial amount of the data in the FARXIGA® dossier appears to be derived from drug price and cost metrics associated with commercial utilization of the products the Board will have deemed unaffordable. The Board exceeds the scope of its currently applicable statutory authority and violates Maryland's APA by considering affordability based on data that clearly, erroneously, unreasonably, and disproportionately skews the Board's findings against manufacturers. For example, relative out-of-pocket costs, payor costs, co-pay and cost-sharing amounts, and various spending metrics, among other data elements, are generally higher for a drug in the commercial context as compared to those entities to and contexts in which a UPL will apply in practice.

- **Clinical Information:** The dossier does not address the quality of evidence related to FDA indications and doses, nor does it assess how this impacts the appropriateness of the adopted therapeutic alternatives. Currently, there is no transparency or standards guiding how the PDAB plans to evaluate evidence or the key factors that will be used in decision-making by the Board as it reviews information in the dossier (Factor 2.1).

- **Disease Burden:** The dossier fails to adequately capture the broader societal and financial burdens, aside from direct medical costs. It also overlooks stakeholder and patient group feedback on living with diabetes and the burdens of inadequate disease control. Notably, for FARXIGA®, there is a lack of reference to the insights from CMS's patient listening sessions,[6] which could have been a valuable resource. A more comprehensive analysis of the additional

[5] Md. Health Gen. § 21-2C-09(b)(2)(x).

[6] Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program, "Transcript: Farxiga, November 2, 2023 Medicare Drug Price Negotiation Program Patient-Focused Listening Session," at https://www.cms.gov/files/document/farxiga-transcript-110223.pdf.

burdens of uncontrolled disease and the impact on quality-of-life metrics and caregiving is needed (Factor 2.2).

- **Health Economics and Outcomes Research:** The methodology for conducting the literature review, including search terminology and criteria for study inclusion, is not disclosed. This lack of transparency raises questions about the choice of included studies. Additionally, there is no clear explanation of how studies across indications are weighted, raising concerns about the results' applicability. The dossier also diminishes the importance of patient preferences and patient-important outcomes such as medical adherence, which should be emphasized (Factor 6.5). Significantly, during the May 19th PDAB meeting, a Board member requested the PDAB to provide the inclusion and exclusion criteria used to determine which literature to include for this section. Another Board member noted that the PDAB should use "as much real world evidence [studies] as possible as opposed to relying on clinical trial data only," which tend to have too many restrictions on who could participate. None of this feedback appears to have been incorporated into the FARXIGA® dossier.

- **Pricing Information:** The dossier should consider changes in total net spending for decision-making rather than gross spending. Annual pricing based on unit prices does not always reflect real-world utilization, especially when different dosing requirements are considered. Additionally, redaction of publicly available pricing information limits stakeholders' ability to verify and correct errors (Factor 4.2 and Factor 5.1). Stakeholders did not get the opportunity to validate or provide feedback or additional context to any data utilized in the selection, which is important because data sources reviewed by the Board may be incomplete or inaccurate for this purpose. For example, the dossier lacks transparency regarding SSR net price estimates and calculation methodology, which prohibits accurate verification and correction of potential errors (Factor 5.2). 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.

- **Utilization of Drug Product Under Review:** For each NDC, Board Staff used MCDB claims data to calculate: (1) the number of patients in Maryland that uses FARXIGA®; (2) the total gross spending in the state; (3) and the percentage of overall total prescription drug product spending that FARXIGA®'s spending represents by payor type. To determine the impact of FARXIGA®'s utilization and spending on public budgets, Board Staff gathered budget data at the county level. In recognizing that the data was not uniform, the Board Staff noted during the May 19th PDAB Meeting that "[i]n future Cost Review Studies, staff will continue to work with state and local governments, and other public budgets, to identify standardized data to support this analysis or develop other methods of conducting this analysis."[7] Significantly, this key limitation was not addressed at all in the dossier published nearly a month later. The Board continues to identify key problems but does nothing to meaningfully address them.

- **Miscellaneous Product Information:** The relevance of the drugs' FDA approval path in the Board's process is unclear, and particularly as to how approval paths impact issues of patient

[7] *See* FARXIGA® Dossier at 42.

affordability and access. It would be beneficial to clarify how breakthrough and priority review commentary within FDA indications is weighed or considered by the Board (Factor 3.1).

- **Lifecycle Management:** While the Board has never explained how it will evaluate lifecycle management issues, much less how those issues are relevant to patient affordability and access, at a minimum any analysis of this information should be conducted by those with expertise in intellectual property and the generic and biosimilar ecosystem. The Board appears to lack that expertise, and the omission of information on expected generic or biosimilar entry timing is a significant omission (Factor 3.3).

- **Patient Assistance Programs:** There is a need for clarification on the relevance of patient access programs in assessing affordability by the Board. It would be beneficial to understand how and **whether** manufacturers' patient assistance programs influence decision-making regarding drug affordability (Factor 7.2).

* * * *

The FARXIGA® dossier amplifies the significant concerns we have with the Board's process for developing these data compilations, which clearly lack rigor, consistency and thoroughness and thus fall short of representing a drug's full value to patients. The Board is well aware of these concerns through comments and other stakeholder engagement throughout the cost review process but continues to ignore this feedback. Indeed, the Board even acknowledges the flaws in its dossier in public meetings yet fails to take any action in its work product to address them.

Thank you for the opportunity to provide this feedback. Please feel free to contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

Helen Kim Fitpatrick
Vice President, State Government Affairs
On behalf of AbbVie Inc

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July 3, 2025

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 FARXIGA (dapagliflozin) Cost Review Study Dossier (June 18, 2025)**

Dear Members of the Maryland Prescription Drug Affordability Board:

AstraZeneca appreciates the opportunity to submit comments regarding the recent FARXIGA (dapagliflozin) cost review dossier. AstraZeneca is a global, science-led biopharmaceutical company dedicated to discovering, developing, and commercializing prescription medicines for many therapeutic areas, including Oncology, Cardiovascular, Renal and Metabolism, Respiratory, and Rare Disease. We remain committed to developing innovative, lifesaving medicines and ensuring accessibility for patients. We are providing comments on several topics discussed in the dossier in order to clarify information that will be helpful as the cost review continues, including information on the relative cost of FARXIGA in Maryland, cost offsets and material savings, the role of plan design in patient affordability, the status of the authorized generic, loss of exclusivity, and the scope of the cost review currently underway.

Relative Cost of FARXIGA in Maryland Context

According to the dossier, the State of Maryland's annual spending on FARXIGA is reported to be $20–$30 million. In contrast, total annual spending on diabetes care alone in Maryland exceeds $6 billion (Dossier, p. 12). FARXIGA therefore accounts for only a very small fraction, approximately 0.5% at the high end of the range, of the State's direct diabetes-related healthcare costs. This fraction is even smaller when factoring in the multi-billion-dollar burden from treating other diseases for which FARXIGA is indicated, particularly heart failure and chronic kidney disease (CKD). Allocating such a small percentage of the overall disease cost to an innovative medicine that addresses multiple high-cost endpoints and improves outcomes such as hospitalization and death is reasonable and beneficial for both the State and patients.

Cost Offsets and Material Savings

It is not sufficient to consider only the drug's gross cost. Consideration must also be given to the overall impact of disease burden and the potential avoidance of meaningful and costly events such as hospitalization, cardiovascular death and the potential progression to kidney failure. These consequences of disease are significant to patients and to overall healthcare spend. Reduction in these meaningful events translates to significant medical care cost offset. Factor 6.4 of the dossier specifically mentions the importance of reductions in healthcare spending due to improving health (offsets). High-quality U.S. analyses have shown that Farxiga offsets much of its acquisition cost

through reduced hospitalizations for heart failure and delayed progression to kidney failure. The true net impact of Farxiga on state budgets must look at overall patient impact and include these avoided downstream costs.

Critically, the dossier does not address the scale of Maryland's financial burden from advanced CKD and dialysis, among the most expensive and devastating complications of diabetes and heart disease. Dialysis typically costs the state tens of thousands of dollars per patient per year, not including productivity loss, increased mortality risk, and quality-of-life reductions.

Similarly, the financial offset of heart failure hospital admissions is not addressed. Hospital admissions for heart failure cost many thousands of dollars per event and represent a significant share of inpatient spending, in addition to resulting in frequent rehospitalizations, loss of independence, and increased mortality.

Omitting even an estimated accounting of avoided dialysis starts, CKD progression, or heart failure admissions overlooks significant cost-saving opportunities associated with FARXIGA's clinical benefit.

Patient Affordability Challenges Reflect Plan Design, Not Drug Price

Where patient affordability challenges are discussed in the dossier, these are primarily the result of insurance benefit design (copay/coinsurance structures, deductibles) rather than the price of FARXIGA itself. For most patients, out-of-pocket costs are modest, and support programs are available to those who qualify. Importantly, federal regulations prohibit manufacturers from providing copay assistance to patients enrolled in federally funded programs, such as Medicare and Medicaid. Thus, patient cost exposure is largely determined by insurance design and federal policy, rather than the drug's pricing or net cost.

Authorized Generic Status

The dossier suggests uncertainty about the existence of an authorized generic for FARXIGA; however, this information is widely and readily available. Prasco Laboratories is the authorized generic distributor for dapagliflozin (FARXIGA) in the U.S. Confirming sources include:

> Prasco: https://prasco.com/authorized-generic-of-farxiga-dapagliflozin-tablets-and-xigduo-dapagliflozin-metformin-extended-release-tablets-available-from-prasco/
>
> Daily Med: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3aba33aa-f8c6-4b10-85c8-dfa14578d07c
>
> Drugs.com: https://www.drugs.com/availability/generic-farxiga.html

Loss of Exclusivity

The Board has stated that it anticipates Loss of Exclusivity on FARXIGA's primary patent in April 2026 but continues to assume lack of competition until the latest expiring patent in 2040. This is contrary to how competition enters the market. Historically, competitors enter the market soon after a new molecule entity patent expires. As of June

2025, the FDA has tentatively approved 18 applications for the generic manufacturing of FARXIGA[1]. AstraZeneca has stated in its Annual Report that it expects to lose exclusivity for Farxiga in April 2026 (see e.g., page 40: https://www.astrazeneca.com/investor-relations/annual-reports/annual-report-2024.html).

Scope of Review

To the extent that the dossier's analysis is based on commercial claims data outside Maryland State employee health plans and Medicaid, it falls outside the intended scope of the Board's statutory authority at the time the review began. For this cost review, the board is only authorized to implement a UPL on state and local funded programs. As a result, the data that has been submitted by private parties was limited to only state and local funded programs. If the board's authority expands in the future, a new affordability determination will be required under that expanded authority and implementing regulations.

FARXIGA's cost to Maryland health budgets is a fraction of the total outlay for diabetes and related chronic conditions, particularly given its impact across multiple high-cost complications. Considering the substantial medical and economic offsets documented in peer-reviewed literature—and the substantial, unaddressed, and escalating burdens of end-stage kidney disease and advanced heart failure in the state—the investment in FARXIGA represents a sound and affordable allocation of resources. Where patients experience cost barriers, these are principally linked to insurance benefit structures and federal regulatory limits on support programs, not to the drug's net value or price. The presence of an authorized generic and the upcoming loss of exclusivity, which will further reduce costs, underscores the poor choice of selecting FARXIGA for review.
Thank you for your consideration.

Sincerely,

Geoffrey A Gallo
Head of Corporate & State Government Affairs

[1] FDA-Approved Drugs, Search Results for "Dapagliflozin." Accessed 30 June 2025.
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

EACH PIC COALITION

July 3, 2025

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

RE: Public Comments on Farxiga 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 Farxiga. 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
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Ensuring Access through Collaborative Health (EACH) Coalition Lead

EACH PIC COALITION

Vanessa Lathan
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Patient Inclusion Council (PIC) Coalition Lead

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 once again offer our support for the work the Prescription Drug Affordability Board (PDAB) and its staff are doing to complete the Cost Review Study for Farxiga, including the published dossier.

Farxiga 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 Farxiga has generated more than $20 billion in revenue for AstraZeneca, largely from charging patients in the United States ten 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 Farxiga. One patient shared her story of having to drastically reduce her spending on groceries after being prescribed Farxiga. She was forced to choose between affording her prescription drug and maintaining a healthy diet to manage her loss of a kidney. Another Marylander was near financial ruin after finding herself in the donut hole, prior to the issue being remedied by President Biden's Inflation Reduction Act. Being 74 and living on a fixed income, she simply could not afford the $8,000 out-of-pocket costs she was required to pay before regaining coverage of essential prescription drugs, and as a result, she frequently had to ration her medications, including Farxiga.

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 Jardiance, so that taxpayers can begin to save millions of dollars that are essential for other critical services.

Importantly, since Farxiga 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 8,000 state residents on Medicare use Farxiga, 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.

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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 Farxiga, we would be happy to connect you with consumers willing to provide feedback.

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Value of Care Coalition

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