Farxiga (dapagliflozin)-
DRAFT Cost Review Study Report

Maryland Prescription Drug Affordability Board

March 16, 2026

Version 1.0

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Executive Summary

This document reflects the cost review study report for Farxiga. The report summarizes the information considered by the Board in conducting the cost review study, the Board's deliberations, the circumstances or indicia reflecting the affordability challenge, and the Board's preliminary determination.

Board staff presented information to the Board for consideration in the form of a cost review dossier and presentations at Board meetings. The dossier included information on the NDCs used in the analysis, clinical information on the drugs and the conditions it treats, information on the utilization and pricing of the drug, information on therapeutic alternatives, information on the cost-sharing related to the drug, and information received from the public and stakeholders. This report summarizes this information, and the complete dossier is included as an appendix.

Farxiga is a drug used for patients with type 2 diabetes (T2DM), heart failure (HF), and chronic kidney disease (CKD). These conditions are common and are of importance to public health. Clinical guidelines for these conditions recommend the use of Farxiga. Initially, Farxiga was approved for T2DM before getting additional indications. Generic versions of the product may enter the market in 2026, depending on resolution of patents other than primary patents. The use of Farxiga was spread across multiple NDCs, but when added together, made up over 1% of the total gross drug spending in some market segments. On a list price basis, the data suggested that Farxiga had prices (not including rebates) in excess of $5,000 per year. However, rebates substantially reduced the average net price of the drug. Generally, the use of Farxiga was associated with higher spending, but better health outcomes. Finally, the average out-of-pocket for the most common NDC (00310-6210-30) was $123.25 for the full year of 2023 for state and local government beneficiaries and $333.48 for patients with commercial insurance.

During the in-person Board Meeting on July 28, 2025, the Board deliberated on whether use of Farxiga has led or will lead to affordability challenges to the State health care system or high out-of-pocket costs for patients. This report includes a summary of the deliberations.

Based on these deliberations, the Board made a preliminary determination that use of Farxiga: (1) Has created an affordability challenge for the State health care system; and (2) That the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice. A final version of this resolution is included as Appendix B.

Background

Established in 2019, the Maryland Prescription Drug Affordability Board ("Board") is an independent agency charged with "protecting 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." Md. Code Ann., Health-Gen. ("HG") § 21-2C-02(b). The Board confers with, and receives input from, a 26-member appointed advisory Stakeholder Council composed of experts across the supply chain and stakeholder representatives.

Under HG § 21-2C-09, the Board may conduct a cost review study to determine whether use of a prescription drug product "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients ("affordability challenges")." *See also* COMAR 14.01.04.05 (establishing Cost Review Study Process). This study involves Board staff compiling and analyzing quantitative data, qualitative data, and public input for the Board to consider and determine whether use of the drug has led or will lead to affordability challenges. This study informs subsequent policy decisions and actions by the Board.

On July 22, 2024, the Board selected Farxiga for study to determine whether use of the drug has or will create an affordability challenge.

In response to this selection, Board staff developed a dossier to provide the Board with information addressing the factors the Board may consider under COMAR 14.01.05. Board Staff conducted literature reviews, analyses of the Maryland Medical Claims Data Base (MCDB), analyses of proprietary datasets, conducted a Request for Information (RFI) from manufacturers, wholesalers, PBMs, and payors. Staff also received public comments that are Exhibits to the dossier in Appendix A. Staff presented iterations of the dossier to the board to get feedback and update the dossier.

On July 28, 2025, the Board, at their open in-person Board meeting, considered whether use of Farxiga has led or will lead to affordability challenges to the State health care system or high out-of-pocket costs for patients, and whether that use was consistent with the labeling approved by the Food and Drug Administration (FDA) or standard medical practice.

The Board considered the data, analyses, and information assembled by staff in the dossier organized, in part, by regulatory factor.

The Board made a preliminary determination that use of Farxiga created an affordability challenge for the State health care system and identified three circumstances under which use of the prescription drug product led to an affordability challenge: (1) the percentage change in WAC over time is substantially larger than the percentage change in inflation (rate of increase in inflation) (closed session); (2) at 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors (closed session); and (3) total gross

spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments (public session).

In accordance with COMAR 14.01.04.05F, staff prepared a draft of the preliminary determination Cost Review Report. This report summarizes the information considered by the Board in conducting the Cost Review Study, the Board's deliberations, the circumstances or indicia reflecting the affordability challenge, and the Board's preliminary determination.

I. Summary of Information Considered by the Board

Introduction

In compliance with COMAR 14.01.04.05B, and to the extent practicable, Board staff assembled a dossier containing the data and analyses specified by Health-General Article §21-2C-09(b), Annotated Code of Maryland, and the regulations. To facilitate review and discussion, Board Staff structured the dossier thematically organizing the regulatory factors, data and analyses into eight sections, with six exhibits.

A redacted version of the dossier and exhibits are incorporated as Appendix A.[1]

The Board reviewed and considered the dossier and exhibits as well as two PowerPoint presentations from staff concerning these materials. This section summarizes the sections of the dossier and the key takeaways from the data considered by the Board.

Dossier Section 1: Background

This section lists the National Drug Codes (NDC-11) identified by staff for use in the cost review study. (Dossier, 5-6.)

Dossier Section 2: Clinical Information

> Factor 2.1: Clinical information, including FDA indications and doses and information concerning standard medical practice.
>
> Factor 2.2: The disease burden of the condition that is treated by the prescription drug product

This section contains information about the drug, including information about the diseases the drug treats, how the drug fits into clinical guidelines, the dosing of the drug, and the burden to society of the diseases treated by the drug. (Dossier, 7-20.)

Farxiga is approved as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus (T2DM), to reduce the risk of hospitalization for heart failure (HF) in adults with T2DM mellitus and either established cardiovascular disease (CVD) or multiple cardiovascular risk factors, and to reduce the risk of sustained eGFR decline, end-stage kidney disease (ESKD), cardiovascular death, and hospitalization for heart failure in patients with chronic kidney (CKD) disease at risk of progression. The Dossier assesses the clinical guidelines for each indication.

SGLT2 inhibitors (the therapeutic class in which Farxiga is a member) are a preferred drug class in the treatment of T2DM. SGLT2 inhibitors are typically considered as a first-line therapy

[1] An unredacted version of the dossier and exhibits are on file with the Board.

option for Type 2 DM given the overall safety (low risk of hypoglycemia), effectiveness in lowering blood glucose, and benefits/protection for CKD, CVD, and HF. Medical professionals prefer Jardiance, Farxiga, and Invokana, given their proven benefits for HF, CVD, and CKD.

To lower the risk of CKD progression and acute kidney injury and improve cardiovascular outcomes, SGLT2 inhibitors (equal weight preference to Jardiance, Farxiga and canagliflozin) are (1) recommended by major guidelines for adult CKD patients with Type 2 DM, HF and/or albuminuria ≥200mg/g; and (2) suggested for adult CKD patients with an eGFR of 20 to 45 ml/min/1.73m2.

SGLT2 inhibitors, specifically Jardiance, Farxiga, or Inpefa, are recommended for all symptomatic HF patients.

Each of these three conditions are conditions of public health importance. They are major sources of morbidity and mortality in the state and have severe public health consequences. Staff also found a significant percentage of patients had experienced comorbidity of multiple of the indications.

Dossier Section 3: Regulatory Approval and Market Context

Factor 3.1: Analysis of the prescription drug product's approval process

Factor 3.2: Analysis of the prescription drug product's shortage status

Factor 3.3: Analysis of the market context of the prescription drug product including the prescription drug product's lifecycle management, patent management, regulatory exclusivities, and product hopping

This section explores the approval of the drug product, information regarding the patents and exclusivities of Farxiga, the shortage status of the drug, and information about the life cycle management of the production.

Farxiga was originally approved to treat T2DM, but over time added additional indications as clinical evidence was gathered.

Farxiga is not in shortage and has not recently been in shortage.

According to patent data, Farxiga has a number of patents. The "primary patents" (the drug substance and product patents) are set to expire in 2026, potentially opening up for the potential of generic entry. However, the manufacturer has other patents that may block generic entry if they are not invalidated by litigation or the generic firms have not developed a product that does not infringe on those patents.

The manufacturer has produced other products that contain the same active ingredient as Farxiga. These other products also treat T2DM. These products are fixed dose combination products with dapagliflozin and other antidiabetic drugs, such as metformin. All of these drug products are

used much less frequently than Farxiga and thus do not tend to show a pattern of product hopping.

Dossier Section 4: Utilization of Drug Product Under Review

Factor 4.1: The total gross spending in the State for the prescription drug product under review, the total number of patients in the State using the prescription drug product, and the percentage of overall total prescription drug product spending that the product's spending represents

Factor 4.2: The change in total gross spending and utilization for a prescription drug product in the State between the two most recent available calendar years and the percent change in total gross spending for a prescription drug product in the State between the two most recent available calendar years

Factor 4.3: Impact of the utilization and spending for the prescription drug product on public budgets and comparison of the spending on the prescription drug product to relevant benchmarks

This section contains information concerning utilization of the drug. Board Staff provided the Board with tables summarizing the patient count, prescriptions, and units. In the Dossier, staff presented NDC level data by different types of insurance (Commercial, State and Local Government, Medicaid, and Medicare). While the information included a variety of NDCs, the utilization data was primarily concentrated in two NDCs, one reflecting 5 MG pills and the other reflecting 10 MG pills. The use of Farxiga was spread acrosss multiple NDCs, but when added together made up over 1% of the gross drug spending in some market segements.

Section 5: Pricing Information and Rebates

Factor 5.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS

Factor 5.2: Information estimating manufacturer net price and net sales amounts of the prescription drug product under review

Factor 5.3: The average price concession, discount, and rebate provided by the manufacturer or expected to be provided to each payor class in the State for the drug under review, expressed as a number and as a percent of the WAC

Factor 5.4: The average price concession, discount, and rebate the manufacturer provided or is expected to provide for the prescription drug product under review to each PBM operating in the State, expressed as a number and as a percent of the WAC

Factor 5.5: Information supplied by the manufacturer, if any, explaining the relationship between the pricing of the prescription drug product and (a) the cost of development and (b) the therapeutic benefit of the prescription drug product, or information that is otherwise pertinent to the manufacturer’s pricing decision

This section contains pricing information for Farxiga. Staff calculated the annual pricing measures based on a patient taking a pill every day for 365 days. Much of the data is redacted from the public versions of the dossier except for publicly available prices such as NADAC, SAAC, and FFS. On a list price basis, the data suggested that Farxiga had prices (not including rebates) in excess of $5,000 per year. The proprietary data found substantial rebates that reduced prices well below the listed prices. In comparison, the Medicare Negotiated Maximum Fair Price was under $2,200 per year.

Section 6: Therapeutic Alternatives, Cost Comparisons, and Health Economics Outcomes and Research (HEOR)

Factor 6.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS at which each therapeutic alternative has been sold in the State

Factor 6.2: The average price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the State for therapeutic alternatives

Factor 6.3: The utilization, costs, and out-of-pocket costs for therapeutic alternatives

Factor 6.4: The incremental costs associated with a prescription drug product, including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives

Factor 6.5: Information derived from health economics and outcomes research that may address the effectiveness of the prescription drug product in treating the conditions for which it is prescribed or in improving a patient's health, quality of life, or overall health outcomes, and the effectiveness of the prescription drug product compared with therapeutic alternatives or no treatment.

Factor 6.6: In the case of generic prescription drug products, the number of pharmaceutical manufacturers that produce the prescription drug product

Factor 6.7: The utilization and pricing of therapeutically equivalent drug products

This section contains information regarding therapeutic equivalent products and therapeutic alternatives.

Farxiga does not have any FDA approved therapeutic equivalent products (this does not include the authorized generic product, which is marketed pursuant to Farxiga's new drug application rather than approved on a separate application). In terms of therapeutic alternatives, the Dossier contains pricing and utilization information for a variety of drugs used to treat diabetes. Some drugs were in the same therapeutic class while others were in different classes. The Dossier also contains information on published studies related to the incremental costs and incremental benefits of the drug.

The pricing information on therapeutic alternatives found dramatic differences in price when compared to some alternatives not in the class, but prices in the same therapeutic class were in the same order of magnitude, except for Brenzavvy (bexagliflozin). Brenzavvy was substantially less expensive than other SGLT-2 inhibitors.

In terms of incremental cost and benefits, the dossier contained studies regarding the incremental effects of Farxiga in diabetes, heart failure, and chronic kidney disease. The studies differed in terms of patient populations, pricing assumptions, and comparator products. The study generally found that Farxiga resulted in increased cost compared to other drugs which were slightly offset by decreases in other health care spending. Depending on the comparator drugs, the studies found Farxiga produced more benefits in at least some subpopulations.

Section 7: Cost-Sharing and Insurance Benefit Design

Factor 7.1: The estimated impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design

Factor 7.2: The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer for the drug product under review and the policies surrounding and implementing such programs

Factor 7.3: The average patient copay and other cost-sharing data for the prescription drug in the State

Factor 7.4: The average cost share

Factor 7.5: The mean, median, and 90th percentile out-of-pocket costs per patient compared to State incomes

Factor 7.6: An assessment of the impact of the prescription drug product's cost to access by priority populations and the impact on equity

Factor 7.7: The costs to health plans based on patient access consistent with FDA-labeled indications or standard medical practice

This section includes information regarding patient access and out-pocket-cost for Farxiga. This section contains analysis of data from the MCDB on out-of-pocket and cost sharing. In addition, this section contains information derived from published studies on how out-pocket-cost impacts access, information derived from published studies on use of Farxiga by priority populations, and information from the manufacturer website regarding patient assistance programs. The average out-of-pocket for the most common NDC (00310-6210-30) was $123.25 for the full year of 2023 for state and local government beneficiaries and $333.48 for patients with commercial insurance.

Section 8: Other Information

Factor 8.1: Input from the Public

Factor 8.2: Analysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product

This section includes input from the public, information from the request for information (RFI), information from state and local government entities, and information on any other relevant regulatory issues. The section attaches input from the public that occurred at various times during the cost. The RFI information is included as an exhibit to the unredacted dossier but is redacted from the public version of the dossier. The Board received no input from state and local government entities. Finally, staff did not identify any other regulatory or compliance issue that would provide additional context for the market related to this prescription drug product.

II. Summary of Deliberations

On July 28, 2025, the Board convened to consider whether use of Farxiga has led or will lead to affordability challenges to the State health care system or high out-of-pocket costs for patients. Staff presented a PowerPoint presentation to the Board reviewing the dossier, as updated, including the sections, regulatory factors, and data and the Board asked clarifying questions.[2] The Board considered the data, analyses, and information assembled in the dossier, and as presented, and the public oral and written comments received as part of the cost review process.

Closed Session

The Board deliberated in closed session concerning confidential, trade secret and proprietary information and the circumstances reflected in and by the confidential, trade secret and proprietary data.

The Board observed that the percentage increase in WAC from launch was larger than increase in inflation over the same period (2014 to 2024).

The Board unanimously passed a motion making a preliminary determination that Farxiga has created an affordability challenge to the State healthcare system and identified as a circumstance: the percentage change in WAC over time is substantially larger than the percentage change in inflation.

The Board observed that the ratio between patient OOP cost and net cost paid by payors demonstrated that patient OOP cost is disproportionate to the net cost paid by payors.

The Board unanimously passed a motion to make a preliminary determination that Farxiga has created an affordability challenge to the State healthcare system and identified as a circumstance: at the 90th percentile, patient out-of-pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors.

Public Deliberations

During deliberations, a Board member observed that the total spending for state and local government employees for Farxiga is greater than 1%, representing a significant portion of drug spending, and proposed that this constitutes a circumstance under which use of Farxiga has created an affordability challenge. The Board member noted that the public data presented in the cost review dossier presentation and in the dossier underpins this circumstance. Another member pointed to the data in the dossier showing gross noted that (when rounded) state and local government spending on Farxiga NDCs were .09%, .and. 02% of total gross spending, adding to up 1.1% (Table 10b).

[2] On May 19, 2025, staff also presented a PowerPoint to the Board reviewing the then-current version of the dossier.

Deliberation also included discussion on the following matters:

- Farxiga is an effective drug and clear from clinical practice that Farxiga should be used;
- Because Farxiga is an effective drug, the Board did not discuss the pricing of therapeutic alternatives;
- The dossier showed the prevalence of diabetes and disease burden in Maryland;
- Concern that a single product (Farxiga) represents so much drug spend;
- Observation and concern regarding the limited utilization of Farxiga among Medicaid patients in the public data; and
- The desire for additional data and analyses on certain topics that would address other circumstances and clarify certain circumstances that could result in affordability challenges.

III. Circumstances and Indicia Reflecting the Affordability Challenge and Preliminary Determination

On July 28, 2025, the Board ratified the preliminary determination made and the two circumstances identified during the closed session, and the affordability determination and circumstance identified in open session, by adopting Resolution 2025-01 by unanimous roll call vote.

That resolution was subsequently amended/corrected, by unanimous vote.

The Corrected Resolution 2025-01 reads, in pertinent part:

> **RESOLVED** that:
>
> The Board makes a preliminary determination that use of Farxiga:
>
> Has created an affordability challenge for the State health care system; and
>
> That the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice.
>
> The circumstances under which the prescription drug product has led to an affordability challenge include:
>
> (1) the percentage change in WAC over time is substantially larger than the percentage change in inflation (rate of increase in inflation) (closed session);
> (2) at 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors (closed session); and
> (3) total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments (public session).
>
> Be it **FURTHER RESOLVED** that:
>
> In accordance with COMAR 14.01.04.05F(2), the Board's preliminary determination is non-final and subject to revision and modification; and
>
> Any circumstance is a sufficient and independent basis for the preliminary affordability challenge determination.

Corrected Resolution 2025-01 (Appendix B).

APPENDIX A-
July 23, 2025
Farxiga Dossier

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  - Exhibit 6D Written Comments (Request June 18, 2025) (PDF)

Farxiga (dapagliflozin)-Dossier

Maryland Prescription Drug Affordability Board

July 23, 2025

Version 2.1

Van T. Mitchell
Board Chair

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Cost Review Study Dossier - Farxiga (dapagliflozin)

Introduction

To the extent practicable, and in compliance with COMAR 14.01.04.05B, staff has assembled the data and analyses specified by Health-General Article §21-2C-09(b), Annotated Code of Maryland, and the regulations for consideration by the Board in conducting its cost review study.

Section 1: Background

The table below displays a list of all possible NDC-11 codes associated with Farxiga (proprietary name) and dapagliflozin (non-proprietary name).[1] The NDC-11 codes were identified by staff through searching the RxNorm database.[2] Some the NDCs included on this list are discontinued. Staff has included discontinued NDCs in the list because some factors include historical data that necessitates including data on discontinued NDCs.

Table 1. NDC List

National Drug Code	Proprietary Name	Non-Proprietary Name	Dosage-Strength
00003-1428-11	Farxiga	Dapagliflozin	10 MG
00003-1428-12	Farxiga	Dapagliflozin	10 MG
00003-1428-13	Farxiga	Dapagliflozin	10 MG
00003-1428-14	Farxiga	Dapagliflozin	10 MG
00003-1428-91	Farxiga	Dapagliflozin	10 MG
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
50090-3481-00	Farxiga	Dapagliflozin	10 MG
55154-6933-08	Farxiga	Dapagliflozin	10 MG
00003-1427-11	Farxiga	Dapagliflozin	5 MG
00003-1427-12	Farxiga	Dapagliflozin	5 MG
00003-1427-13	Farxiga	Dapagliflozin	5 MG
00003-1427-14	Farxiga	Dapagliflozin	5 MG
00003-1427-91	Farxiga	Dapagliflozin	5 MG
00310-6205-90	Farxiga	Dapagliflozin	5 MG
00310-6205-30	Farxiga	Dapagliflozin	5 MG
00310-6205-95	Farxiga	Dapagliflozin	5 MG
50090-3482-00	Farxiga	Dapagliflozin	5 MG
55154-6932-08	Farxiga	Dapagliflozin	5 MG

[1] The standard practice in published literature is to refer to drugs by the name of the molecule rather than the brand name of the drug. Staff has retained that convention. As a result, when discussing literature Farxiga is referred to as dapagliflozin.

[2] https://www.nlm.nih.gov/research/umls/rxnorm/index.html

The Board received comment letters concerning the dossier (see exhibit 6), regarding authorized generics. Authorized generics are excluded from the statutory definition of branded drug product. Previously, staff attempted to verify the classification of certain NDCs as authorized generics through published FDA sources.[3] Farxiga does not appear on this list.

Subsequently, using a different FDA data source staff was able to confirm certain NDCs as authorized generics and have removed those NDCs from tables located in sections 1 through 7.[4] A Table in Section 8 has been added to include information on authorized generics.

[3] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs (last checked July 18, 2025)

[4] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory (last checked July 14, 2025)

Section 2: Clinical Information

Factor 2.1: Clinical information, including FDA indications and doses and information concerning standard medical practice.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(i)
Methodology: Literature review
Data Sources: FDA labels and clinical guidelines

Table 2. Farxiga® (dapagliflozin): FDA-approved indications and associated dosing regimen(s)[5]

Indication	*Dosing Regimen(s)*
As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.	5mg (1 tablet) by mouth once daily, eGFR ≥ 45 mL/min/1.73m^2 10mg (1 tablet) by mouth once daily, eGFR ≥ 45 mL/min/1.73m^2 if further glycemic control is needed Not recommended for eGFR <45 mL/min/1.73 m^2
To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors	10mg (1 tablet) by mouth once daily, eGFR ≥ 25 mL/min/1.73 m^2 Not recommended for eGFR < 25 mL/min/1.73 m^2
To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure	10mg (1 tablet) by mouth once daily, eGFR ≥ 25 mL/min/1.73 m^2 Not recommended for eGFR < 25 mL/min/1.73 m^2
To reduce the risk of sustained eGFR decline, end-stage kidney disease (ESKD), cardiovascular (CV) death, and hospitalization for heart failure (hHF) in patients with chronic kidney disease at risk of progression	10mg (1 tablet) by mouth once daily, eGFR ≥ 25 mL/min/1.73 m^2 Not recommended for eGFR < 25 mL/min/1.73 m^2

[5] Farxiga. Wilmington (DE): AstraZeneca Pharmaceuticals LP; 2024 Jun. Package Insert. NDC 0310-6205-30.

Standard Medical Practice Recommendations

Farxiga (dapagliflozin) Placement in Therapy for Diabetes Mellitus Type 2

Diabetes mellitus (DM) describes a group of chronic metabolic disorders of blood glucose in which the body both underuses and overproduces glucose, resulting in high blood glucose. Underuse of blood glucose may be caused by either an inability of the body to make sufficient (or any) insulin, such as in Type 1 DM, or resistance to insulin, as found in Type 2 DM.[6]

Farxiga is a member of the sodium-glucose cotransporter 2 (SGLT2) inhibitor class. This medication class is recommended by the American Diabetes Association (ADA) and the American Association of Clinical Endocrinology (AACE) as one of the seven medication class options that may be used to lower blood glucose in patients with Type 2 DM.[7,8]

The ADA does not specify an order of use preference; choice of medication class option is based on a variety of patient-specific factors such as administration preference, cost, absolute ability to lower glucose, risk of low blood glucose, dosing frequency, etc. For treatment of glycemic control only, use of Farxiga is within the same line of therapy as other therapeutic options indicated for Type 2 DM (such as insulin, metformin, GLP-1 receptor agonists, sulfonlyureas, etc).[3] The AACE similarly considers patient-specific factors and explicitly prefers SGLT2 inhibitors (or GLP-1 receptor agonists) for patients who are overweight, obese, or at risk of low blood glucose.[4] These guideline recommendations are in line with other guidelines from major societies including the American College of Physicians and the National Kidney Foundation Kidney Disease Improving Global Outcomes.[9,10]

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[6] American Diabetes Association Professional Practice Committee; 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S27–S49. https://doi.org/10.2337/dc25-S002.

[7] American Diabetes Association Professional Practice Committee; 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S181–S206. https://doi.org/10.2337/dc25-S009.

[8] Samson, Susan L. et al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update. Endocrine Practice, Volume 29, Issue 5, 305 – 340.

[9] Amir Qaseem, Adam J. Obley, Tatyana Shamliyan, et al; Clinical Guidelines Committee of the American College of Physicians. Newer Pharmacologic Treatments in Adults With Type 2 Diabetes: A Clinical Guideline From the American College of Physicians. Ann Intern Med.2024;177:658-666. [Epub 19 April 2024]. https://doi.org/10.7326/M23-2788.

[10] Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2022;102 (5S):S1–S127. https://doi.org/10.1016/j.kint.2022.06.008.

In adult patients with Type 2 DM and established cardiovascular disease (CVD) (including prior heart attack, stroke, or revascularization procedure) or multiple risk factors for CVD (including obesity, high blood pressure, protein in urine, smoking, and high cholesterol), the ADA and AACE recommend the use of SGLT2 inhibitors with proven benefit (Jardiance [empagliflozin] or Invokana [canagliflozin]) as first-line therapy.[3,4]

- This recommendation is independent of the patient's use of other medications (unless specifically unable to use with a particular medication) and glycemic control.
- Farxiga is not included in either guideline's category for reduction of major adverse cardiovascular events. This guideline distinction is based on clinical trial data that Farxiga reduces risk of hospitalization for heart failure only, not risk of cardiovascular death.
- Equally weighted recommendation for GLP-1 receptor agonists (GLP-1 RAs) with proven benefit (Trulicity [dulaglutide], Victoza [liraglutide], Ozempic [semaglutide]).[3,4]

In adult patients with Type 2 DM and heart failure (HF), the ADA and AACE recommend the use of SGLT2 inhibitors with proven benefit for control of blood glucose and reduction of HF-related symptoms as first-line therapy (Farxiga, Jardiance, Invokana, or Steglatro [ertugliflozin]).[3,4]

- This recommendation is independent of the patient's use of other medications (unless specifically unable to use with a particular medication) and glycemic control.
- There is no other first-line or alternative therapy for this patient population.

In adult patients with Type 2 DM and chronic kidney disease (CKD), the ADA and AACE recommend the use of SGLT2 inhibitors with proven benefit for control of blood glucose and slowing progression of CKD (Farxiga, Jardiance, Invokana) as first-line therapy.

- This recommendation is independent of the patient's use of other medications (unless specifically unable to use with a particular medication) and glycemic control.
- Equally weighted recommendation for GLP-1 RAs with proven benefit (Trulicity, Victoza, Ozempic).[3,4]

Clinical use in DM Key Takeaway: SGLT2 inhibitors are a preferred drug class in the treatment of Type 2 DM. SGLT2 inhibitors are typically considered as first-line therapy options for Type 2 DM given the overall safety (low risk of hypoglycemia), effectiveness in lowering blood glucose, and benefits/protection for CKD, CVD, and HF. GLP-1 RAs have demonstrated similar outcomes and are alternative first-line therapy options. Metformin, a biguanide, is also considered first-line therapy with effectiveness in lowering blood glucose, low hypoglycemia risk, and potential CVD benefit, but has not demonstrated benefit in HF or progression of CKD. Medical professionals prefer Jardiance, Farxiga, and Invokana, given their proven benefits for HF, CVD, and CKD.

Farxiga® (dapagliflozin) Placement in Therapy for Heart Failure

Heart failure (HF) is a complex, symptomatic, and chronic condition resulting from the heart's inability to adequately pump blood to the rest of the body. Fluid then builds up in parts of the body it otherwise would not and causes symptoms of heart failure, such as difficulty breathing and swelling in feet and legs. Generally, there are two categories of HF: HFrEF (Heart Failure with Reduced Ejection Fraction) and HFpEF (Heart Failure with Preserved Ejection Fraction). HFrEF (Reduced) occurs when the heart muscle is weak, and HFpEF (Preserved) occurs when the heart muscle is stiff. Guideline medication recommendations are different for HFrEF vs. HFpEF.[11]

Per ACC/AHA guidelines, SGLT2 inhibitors are recommended for all symptomatic, chronic HFrEF patients to reduce the risk of hospitalization for heart failure and cardiovascular death. The guidelines specify the use of Jardiance, Farxiga, or Inpefa (sotagliflozin), based on supporting clinical trial data for benefit.[7,12]

Per ACC/AHA guidelines, SGLT2 inhibitors, specifically Jardiance and Farxiga, are recommended for all patients with symptomatic HFpEF.[7,13] Sotagliflozin, while mentioned due to clinical trial benefits, was not recommended, as it was not FDA-approved at the time of publication.[9] It is now FDA-approved and available for use.

Clinical use in HF Takeaway: SGLT2 inhibitors, specifically Jardiance, Farxiga, and Inpefa, are recommended for all symptomatic HF patients.

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[11] Heidenreich, P, Bozkurt, B, Aguilar, D. et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *JACC.* 2022 May, 79 (17) e263–e421. https://doi.org/10.1016/j.jacc.2021.12.012.

[12] Maddox TM, Januzzi JL Jr, et.al. 2024 ACC expert consensus decision pathway for treatment of heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2024;83(15):1444-1488.

[13] Kittleson MM, Panjrath GS, et. al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. Published online April 19, 2023. https://doi.org/10.1016/j.jacc.2023.03.393.

Farxiga (dapagliflozin) Placement in Therapy for Chronic Kidney Disease

Chronic Kidney Disease (CKD) encompasses abnormalities of kidney function or structure that are present for at least 3 months. This carries health implications because the kidneys are unable to filter blood as well as they should.[14] Kidney function is measured through estimated glomerular filtration rate (eGFR) and the loss of protein in the form of albumin in the urine.

The Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend SGLT2 inhibitors for all adult patients with (1) Type 2 DM, CKD, and eGFR ≥ 20 mL/min/1.73m^2; (2) all adult patients with CKD, urinary albumin ≥200mg/g, and eGFR ≥ 20 mL/min/1.73m^2; and (3) all adult patients with CKD and HF.[10]

The KDIGO guidelines also suggest treating all adult patients with an eGFR of 20 to 45 ml/min/1.73m^2 with an SGLT2 inhibitor.[10]

The KDIGO guidelines do not recommend or specify any particular drug within the SGLT2 inhibitor class. The guidelines, per a review of large randomized controlled trials in support of the overall recommendations/suggestions, mention evidence for Farxiga, Jardiance, Inpefa, and Invokana.[10]

Clinical use in CKD Takeaway: To lower the risk of CKD progression and acute kidney injury and improve cardiovascular outcomes, SGLT2 inhibitors (equal weight preference for Jardiance, Farxiga, and Invokana) are (1) recommended by major guidelines for adult CKD patients with Type 2 DM, HF, and/or albuminuria ≥200mg/g; and (2) suggested for adult CKD patients with an eGFR of 20 to 45 ml/min/1.73m^2.

[14]Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int. 2024;105(4S): S117–S314. https://doi.org/10.1016/j.kint.2023.10.018.

Factor 2.2: The disease burden of the condition that is treated by the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(ii)
Methodology: Literature review
Data Sources: Medical literature and clinical guidelines

Farxiga treats multiple conditions. The information below summarizes the disease burden of these conditions.

Type 2 Diabetes Mellitus (DM)

Prevalence

- In the United States (US), 38.4 million (11.6%) people have diagnosed or undiagnosed diabetes mellitus (DM).[15,16] Type 2 DM accounts for 90-95% of all diagnosed cases of diabetes.[14]
- In Maryland, the total age-adjusted percentage of adults aged 18 years or older with diagnosed diabetes was 10.5% in 2022.[17]

Incidence

- In 2021, 1.2 million adults were diagnosed with diabetes (rate of 5.9 per 1000 people).[14,15] Notably, 98 million adults, more than 1 in 3 people, have prediabetes (38% of adult US population).[14,15] In individuals 65 years or older, 48.8% have prediabetes.[15]
- In Maryland, the age-adjusted rate of adults aged 18 years or older with newly diagnosed diabetes was 7.8 per 1000 in 2022.[16]

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[15] Centers for Disease Control and Prevention. Diabetes in the US, a US Report Card [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2022 [cited 2025 Jan 4]. Available from: https://www.cdc.gov/diabetes/images/library/socialmedia/diabetesintheus_print.pdf.
[16] Centers for Disease Control and Prevention. National Diabetes Statistics Report website [Internet]Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2024 [cited 2025 Jan 4]. Available from: https://www.cdc.gov/diabetes/php/data-research/index.html.
[17] United States Diabetes Surveillance System [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention. 2000 - [cited 2025 Jan 4]. Available from: https://gis.cdc.gov/grasp/diabetes/diabetesatlas-surveillance.html#.

Disease Severity

- Diabetes is classified into categories, including Type 1 (immune destruction of insulin-producing pancreatic cells), Type 2 (non-immune, progressive loss of insulin secretion, frequently with an inability of the body to use available insulin), gestational (diagnosed in 2nd or 3rd trimester of pregnancy and not present pre-pregnancy), and other causes.[18] The primary tool to assess glycemic status is the A1c test, as it reflects the average blood glucose value over the preceding 2-3 months and is strongly linked to diabetes complications. Higher A1c values correspond to higher complication rates of diabetes.[19]

Cost of Illness/Financial Impact

- Total direct and indirect estimated costs of diagnosed diabetes in the US were $413 billion in 2022. Excess medical costs per person associated with diabetes were $12,022 in 2022.[15]
- In Maryland in 2021, total and per patient medical costs attributable to diabetes were $6.506 billion and $11,909, respectively.[20]
    - In Maryland in 2021, diabetes-attributable total and per-person productivity losses due to morbidity were $3.4 billion and $6,224, respectively.[19]

Morbidity

In 2020, about 16.8 million emergency department visits were reported with diabetes as any listed diagnosis among adults aged 18 years or older. Of these, 267,000 were for hyperglycemic crisis (11.4 per 1,000 adults with diabetes) and 202,000 were for hypoglycemia (8.6 per 1,000 adults with diabetes).[15]

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[18] American Diabetes Association Professional Practice Committee; 2. Diagnosis 18and Classification of Diabetes: Standards of Care in Diabetes—2025. Diabetes Care 1 January 2025; 48 (Supplement_1): S27–S49. https://doi.org/10.2337/dc25-S002.

[19] American Diabetes Association Professional Practice Committee; 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes—2025. Diabetes Care 1 January 2025; 48 (Supplement_1): S128–S145. https://doi.org/10.2337/dc25-S006.

[20] A. Khavjou, Olga; Sun, Minglu; R. D'Angelo, Sophia; J. Neuwahl, Simon; J. Hoerger, Thomas; Cho, Pyone; et al. (2024). Economic Costs Attributed to Diagnosed Diabetes in Each US State and the District of Columbia, 2021. American Diabetes Association. Figure. https://doi.org/10.2337/figshare.26351743.v1.

Table 3. Number and rate of hospitalizations per 1,000 adults aged 18 years or older with diabetes for selected causes, United States, 2019-2020[15]

Risk factor	2019 Number	2019 Crude rate per 1,000 (95% CI)	2020 Number	2020 Crude Rate per 1,000 (95% CI)
Diabetes as any listed diagnosis	**8,341,000**	**356.1 (337.0–375.3)**	**7,856,000**	**335.4 (316.5–354.4)**
Major cardiovascular disease	1,920,000	82.0 (77.4–86.5)	1,677,000	71.6 (67.4–75.8)
Ischemic heart disease	443,000	18.9 (17.8–20.0)	368,000	15.7 (14.7–16.7)
Stoke	346,000	14.8 (13.9–15.6)	321,000	13.7 (12.9–14.5)
Lower-extremity amputation	162,000	6.9 (6.5–7.3)	160,000	6.8 (6.4–7.2)
Hyperglycemic crisis	231,000	9.9 (9.3–10.4)	232,000	9.9 (9.3–10.5)
Diabetic ketoacidosis	205,000	8.8 (8.3–9.2)	206,000	8.8 (8.3–9.3)
Hyperosmolar hyperglycemic syndrome	26,000	1.1 (1.0–1.2)	26,000	1.1 (1.1–1.2)
Hypoglycemia	60,000	2.5 (2.4–2.7)	51,000	2.2 (2.1–2.3)

Notes: CI = confidence interval. Numbers rounded to the nearest thousand. Data sources: 2019 and 2020 National Inpatient Sample; 2019 and 2020 National Health Interview Survey.

- Among adults aged 18 years or older with diagnosed diabetes (data from 2017-2020), 39.2% had chronic kidney disease (CKD, stages 1–4), based on the updated 2021 CKD Epidemiology Collaboration (CKD-EPI) equation for estimated glomerular filtration rate (eGFR).[15]
- Diabetes is the leading cause of new cases of blindness for adults aged 18-64 years. In 2021, 10.1% of adults with diagnosed diabetes reported severe vision difficulty or blindness.[15]

Mortality

- Diabetes was the 8th leading cause of death in the US in 2021, based on 103,294 death certificates with diabetes as underlying cause (rate of 31.1 per 100,000 people).[15] Including diabetes as a contributing cause of death, the rate increases to 120.3 per 100,000 people (399,401 death certificates).[15]
- In Maryland, the age-adjusted rate of diabetes death and diabetes-related death in adults aged 18 years older was 33.5 and 145.5 per 100,000 people, respectively, in 2022.[16]

Heart Failure (HF)

Prevalence

- The overall population rate of heart failure is 1.9-2.8%. Based on NHANES 2017-2020, approximately 6.7 million US adults have HF. Prevalence progressively increases with each decade of life; individuals over age 65 have a 4-fold higher prevalence of HF (8-9.1%) vs. those under 65 years.[21]
- Within Maryland, the 2016 age-adjusted prevalence of heart failure is approximately 1100 per 100,000 persons. Relative to other states, MD prevalence is moderately elevated (prevalence range 700-1300 per 100,000 persons).[22,23]

Incidence

- A variation in incidence rates reported in studies is surmised to be due to differences in data sources, population demographics and composition, HF ascertainment methodology, and periodic differences. The inclusion of HFpEF also influences results as it becomes the dominant phenotype, attributed to increasing prevalence of underlying risk factors for HF (including diabetes and obesity).[21]

Disease Severity

- Heart failure severity is categorized into stages A, B, C, and D by the AHA/ACC. The following table defines each stage.[22] Stages A and B represent those individuals without signs or symptoms of heart failure but either at risk for or with pre-heart failure. Stages C and D represent individuals with symptomatic heart failure, Stage D representing more severe symptoms interfering with activities of daily living.[24]

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[21] Bozkurt B, Ahmad T, et.al. WRITING COMMITTEE MEMBERS. HF STATS 2024: Heart Failure Epidemiology and Outcomes Statistics An Updated 2024 Report from the Heart Failure Society of America. J Card Fail. 2025 Jan;31(1):66-116. doi: 10.1016/j.cardfail.2024.07.001. Epub 2024 Sep 24.
[22] Bozkurt B, Ahmad T. et. al. Writing Committee Members. Heart Failure Epidemiology and Outcomes Statistics: A Report of the Heart Failure Society of America. J Card Fail. 2023 Oct;29(10):1412-1451. https://doi.org/10.1016/j.cardfail.2023.07.006.
[23] Global Burden of Cardiovascular Diseases Collaboration; Roth GA, Johnson CO,et.al. The Burden of Cardiovascular Diseases Among US States, 1990-2016. JAMA Cardiol. 2018 May 1;3(5):375-389. https://doi.org/10.1001/jamacardio.2018.0385.
[24] Heidenreich PA, Bozkurt B, et.al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145:e895–e1032. https://doi.org/10.1161/CIR.0000000000001063.

Table 4. Stages of HF[23]

Stages	Definition and Criteria
Stage A: At Risk for HF	At risk for HF but without symptoms, structural heart disease, or cardiac biomarkers of stretch or injury (eg, patients with hypertension, atherosclerotic CVD, diabetes, metabolic syndrome and obesity, exposure to cardiotoxic agents, genetic variant for cardiomyopathy, or positive family history of cardiomyopathy).
Stage B: Pre-HF	No symptoms or signs of HF and evidence of 1 of the following:
	*Structural heart disease** Reduced left or right ventricular systolic function Reduced ejection fraction, reduced strain Ventricular hypertrophy Chamber enlargement Wall motion abnormalities Valvular heart disease
	*Evidence for increased filling pressures** By invasive hemodynamic measurements By noninvasive imaging suggesting elevated filling pressures (eg, Doppler echocardiography)
	Patients with risk factors and *Increased levels of BNPs* or* *Persistently elevated cardiac troponin* in the absence of competing diagnoses resulting in such biomarker elevations such as acute coronary syndrome, CKD, pulmonary embolus, or myopericarditis
Stage C: Symptomatic HF	Structural heart disease with current or previous symptoms of HF.
Stage D: Advanced HF	Marked HF symptoms that interfere with daily life and with recurrent hospitalizations despite attempts to optimize GDMT.

BNP indicates B-type natriuretic peptide; CKD, chronic kidney disease; CVD, cardiovascular disease; GDMT, guideline-directed medical therapy; and HF, heart failure.
*For thresholds of cardiac structural, functional changes, elevated filling pressures, and biomarker elevations, refer to Appendix 3.

Cost of illness/Financial Impact

- In 2012, total cost for HF was estimated to be $30.7 billion (2010 dollars), of which more than two-thirds was attributable to direct medical costs. Projections suggest that by 2030, the total cost of HF will increase by 127% to $69.8 billion, amounting to ~$244 for every US adult.[25]
- In a systematic review of HF-associated medical costs in the United States from 2014 to 2020, the annual median total cost was estimated at $24,383 per patient, with HF hospitalizations accounting for the majority ($15,879 per patient).[24]

Morbidity

- In 2019, there were 8,054,000 physician office visits with a primary diagnosis of HF. In 2020, there were 1,361, 493 emergency department visits for HF. In 2020, there were 1,111,500 principal diagnosis hospital discharges for HF.[24]

Mortality

- One-third of all cardiovascular deaths are usually attributable to HF. However, coding guidelines consider HF as a mediator rather than the underlying cause of death. Therefore, mortality from HF is underestimated. The reported absolute number of deaths with HF as an underlying cause of death was 85,855, whereas the total

[25] Martin SS, Aday AW, Almarzooq ZI, et al. American Heart Association Council on Epidemiology and Prevention Statistics Committee; Stroke Statistics Subcommittee. 2024 heart disease and stroke statistics: a report of US and global data from the American Heart Association. Circulation. 2024;149:e347–913.

number of cardiovascular deaths was 928,741 (deaths in the US by 2020). By including any mention of HF on death certificates, HF was a contributing cause in 415,922 deaths in the US in 2020.[21]

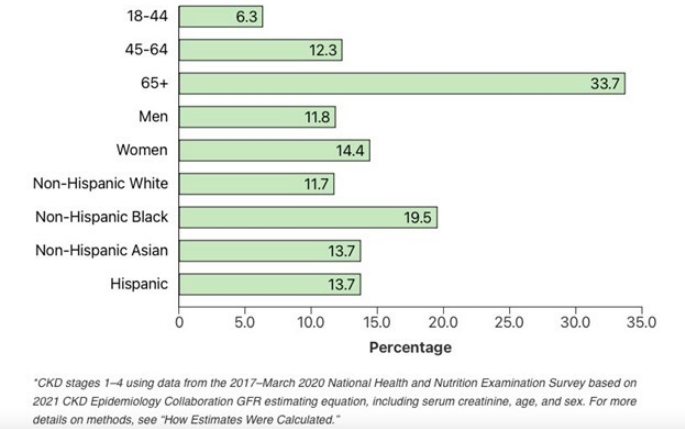
- In 2022, heart failure was mentioned on 457,212 death certificates (and responsible for 13.9% of all causes of death).[26]
- For adults aged 65-90 years, HF is associated with a loss of 15 years of median survival compared with the general US population.[21]
- The 1-year HF mortality rate is approximately 30%, increasing to approximately 40% at 5 years.[27]

Chronic Kidney Disease (CKD)

Prevalence

- Based on data from 2017 - March 2020, 35.5 million (14%) US adults have CKD.[15,17] About 1 in 3 people with diabetes and 1 in 5 people with high blood pressure have kidney disease.[15]

Figure 1. Percentage of US Adults Aged 18 years or Older with CKD*, by Age, Sex and Race/Ethnicity[28]



[26] Centers for Disease Control and Prevention. About Heart Failure [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2024 [cited 2025 Jan 4]. Available from: https://www.cdc.gov/heart-disease/about/heart-failure.html.
[27] Osenenko KM, Kuti E, Deighton AM, Pimple P, Szabo SM. Burden of hospitalization for heart failure in the United States: a systematic literature review. J Manag Care Spec Pharm. 2022 Feb;28(2):157-167. https://doi.org/10.18553/jmcp.2022.28.2.157.
[28] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2023 [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2023 [cited 2025 Jan 2]. Available from: https://www.cdc.gov/kidney-disease/php/data-research/index.html.

Incidence

- There are approximately 360 new dialysis starts daily.[27]
- Incidence rates are not available for new diagnoses of CKD, however, it is estimated that 1 in 3 US adults is at risk for CKD. This estimate is based on the prevalence of diabetes, hypertension (high blood pressure), and obesity in the population and without treatment.[29]

Disease Severity

- CKD severity is based on estimated glomerular filtration rate (eGFR), a calculation to estimate how well an individual's kidneys filter blood, and albumin-to-creatinine ratio (ACR), a measure of protein found in the urine. Lower eGFR values and higher albuminuria levels (ACR) correspond to reduced kidney function. In the following table, eGFR categories G1-G5 are equivalent to Stages 1-5 in subsequent table(s).[28]

Table 5. Percentage by eGFR and ACR, 2017-March, 2020[28]

eGFR Categories	A1: Normal to mildly increased (ACR <30 mg/g)	A2: Moderately increased (ACR 30-299 mg/g)	A3: Severely increased (ACR ≥300 mg/g)	Total
G1: Normal or high (eGFR ≥90mL/min/1.73m²)	59.8	5.0	0.68	65.5
G2: Mildly decreased (eGFR 60-89 mL/min/1.73m²)	26.2	2.4	0.35	28.9
G3a: Mildly to moderately decreased (eGFR 45-59 mL/min/1.73m²)	3.1	0.79	0.12	4.0
G3b: Moderately to severely decreased (eGFR 30-44 mL/min/1.73m²)	0.61	0.32	0.18	1.1
G4: Severely decreased (eGFR 15-29 mL/min/1.73m²)	0.07	0.08	0.18	0.34
G5: Kidney failure (eGFR <15 mL/min/1.73m²)	0.00	0.02	0.13	0.15
Total	89.8	8.6	1.6	100

[29] National Kidney Foundation. Kidney Disease: Fact Sheet, Fast Facts 2024 update [Internet]. New York, NY: National Kidney Foundation; 2025 [cited 2025 Jan 4]. Available from: https://www.kidney.org/about/kidney-disease-fact-sheet.

Cost of illness/Financial Impact

- Medicare beneficiaries with CKD cost $87.2 billion in 2019.[27]
- Medicare spending for beneficiaries with CKD (not including ESKD) ages 66 or older was nearly $77 billion in 2021, representing 24.1% of Medicare spending in this age group.[30]
- In 2021, annual per-person spending attributable to Medicare Parts A, B, and D was more than double for beneficiaries ages 66 or older with CKD ($28,162) compared to those without CKD ($13,604).[29]

Table 6. Per person per year Medicare FFS Spending among older adults with CKD, by CKD stage overall and by patient characteristics, 2022[28]

	All CKD	Stages 1-2	Stage 3	Stages 4-5
Patient counts	2,649,040	280,940	1,565,020	234,060
Patient years at risk	2,461,388	267,024	1,461,236	200,395
All patients	$28,116	$24,640	$27,327	$38,691
Age				
66-69	$27,795	$23,405	$27,676	$44,136
70-74	$26,330	$22,152	$26,102	$40,598
75-79	$27,705	$24,505	$26,821	$36,833
80-84	$28,258	$25,926	$26,825	$38,892
85+	$30,591	$29,299	$29,230	$36,668
Sex				
Female	$27,290	$23,475	$25,954	$37,343
Male	$28,990	$25,862	$28,963	$40,498
Race				
White	$27,636	$24,650	$26,784	$37,726
Black	$32,384	$26,062	$31,561	$45,473
Other	$29,305	$23,418	$29,811	$40,274
Diabetes				
No	$24,093	$20,783	$23,293	$32,287
Yes	$32,591	$29,120	$32,129	$43,725
Heart Failure				
No	$22,689	$20,369	$21,784	$30,548
Yes	$44,973	$42,832	$43,582	$52,022

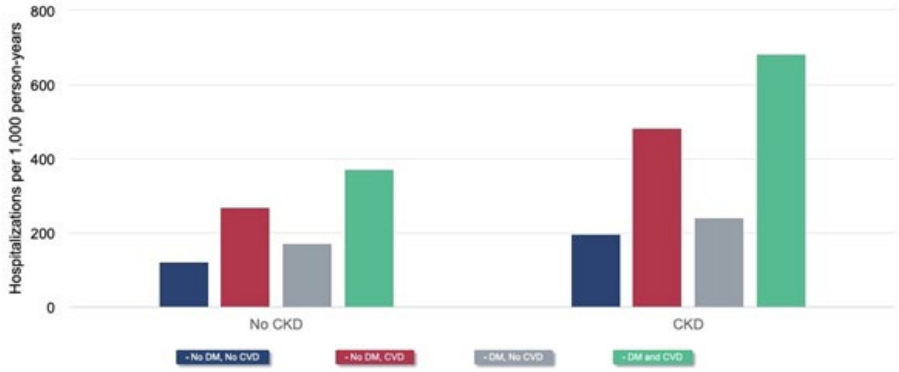
[30] National Institute of Diabetes and Digestive and Kidney Diseases. Kidney Disease Statistics for the United States [Internet]. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, US Department of Health and Human Services; 2023 [cited 2025 Jan 2]. Available from: https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

Data source: Medicare 5% FFS sample. Point prevalent individuals aged ≥66 years on January 1, 2022, with CKD and Medicare Parts A, B, & D coverage in 2021 (ESRD excluded)

Figure 2. All-cause hospitalization rates in older adults, Medicare FFS, 2012-2022, by CKD status, adjusted for demographics and comorbidities[28]

Data source: Medicare 5% random sample database. January 1 point prevalent Medicare FFS beneficiaries aged 66 years or older, 2012-2022. Age, sex, race/ethnicity, and comorbidity were used in adjusted analyses with the 2020 Medicare FFS 5% sample as the reference population. Abbreviations: FFS, fee-for-service.

Figure 3. All-cause hospitalization rates in older adults, by presence of diabetes mellitus and cardiovascular disease, Medicare FFS, 2022, Adjusted by CKD Status[28]



Data source: Medicare 5% random sample database for No CKD, All CKD, and CKD stage 3 cohorts and Medicare 100% CKD 4/5 database for CKD stages 4 and 5 cohorts. January 1, 2022 point prevalent Medicare FFS beneficiaries aged 66 years and older. Age, sex, and race/ethnicity were used in adjusted analyses with the 2022 5% Medicare population as the reference. Abbreviations: FFS, fee-for-service; DM: diabetes; CVD, cardiovascular disease.

Mortality

- In 2021, the demographic-adjusted mortality rate was more than twice as high among Medicare beneficiaries ages 66 years or older with CKD (101.8 per 1,000 person-years) than among those without CKD (46.3 per 1,000 person-years).[29]
- Specifically in Maryland, all-cause mortality in older adults in 2022 in persons without CKD vs. all stages of CKD was 39.4 vs. 114.5 per 1,000 PY, respectively.[28]

Section 3: Regulatory Approval and Market Context

Factor 3.1: Analysis of the prescription drug product's approval process

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(ix)
Methodology: Review of databases and sites
Data Sources: FDA databases and manufacturer website

The U.S. Food and Drug Administration (FDA) approved Farxiga on January 8, 2014.[31] In 2011, the FDA referred the drug to the advisory committee because it would have been the first-in-class drug. At the July 19, 2011 FDA Endocrinologic and Metabolic Drugs Advisory Committee meeting, the committee voted six to nine (yes/no) on the question "Do the efficacy and safety data provide substantial evidence to support approval of dapagliflozin as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus?"[32]

After receiving additional information, the FDA approved Farxiga in 2014. At the time of approval, Farxiga was the second SGLT-2 inhibitor approved.[33] Since the original approval, the FDA has approved 22 supplemental applications. Eight of these 22 supplemental applications relate to new efficacy data, including four for new indications and one for a new patient population. Farxiga was originally approved as "a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."[34]

FDA approved Farxiga with the post-market commitment to conduct:

> [a] randomized, double-blind, placebo-controlled trial (the DECLARE trial) evaluating the effect of dapagliflozin on the incidence of major adverse cardiovascular events (MACE) in patients with type 2 diabetes mellitus. The primary objective of the trial should be to demonstrate that the upper bound of the 2-sided 95% confidence interval for the estimated risk ratio comparing the incidence of MACE (non-fatal myocardial infarction, non-fatal stroke, cardiovascular death) observed with

[31] Drugs@FDA Search
[32] http://web.archive.org/web/20161023221930/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM268726.pdf
[33] Drugs@FDA Search
[34] https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202293s000lbl.pdf

> dapagliflozin to that observed in the placebo group is less than 1.3. The long-term effects of dapagliflozin on the incidence of liver toxicity, bone fractures, nephrotoxicity/acute kidney injury, breast and bladder cancer, complicated genital infections, complicated urinary tract infections/pyelonoephritis/urosepsis, serious events related to hypovolemia and serious hypersensitivity reactions should also be assessed. The estimated glomerular filtration rate (eGFR) should also be monitored over time to assess for worsening of renal function.[35]

The results of this post-marketing commitment led to the FDA approving, on October 18, 2019, a second indication "to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors."[36]

The sponsors submitted a supplemental application for Type 1 diabetes. In July 2019, the FDA issued a complete response letter advising that the application was not approved.[37]

On May 5, 2020, the FDA approved Farxiga for a new indication "to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV)."[38]

On April 30, 2021, the FDA approved Farxiga "to reduce the risk of sustained eGFR decline, end stage kidney disease cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression."[39]

On May 8, 2023, the FDA approved Farxiga "to reduce the risk of cardiovascular death, hospitalization for heart failure and urgent heart failure visit in adults with heart failure."[40]

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[35] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/202293Orig1s000ltr.pdf
[36] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202293s018lbl.pdf
[37] https://www.astrazeneca.com/media-centre/press-releases/2019/update-on-us-regulatory-decision-for-farxiga-in-type-1-diabetes-15072019.html#
[38] https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293s020lbl.pdf
[39] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202293s024lbl.pdf
[40] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s026lbl.pdf

On June 12, 2024, the FDA expanded Farxiga's diabetes indication to children ages 10 and above.[41] This fulfilled a Pediatric Research Equity Act (PREA) requirement.[42] They have no outstanding PREA requirements.[43]

The FDA granted Farxiga Fast Track Designation in the US for heart failure following acute myocardial infarction.[44] The FDA granted Farxiga Breakthrough Therapy Designation for chronic kidney disease.[45] The FDA granted Farxiga Priority Review for the treatment of patients with chronic kidney disease.[46]

[41] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/202293s031lbl.pdf
[42] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/202293Orig1s031,205649Orig1s022ltr.pdf
[43] https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm
[44] https://www.astrazeneca.com/media-centre/press-releases/2020/farxiga-granted-fast-track-designation-in-the-us-for-heart-failure-following-acute-myocardial-infarction-leveraging-an-innovative-registry-based-trial-design.html#
[45] https://www.astrazeneca.com/media-centre/press-releases/2020/farxiga-granted-breakthrough-therapy-designation-in-us-for-chronic-kidney-disease.html#
[46] https://www.astrazeneca.com/media-centre/press-releases/2021/farxiga-granted-us-priority-review-for-ckd.html#

Factor 3.2: Analysis of the prescription drug product's shortage status

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(x)
Methodology: Review of databases
Data Sources: FDA Databases

Farxiga is not in shortage.[47]

[47] FDA Drug Shortage Databases. https://dps.fda.gov/drugshortages

Factor 3.3: Analysis of the market context of the prescription drug product including the prescription drug product's lifecycle management, patent management, regulatory exclusivities, and product hopping

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(xi)
Methodology: Review of databases and sites, aggregation of claims data to understand spending and utilization of other products with the same active ingredient by the same manufacturer
Data Sources: FDA Databases, MCDB

Patent and Exclusivity Data

Eighteen listed patents apply to two strengths of Farxiga: 5 MG and 10 MG.[48] Fifteen of those patents are listed for both strengths and three are listed for only one of the strengths. One of the listed patents has already expired and two more expire in October of 2025. The primary patent (listed as both a drug substance and a drug product patent) expires on April 4, 2026. A separate drug substance patent expires on June 16, 2030. There are five additional drug product patents, the last of which expires July 18, 2030 (but there has been a manufacturer request to delist this patent). Another drug product patent expires February 19, 2029. The last patent expires September 9, 2040, and was listed in the Orange Book on March 13, 2024. *See* Patent Listing Table below.

[48] "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book" U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book. Search Term: "Farxiga".

Table 7. Patent Listing Table

Patent Number	DS Patent[1]	DP Patent[2]	Patent Use Code	Submission Date	Original Patent Expiration	Patent Extension Expiration[3]	Listed for 5 MG	Listed for 10 MG
9238076	No	No	U-2139	11/15/2017	4/15/2024		Yes	Yes
8431685	No	No	U-2139	11/15/2017	4/13/2025	10/13/2025	Yes	Yes
8461105	No	No	U-2139	11/15/2017	4/13/2025	10/13/2025	Yes	Yes
7456254	No	No	U-2139	11/15/2017	6/30/2025	12/30/2025	Yes	Yes
6515117	Yes	Yes	U-493 U-2139	2/5/2014	10/4/2025	4/4/2026	Yes	Yes
8329648	No	No	U-2139 U-2212 U-2213	11/15/2017	8/18/2026	2/18/2027	Yes	Yes
8906851	No	No	U-2139	11/15/2017	8/18/2026	2/18/2027	Yes	Yes
8501698	No	Yes	U-493	2/5/2014	6/20/2027	12/20/2027	Yes	Yes
8221786	No	Yes		2/5/2014	3/21/2028	9/21/2028	Yes	Yes
8361972	No	No	U-493 U-2139	2/5/2014	3/21/2028	9/21/2028	Yes	Yes
8716251	No	Yes		6/2/2014	3/21/2028	9/21/2028	Yes	Yes
7851502	No	Yes		2/5/2014	8/19/2028	2/19/2029	Yes	Yes
7919598	Yes	No		2/5/2014	12/16/2029	6/16/2030	Yes	Yes
8721615	No	Yes		11/15/2017	1/18/2030	7/18/2030	Yes	Yes
8685934	No	No	U-1522	6/25/2014	5/26/2030	11/26/2030	Yes	Yes
11826376	No	No	U-3766	12/19/2023	7/18/2039	1/18/2040	No	Yes
10973836	No	No	U-3127	4/21/2021	3/9/2040	9/9/2040	No	Yes
11903955	No	No	U-3825	3/13/2024	3/9/2040	9/9/2040	No	Yes

1 DS Patent refers to the Drug Substance Patent
2 DP Patent refers to a Drug Product Patent
3 There are some patents with extended expiration dates because of incentives that extend the life of patents when a sponsor performs pediatric studies.

Farxiga has three exclusivities for various additional indications: one of the listed exclusivities has already expired, and the last exclusivity expires on December 12, 2027.

Other Products with the Same Active Ingredient

The manufacturer markets multiple products that contain the same active ingredient as Farxiga (dapagliflozin), including several fixed-dose combination products. Xigduo XR (dapagliflozin and metformin hydrochloride) is a fixed-dose combination product with one of the same active ingredients as the active ingredient in Farxiga. Xigduo was approved on October 29, 2014.[49] The Xigduo XR label states that it "is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin hydrochloride (HCl), a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus."[50]

The label further provides that dapagliflozin is indicated to reduce:

- The risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.
- The risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.
- The risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Qtern (dapagliflozin and saxagliptin hydrochloride) is a fixed-dose combination product with one of the same active ingredients as the active ingredient in Farxiga (dapagliflozin). Qtern was approved on February 27, 2017.[51] Qtern's label says it "is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor and saxagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."[52]

Qternmet XR (dapagliflozin, metformin hydrochloride, and saxagliptin hydrochloride) is a fixed-dose combination product with one of the same active ingredients as the active

[49] https://www.astrazeneca.com/media-centre/press-releases/2014/us-fda-approved-xigduo-type-2-diabetes-patients-30102014.html#

[50] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/205649s023lbl.pdf

[51] https://www.astrazeneca.com/media-centre/press-releases/2017/fda-approves-once-daily-qtern-dapagliflozin-and-saxagliptin-tablets-for-adults-with-type-2-diabetes-240217.html#

[52] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209091s008lbl.pdf

ingredient in Farxiga (dapagliflozin). Qternmet XR was approved on May 2, 2019.[53] Qternmet XR's label provides that it "is a sodium-glucose cotransporter 2 (SGLT2) inhibitor, a dipeptidyl peptidase-4 (DPP-4) inhibitor and a biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."[54]

The tables below display Maryland Medical Care Database ("MCDB") data on patient counts and total gross spending in each market segment. For each drug, there are two tables. One table contains data from the Commercial Market Segment and a subset of the Commercial Market Segment (state/local government employees); the other contains data from the Medicare and Medicaid segments.

Qternmet

No utilization was observed in the MCDB.

[53] https://www.astrazeneca.com/media-centre/press-releases/2019/qternmet-xr-approved-in-the-us-for-the-treatment-of-type-2-diabetes-03052019.html#

[54] https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210874s003lbl.pdf

Qtern

Table 8a. Qtern Spending and Utilization

Drug Information			Commercial 2023		State Local Gov Emp 2023	
National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Patient Count	Gross Spending	Patient Count	Gross Spending
00310-6780-30	Qtern	10-5 MG	***	***	***	***
00310-6770-30	Qtern	5-5 MG	***	***	***	***

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Table 8b. Qtern Spending and Utilization

Drug Information			Medicaid 2022		Medicare 2022	
National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Patient Count	Gross Spending	Patient Count	Gross Spending
00310-6780-30	Qtern	10-5 MG			***	***
00310-6770-30	Qtern	5-5 MG			***	***

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Xigduo XR

Table 9a. Xigduo XR Spending and Utilization

Drug Information			Commercial 2023		State Local Gov Emp 2023	
National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Patient Count	Gross Spending	Patient Count	Gross Spending
66993-0361-60	Xigduo XR		***	***	***	***
66993-0362-30	Xigduo XR		***	***	***	***
00310-6280-30	Xigduo XR	10-1000 MG	689	$4,250,226.00	59	$272,607.00
00310-6270-30	Xigduo XR	10-500 MG	98	$497,319.00	11	$49,185.00
00310-6225-60	Xigduo XR	2.5-1000 MG	72	$333,546.00	***	***
00310-6260-60	Xigduo XR	5-1000 MG	1,147	$5,994,739.00	118	$511,125.00
00310-6250-30	Xigduo XR	5-500 MG	110	$739,682.00	12	$65,034.00

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
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Blank spaces indicate that no data was provided.

Table 9b. Xigduo XR Spending and Utilization

Drug Information			Medicaid 2022		Medicare 2022	
National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Patient Count	Gross Spending	Patient Count	Gross Spending
66993-0361-60	Xigduo XR					
66993-0362-30	Xigduo XR					
00310-6280-30	Xigduo XR	10-1000 MG	15	$71,037.39	177	$807,630.28
00310-6270-30	Xigduo XR	10-500 MG	***	***	21	$105,926.85
00310-6225-60	Xigduo XR	2.5-1000 MG	***	***	18	$67,453.16
00310-6260-60	Xigduo XR	5-1000 MG	33	$87,250.08	297	$1,277,040.99
00310-6250-30	Xigduo XR	5-500 MG	***	***	35	$146,078.42

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Blank spaces indicate that no data was provided.

Section 4: Utilization of Drug Product Under Review

Factor 4.1: The total gross spending in the State for the prescription drug product under review, the total number of patients in the State using the prescription drug product, and the percentage of overall total prescription drug product spending that the product's spending represents

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05.C(1)(g)(iv)
Methodology: Calculations
Data Sources: MCDB

For each NDC, the following tables provide the gross spending and number of patients by payor type.

Table 10a. Farxiga Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Commercial (2023) Gross Spending	Commercial (2023) Patient Count	Commercial (2023) Pct Total Gross Spend
66993-0457-30	Farxiga	10 MG	$44,138.00	35	0.0004%
00310-6210-39	Farxiga	10 MG	$22,435.00	13	0.0002%
00310-6210-30	Farxiga	10 MG	$84,456,698.00	15,568	0.8428%
00310-6205-30	Farxiga	5 MG	$24,222,385.00	5,379	0.2417%
66993-0456-30	Farxiga	5 MG	***	***	***

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Table 10b. Farxiga Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	State Local Gov. Emp. (2023) Gross Spending	State Local Gov. Emp. (2023) Patient Count	State Local Gov. Emp. (2023) Pct Total Gross Spend
66993-0457-30	Farxiga	10 MG	$21,612.00	18	0.0032%
00310-6210-39	Farxiga	10 MG			
00310-6210-30	Farxiga	10 MG	$5,938,802.00	1,300	0.8660%
00310-6205-30	Farxiga	5 MG	$1,465,689.00	405	0.2137%
66993-0456-30	Farxiga	5 MG	***	***	***

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Blank spaces indicate that no data was provided.

Table 10c. Farxiga Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicaid (2022) Gross Spending	Medicaid (2022) Patient Count	Medicaid (2022) Pct Total Gross Spend
66993-0457-30	Farxiga	10 MG			
00310-6210-39	Farxiga	10 MG			
00310-6210-30	Farxiga	10 MG	$3,165,622.96	949	0.1730%
00310-6205-30	Farxiga	5 MG	$930,075.01	334	0.0508%
66993-0456-30	Farxiga	5 MG			

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Table 10d. Farxiga Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicare (2022) Gross Spending	Medicare (2022) Patient Count	Medicare (2022) Pct Total Gross Spend
66993-0457-30	Farxiga	10 MG			
00310-6210-39	Farxiga	10 MG			
00310-6210-30	Farxiga	10 MG	$26,705,273.59	6,286	0.7383%
00310-6205-30	Farxiga	5 MG	$9,661,706.88	2,749	0.2671%
66993-0456-30	Farxiga	5 MG			

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements.
Blank spaces indicate that no data was provided.

Benchmarks are included for comparison under COMAR 14.01.04.05.C(1)(g)(xv).

Factor 4.2: The change in total gross spending and utilization for a prescription drug product in the State between the two most recent available calendar years and the percent change in total gross spending for a prescription drug product in the State between the two most recent available calendar years

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(v)
Methodology: Aggregation of claims to calculate the total gross spending and utilization
Data Sources: MCDB

For each NDC and payor type, the tables below show the change in total gross spending and utilization.

Table 11a. Farxiga Change in Spending and Utilization

Drug Information			Change in Commercial Data (2022-2023)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
66993-0457-30	Farxiga	10 MG					
00310-6210-39	Farxiga	10 MG					
00310-6210-30	Farxiga	10 MG	$27,844,079.00	49.18%	2,373	12,305	560,680
00310-6205-30	Farxiga	5 MG	$6,333,021.00	35.40%	247	1,594	-9,750
66993-0456-30	Farxiga	5 MG	***	***	***	***	***

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Blank spaces indicate that no data was provided.

Table 11b. Farxiga Change in Spending and Utilization

Drug Information			Change in State Local Gov. Emp. Data (2022-2023)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
66993-0457-30	Farxiga	10 MG					
00310-6210-39	Farxiga	10 MG					
00310-6210-30	Farxiga	10 MG	$1,460,268.00	32.61%	289	1,104	38,533
00310-6205-30	Farxiga	5 MG	$93,199.00	6.79%	26	31	-7,570
66993-0456-30	Farxiga	5 MG	***	***	***	***	***

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Blank spaces indicate that no data was provided.

Table 11c. Farxiga Change in Spending and Utilization

Drug Information			Change in Medicaid Data (2021-2022)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
66993-0457-30	Farxiga	10 MG					
00310-6210-39	Farxiga	10 MG					
00310-6210-30	Farxiga	10 MG	$1,390,252.84	78.31%	312	815	74,887
00310-6205-30	Farxiga	5 MG	$347,709.22	59.71%	83	190	18,479
66993-0456-30	Farxiga	5 MG					

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Blank spaces indicate that no data was provided.

Table 11d. Farxiga Change in Spending and Utilization

Drug Information			Change in Medicare Data (2021-2022)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
66993-0457-30	Farxiga	10 MG					
00310-6210-39	Farxiga	10 MG					
00310-6210-30	Farxiga	10 MG	$11,119,585.58	71.34%	2,176	9,264	567,851
00310-6205-30	Farxiga	5 MG	$2,572,180.80	36.28%	548	2,385	123,304
66993-0456-30	Farxiga	5 MG					

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Factor 4.3: Impact of the utilization and spending for the prescription drug product on public budgets and comparison of the spending on the prescription drug product to relevant benchmarks

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xv)
Methodology: Research, review, and aggregation of claims data to calculate utilization and spending
Data Sources: MCDB and public budget data

Staff conducted research to understand the impact of the utilization and spending on the prescription drug product on public budgets and to compare spending on the prescription drug product to relevant benchmarks. The utilization and spending data is captured for Commercial, State and Local Government Employee, and Medicaid populations in Factor 4.1 “Pct Total Gross Spend” column in Tables 9a, 9b, and 9c.

Staff gathered budget data from local governmental entities (counties). Because the data was not uniform—some local government budgets reflect spending for employee health, some reflect employee prescriptions, and some do not contain information at that level of specificity—staff was unable to assess the impact on public budgets for specific local governments.

In 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.

Section 5: Pricing Information and Rebates

Factor 5.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(i);
COMAR 14.01.04.05.C(1)(a)(i)
Methodology: Research and calculations to convert unit prices to annual prices
Data Sources: UpToDate (MediSpan), Centers for Medicare and Medicaid Services, Myers and Stauffer, Department of Veterans Affairs, FDA Databases

This section covers various drug pricing metrics, including the Wholesale Acquisition Cost (WAC), Average Wholesale Price (AWP), National Average Drug Acquisition Cost (NADAC), State Average Acquisition Cost (SAAC), Average Sales Price (ASP), and Federal Supply Schedule (FSS) price. The WAC and AWP are proprietary and commercially licensed from UpToDate (MediSpan). The NADAC is publicly available from the Centers for Medicare and Medicaid Services.[55] The SAAC is provided by Myers and Stauffer, a contractor of the State of Maryland.[56] The ASP is publicly available from the Centers for Medicare and Medicaid Services.[57] The FSS is publicly available from the U.S. Department of Veterans Affairs.[58] Staff converted unit prices (in this case the price per pill) to annual prices based on the FDA labels (number of pills per day times 365). Because none of the identified drugs have a reported ASP, that pricing metric is not included in the attached tables.

For each NDC associated with the prescription drug product under review, the following tables provide: (a) the effective date of the price; (b) the current* unit price; and (c) the estimated annual price (based on the FDA's recommended dosing regimens and current* unit prices).

*Current prices do not reflect price changes after August 1, 2024.

[55] https://www.medicaid.gov/medicaid/nadac
[56] https://myersandstauffer.com/client-portal/maryland/maryland-pharmacy/
[57] https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files
[58] https://www.va.gov/opal/nac/fss/pharmprices.asp

Table 12a. Farxiga WAC and AWP Pricing

National Drug Code	WAC Unit Price	Est. WAC per Year	AWP Unit Price	Est. AWP per Year
00003-1427-11 (5 MG)				
00003-1428-11 (10 MG)				
00310-6205-30 (5 MG)				
00310-6205-90 (5 MG)				
00310-6205-95 (5 MG)				
00310-6210-30 (10 MG)				
00310-6210-39 (10 MG)				
00310-6210-90 (10 MG)				
00310-6210-95 (10 MG)				
50090-3481-00 (10 MG)				
50090-3482-00 (5 MG)				
50090-7056-00 (5 MG)				
50090-7057-00 (10 MG)				
55154-6932-08 (5 MG)				
55154-6933-08 (10 MG)				
66993-0456-30 (5 MG)				
66993-0457-30 (10 MG)				

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Blank spaces indicate that no data was provided.

Table 12b. Farxiga NADAC, SAAC, and FSS Pricing

National Drug Code	NADAC Unit Price	Est. NADAC per Year	SAAC Rate	Est. SAAC per Year	FSS Unit Price	Est. FSS per Year
00003-1427-11 (5 MG)	$13.79	$5,032.51			$9.85	$3,595.01
00003-1428-11 (10 MG)	$13.78	$5,029.74			$9.85	$3,595.01
00310-6205-30 (5 MG)	$18.63	$6,799.29	$18.46	$6,737.91	$15.08	$5,502.98
00310-6205-90 (5 MG)	$18.63	$6,799.29	$18.46	$6,737.91	$13.98	$5,101.69
00310-6205-95 (5 MG)			$18.46	$6,737.91		
00310-6210-30 (10 MG)	$18.64	$6,802.61	$18.50	$6,751.69	$15.08	$5,502.98
00310-6210-39 (10 MG)	$18.64	$6,802.61	$18.50	$6,751.69	$15.53	$5,668.09
00310-6210-90 (10 MG)	$18.64	$6,802.61	$18.50	$6,751.69	$13.99	$5,107.57
00310-6210-95 (10 MG)			$18.50	$6,751.69		
50090-3481-00 (10 MG)						
50090-3482-00 (5 MG)						
50090-7056-00 (5 MG)						
55154-6932-08 (5 MG)						
55154-6933-08 (10 MG)						
66993-0456-30 (5 MG)	$11.17	$4,078.40			$12.55	$4,581.97
66993-0457-30 (10 MG)	$11.37	$4,149.78			$12.55	$4,581.97

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Blank spaces indicate that no data was provided.

Exhibit 1 (attached) reflects pricing history for Farxiga.

Factor 5.2: Information estimating manufacturer net price and net sales amounts of the prescription drug product under review

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(a)(ii)
Methodology: Develop and apply equations to data
Data Sources: Proprietary databases including SSR Health and UpToDate (MediSpan), MCDB

For each NDC-11 associated with the prescription drug product under review, the following table provides: (a) the most recently available SSR rebate estimate (2024 Q2) for the drug product; (b) estimated manufacturer net prices using *equation 1*, below; and (c) estimated net sales amount for each APCD segment using *equation 2,* below. The previously mentioned data elements are presented at the NDC-11 level.

The proprietary data and the equations used in calculating the estimated net price are redacted to protect confidential and proprietary information in accordance with Health-General Article §§ 21-2C-10 and 21-2C-03 and applicable data and licensing agreements. The equation and estimated net sales calculation are likewise redacted to protect confidential and proprietary information.

[redacted]

Table 13. Farxiga Net Price and and Net Spending Estimates

Drug Information			Annual Price or Sales After SSR Application [redacted]			
National Drug Code	Strength	SSR Rebate	Est. Net Price per Year	Commercial (2023) Estimated Net Spend	State Local Govt Emp (2023) Estimated Net Spend	Medicare (2022) Estimated Net Spend
00310-6210-30	10 MG	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00310-6205-30	5 MG	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
66993-0457-30	10 MG	[redacted]	[redacted]	[redacted]	[redacted]	
00310-6210-39	10 MG	[redacted]	[redacted]	[redacted]		
66993-0456-30	5 MG	[redacted]	[redacted]	***	***	
00310-6210-90	10 MG	[redacted]	[redacted]			
55154-6933-08	10 MG	[redacted]	[redacted]			
00003-1427-11	5 MG	[redacted]	[redacted]			
00310-6205-90	5 MG	[redacted]	[redacted]			
55154-6932-08	5 MG	[redacted]	[redacted]			
00003-1428-11	10 MG	[redacted]	[redacted]			

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.

Blank spaces indicate that no data was provided.

Factor 5.3: The average price concession, discount, and rebate provided by the manufacturer or expected to be provided to each payor class in the State for the drug under review, expressed as a number and as a percent of the WAC

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(ii);
COMAR 14.01.04.05C(1)(b)(i)
Methodology: Calculation of discount as percentage of WAC
Data Sources: Centers for Medicare and Medicaid Services

Under the Medicare Drug Price Negotiation Program authorized by the Inflation Reduction Act of 2022 (P.L. 117-169), beginning January 1,2026, Farxiga is subject to a negotiated Maximum Fair Price (MFP) for the Medicare program.[59] Using this information, staff calculated the expected price concession, discount, and rebate for Medicare Plans in Maryland. The table below calculates the price concession, rebate, and discounts as a percentage of WAC.

[59] Data available at "File for Negotiated Prices, also known as Maximum Fair Prices in Statute (ZIP)" located at https://www.cms.gov/files/zip/file-negotiated-prices-also-known-maximum-fair-prices-statute.zip (last checked May 1, 2025)

Table 14. Farxiga Price Concessions for Medicare under MFP

Drug	National Drug Code	WAC Unit Per Unit	MFP Per Unit	Price Concession As A Percent of WAC
Farxiga	00003-1427-11	[redacted]	$6.05	[redacted]
Farxiga	00003-1428-11	[redacted]	$6.05	[redacted]
Farxiga	00310-6205-30	[redacted]	$6.05	[redacted]
Farxiga	00310-6205-90	[redacted]	$6.05	[redacted]
Farxiga	00310-6205-95			
Farxiga	00310-6210-30	[redacted]	$6.05	[redacted]
Farxiga	00310-6210-39	[redacted]	$6.05	[redacted]
Farxiga	00310-6210-90	[redacted]		
Farxiga	00310-6210-95			
Farxiga	50090-3481-00			
Farxiga	50090-3482-00			
Farxiga	50090-7056-00			
Farxiga	55154-6932-08	[redacted]		
Farxiga	55154-6933-08	[redacted]		
Farxiga	66993-0456-30	[redacted]	$6.05	[redacted]
Farxiga	66993-0457-30	[redacted]	$6.05	[redacted]

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Factor 5.4: The average price concession, discount, and rebate the manufacturer provided or is expected to provide for the prescription drug product under review to each PBM operating in the State, expressed as a number and as a percent of the WAC

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iii); COMAR 14.01.04.05C(1)(b)(ii); COMAR 14.01.04.05C(1)(g)(xviii); COMAR 14.01.04.04B(3)(b)
Methodology: Reported by entities
Data Sources: Reported by entities

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as exhibits to the dossier.

Exhibit 2 contains information responsive to this element.

Factor 5.5: Information supplied by the manufacturer, if any, explaining the relationship between the pricing of the prescription drug product and (a) the cost of development and (b) the therapeutic benefit of the prescription drug product, or information that is otherwise pertinent to the manufacturer's pricing decision

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iii); COMAR 14.01.04.05C(1)(g)(viii); COMAR 14.01.04.05C(1)(g)(xviii); COMAR 14.01.04.04B(1)(a)
Methodology: Reported by entities
Data Sources: Reported by entities

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as exhibits to the dossier.

Exhibit 2 contains information responsive to this element.

Section 6: Therapeutic Alternatives, Cost Comparisons, and Health Economics Outcomes and Research (HEOR)

Factor 6.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS at which each therapeutic alternative has been sold in the State

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iv);
COMAR 14.01.04.05C(1)(c)(ii)
Methodology: Calculation of number of units per year and calculation pricing per year
Data Sources: Proprietary databases including UpToDate (MediSpan); and Centers for Medicare and Medicaid Services, Myers and Stauffer, Department of Veterans Affairs

Factor 6.2: The average price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the State for therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(v);

COMAR 14.01.04.05.C(1)(c)(i)

Methodology: Calculation using equation

Data Sources: Proprietary databases including SSR Health and UpToDate (MediSpan)

This section provides pricing and concession information for each therapeutic alternative.

Factor 6.1 (COMAR 14.01.04.05C(1)(c)(ii) and Health-General § 21-2C-09(b)(2)(iv)) address pricing metrics (WAC, AWP, NADAC, SAAC, ASP, and FSS) for therapeutic alternatives. For each therapeutic alternative, staff identified the number of units per year for each alternative based on the FDA label. For pills, the number of units per year is the number of pills per year. For injections, the units are either milliliters, vials, or autoinjectors. For most therapeutic alternatives, staff identified the unit for each drug and the number of units per year. For drugs that have initial loading doses, staff assumed a full year of use for a patient who has previously taken the loading dose.

Factor 6.2 (COMAR 14.01.04.05.C(1)(c)(i) and Health-Gen. § 21-2C-09(b)(2)(v)) address the average price concession, discount, or rebate the manufacturer provides for each therapeutic alternative. Staff calculated the estimated dollar rebate using proprietary data from SSR health.

[redacted]

Staff developed the attached supplemental excel document (Exhibit 3_REDACTED "FARXIGA Therapeutic Alternative Pricing_REDACTED") to organize these two factors and the following data for each therapeutic alternative: (a) the effective date of the price; (b) the current* unit price for WAC, AWP, NADAC, FSS and SAC; (c) the estimated annual price (based on the FDA's recommended dosing regimens and current* unit prices); and (d) calculated average dollar rebate.

Sheet 1 of Exhibit 3_REDACTED contains the information specified above for non-insulin therapeutic alternatives.

Sheet 2 of Exhibit 3_REDACTED contains the specified information for insulin therapeutic alternatives with a single exception. The insulin sheet provides estimated price metrics per 50 units (*e.g.*, WAC per 50 Units).

Sheet 3 of Exhibit 3_REDACTED provides a summary for each non-insulin therapeutic alternative, displaying the number of NDCs associated with the therapeutic alternative, along with the minimum, maximum and average annual price estimates observed among their NDCs.

*Current prices do not reflect price changes that occurred after August 1, 2024.

Factor 6.3: The utilization, costs, and out-of-pocket costs for therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(c)(iii)
Methodology: Aggregation of claims to calculate utilization, spending, and out-pocket cost measures
Data Sources: MCDB

Staff developed the attached supplemental excel document Exhibit 4 (Farxiga Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)) to organize the following data for each NDC-11 associated with each approved therapeutic alternative by MCDB segment: (a) patient counts; (b) total units dispensed; (c) total gross spending; (d) average, median, and 90th percentile of annual patient OOP costs; and (e) the average deductible, coinsurance, copayment, and other patient liability for applicable MCDB segments.

Factor 6.4: The incremental costs associated with a prescription drug product, including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(ix); COMAR 14.01.04.05C(1)(e)(i)
Methodology: Literature review
Data Sources: Published cost-effectiveness studies and literature

This subsection concerns the incremental costs associated with a prescription drug product. This includes the cost of using the drug and the cost of using other health, medical, and social services to manage other aspects of health addressed by the therapy. Staff compared these costs—cost of using the drug and the cost of using other health, medical and social services—to the same costs when using a therapeutic alternative. Staff considered the costs associated with the use of the therapeutic alternative as the baseline effect. The incremental cost of the therapy is the change in all of these costs compared to the costs associated with the therapeutic alternative.

Staff reviewed published cost-effectiveness literature in the United States to identify the potential incremental costs associated with the use of Farxiga (dapagliflozin). Staff used the Tufts Medical Center's Center for the Evaluation of Value and Risk in Health's Cost Effectiveness Analysis Registry to identify potential analyses.[60] Staff searched for articles containing dapagliflozin in the United States. In total, staff reviewed ten articles with varying results.

The majority of the literature assesses the cost of the drug over a lifetime which necessarily includes the assessment of three components: (1) the incremental impact of the cost of the drug product; (2) the reductions in healthcare spending due to the drug product improving health (offsets); and (3) additional healthcare costs incurred from living longer. The results varied because of assumptions about the cost of Farxiga, the use of Farxiga for different indications, and differing comparators. The results of these studies are summarized in Exhibit 5A.

[60] CEA Registry. Tufts Medical Center. https://cear.tuftsmedicalcenter.org/

Factor 6.5: Information derived from health economics and outcomes research that may address the effectiveness of the prescription drug product in treating the conditions for which it is prescribed or in improving a patient's health, quality of life, or overall health outcomes, and the effectiveness of the prescription drug product compared with therapeutic alternatives or no treatment.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(e)(ii)
Methodology: Literature review
Data Sources: Published cost-effectiveness studies and literature and published comparative effectiveness research and literature

Health Economics and Outcomes Research (HEOR) is a field of study that provides patients, providers, and decision makers with information concerning the effectiveness, costs, and quality of life resulting from health care interventions. This includes both cost effectiveness and comparative effectiveness research: cost effectiveness research compares the relative costs and outcomes (or effects) of different healthcare treatments or interventions; comparative effectiveness research compares different healthcare interventions or therapies to determine clinical effectiveness, benefits, and safety.

This research may be published in academic journals or by non-profit institutions and governmental entities.

Staff reviewed literature from two different sources. First, staff reviewed the same articles identified in Factor 6.4. In addition, staff reviewed literature identified by the Centers for Medicare and Medicaid Services for the Medicare Drug Price Negotiation Program. In explaining the resulting Maximum Fair Price, CMS published a list of studies that it considered during the process.[61] Staff reviewed this list for relevant Comparative Effectiveness Research. See Exhibits 5A and 5B for a summary of the literature.

[61] File for the MFP Explanation for Farxiga. Center for Medicare and Medicaid Services. https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices

Factor 6.6: In the case of generic prescription drug products, the number of pharmaceutical manufacturers that produce the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(iii)
Methodology: Research and review of databases
Data Sources: Drugs@FDA database, FDA Orange Book

Farxiga is not a generic drug product.

Factor 6.7: The utilization and pricing of therapeutically equivalent drug products

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(xii)
Methodology: Research and review
Data Sources: FDA Orange book

For Farxiga, there are no therapeutically equivalent drug products approved by the FDA under other applications.

Section 7: Cost-Sharing and Insurance Benefit Design

Factor 7.1: The estimated impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(vii);
COMAR 14.01.04.05C(1)(d)(ii)
Methodology: Analyses using claims data (see below) and literature review
Data Sources: MCDB

MCDB Analysis

The following analysis estimates the impact on patient access resulting from the cost of the prescription drug product under study relative to insurance benefit design. Two items may be of particular interest to the Board: (a) the distribution of coinsurance/copayment utilization among claims for the drug under study; and (b) whether increases or decreases in a patient's average copay/coinsurance per claim impact their utilization of the drug. In the second analysis, we examined how increases in copayment impact the number of prescriptions a patient has in a year. Some patients had previously begun using Farxiga. Meanwhile, others began Farxiga during the year. As a result, staff attempted to see if the impact differed for new patients compared to pre-existing patients using an interaction term.

Methods

1. Extract claims for the prescription drug product from commercial eligibility file
    a. Initial Inclusion Criteria:
        i. Patients filling claims for the prescription drug product must have pharmacy coverage for at least 11 months of the calendar year;
        ii. Patients must reside in Maryland as indicated on their pharmacy claims;
        iii. Claims must not be denied or contain indicators that the claim was a duplicate submission from either a third-part administrator (*i.e.*, PBM), health plans providing Medicare Part D, Fee-For-Service, coverage, or commercial health plan providing Medicaid/Medicare managed care coverage;
        iv. Claims must have positive non-zero values for the total paid amount field (i.e., total gross spending) and values greater than 0 for cost-sharing payment fields (i.e., deductible amounts, copay amounts, coinsurance amounts, and other member liability amounts);
        v. Restrictions based on the 30-day equivalent field:

1. HSCRC's commercial claims include a 30-day equivalent field. Values of 1 in the 30-day equivalent field indicate a patient received a 30 days' supply of the drug, values of 2 indicate the patient received a 60-days' supply of the drug and so on. To ensure robust results for Farxiga claims, which are each once a day tablets, staff restricted the analysis to the following:
    a. Claims with a value of 1 in the 30-day equivalent field should have values of 15, 30, or 60 in the quantity dispensed field. These account for the fact that a beneficiary may receive an appropriate dosage, half dosage, or double dosage of the drug product;
    b. Claims with a value of 2 in the 30-day equivalent field should have values of 30, 60, or 120; and
    c. Claims with a value of 3 in the 30-day equivalent field should have values of 45, 90, or 180;

vi. Claims for patients whose 30-day normalized ratio (i.e., [total 30-day equivalents received]/[expected 30-day equivalents]) >1 are excluded; and

vii. Claims for patients whose first instance of use of the prescription drug product was in December were excluded.

2. Assign copay and coinsurance flags to each eligible claim and determine the rate at which these cost sharing measures are utilized.
3. Prepare for regression analysis by summarizing patient information among eligible claims
    a. Sum all 30-day equivalents (*total 30-day equivalents)*
    b. Calculate expected 30-day equivalents as
        i. (Total Covered Months +1) – (Month of first prescription fill date)
    c. Calculate Normalized 30-Day Equivalent as
        i. (Total 30-Day Equivalents)/(Expected 30-Day Equivalents)
    d. Assign Continuous user flag for patients who received the drug in January or February of the calendar year
    e. Calculate the average coinsurance and copayment for each patient
    f. Create interaction term between average coinsurance/copayment as
        i. Interaction 1: (cont_user)*(average coinsurance)
        ii. Interaction 2 : (cont_user)*(average copay)

4. Run following regression on data

$$Y_i = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4 + \beta_5 x_5$$

where

Y_i = Normalized 30 Day Equivalent
β_0 = Intercept
β_1 = Patient's Average Copay per Claim
β_2 = Patient's Average Coinsurance per Claim
β_3 = Continuous User Indicator (if the patient had already been using the drug)
β_4 = Interaction Term – Continuous User*Avg Copay
β_5 = Interaction Term – Continuous User*Avg Coinsurance

Results

Data Characteristics

Table 15. 2023 Commercial Pharmacy Claims Characteristics for Farxiga Analysis

	Patient Count	**Claim Count**
Total Population		
Counts	19,698	81,143
Eligible Patients (≥ 11 months of pharmacy coverage)		
Counts	17,359	67,775
Final Summary File for Eligible Claims		
Counts	10,641	40,190

Farxiga

Table 16. Farxiga Out of Pocket Cost Frequency Analysis

COIN_FLAG	COPAY_FLAG	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	0	9963	24.79	9963	24.79
0	1	25574	63.63	35537	88.42
1	0	4098	10.20	39635	98.62
1	1	555	1.38	40190	100.00

Among eligible commercial claims for Farxiga, copay is used most often (64%) as part of the insurance benefit design. Use of coinsurance as part of the benefit design, either by itself or in conjunction with coinsurance payments, is observed in slightly less than 12% of claims.

Regression Analysis

Table 17. Summary statistics for regression variables

	N	NMiss	Min	Max	Mean	Std
Normalized 30 Day Equivalent	10641	0	0.08	1.00	0.73	0.28
Continuous User Indicator	10641	0	0.00	1.00	0.50	0.50
Average Coinsurance	10641	0	0.00	1199.00	15.13	57.03
Average Copay	10641	0	0.00	825.00	34.58	39.62
Continuous User*Avg. Coinsurance	10641	0	0.00	916.00	6.94	37.02
Continuous User*Avg. Copay	10641	0	0.00	825.00	17.08	32.74

Table 18. Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	8.96869	1.79374	22.76	<.0001
Error	10635	838.09413	0.07881		
Corrected Total	10640	847.06282			

Table 19. Model Statistics.

Root MSE	0.28072	**R-Square**	0.0106
Dependent Mean	0.73214	**Adj R-Sq**	0.0101
Coeff Var	38.34276		

Table 20. Parameter Estimates						
Variable	**Label**	**DF**	**Parameter Estimate**	**Standard Error**	**t Value**	**Pr > |t|**
Intercept	Intercept	**1**	0.70421	0.00538	130.81	<.0001
AVG_COPAY	Average Copay	**1**	0.00055965	0.00009868	5.67	<.0001
AVG_COIN	Average Coinsurance	**1**	-0.00017931	0.00006331	-2.83	0.0046
CONT_USER	Continuous User Indicator	**1**	0.03235	0.00764	4.24	<.0001
INTX_COIN	Continuous User*Avg. Coinsurance	**1**	-0.00020089	0.00009925	-2.02	0.0430
INTX_COPAY	Continuous User*Avg. Copay	**1**	-0.00019769	0.00014034	-1.41	0.1590

The analysis above suggests that while there are statistically significant relationships between average copays and coinsurance and the number of prescriptions people use in a year, any impact is small.

Literature Review

Staff conducted a literature review of the published literature to determine whether similar results exist nationally. Staff conducted a literature review using Google Scholar and PubMed for articles using the search term "Co-payment Adherence dapagliflozin." Staff identified two articles.

The first article examined the relationship between copayments and utilization in a database of commercial insurance and Medicare Part D plans associated with Medicare Advantage.[62] The researchers categorized patients into three groups based on their copay levels: low (less than $10), medium (between $10 and $50), and high (greater than $50). They then examined the proportion of days covered by prescriptions. The researchers examined the relationship between the copayment categories and the probability of having more than 80% of the prescription days covered in a year. Without controlling for other factors, they found that 77% of patients with low copayment levels had more than 80% of prescription days covered. In comparison, 72% of those with medium and 72% of those with high copayments had 80% covered. Controlling for demographic, clinical, and socioeconomic factors, the authors found that the odds ratio for those with medium

[62] Essien UR, Singh B, Swabe G, et al. Association of Prescription Co-payment With Adherence to Glucagon-Like Peptide-1 Receptor Agonist and Sodium-Glucose Cotransporter-2 Inhibitor Therapies in Patients With Heart Failure and Diabetes. JAMA Netw Open. 2023;6(6):e2316290. doi:10.1001/jamanetworkopen.2023.16290

copayments was 0.67 and those with high copayments was 0.68 compared to the low copayment group.

The second article examined adherence during the first year of SGLT2 inhibitor use in Medicare beneficiaries.[63] In this study, researchers found that increased copays were associated with more prescription days covered.

[63] Chelsea E. Hawley, Julie C. Lauffenburger, Julie M. Paik, Deborah J. Wexler, Seoyoung C. Kim, Elisabetta Patorno; Three Sides to the Story: Adherence Trajectories During the First Year of SGLT2 Inhibitor Therapy Among Medicare Beneficiaries. Diabetes Care 1 March 2022; 45 (3): 604–613. https://doi.org/10.2337/dc21-1676

Factor 7.2: The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer for the drug product under review and the policies surrounding and implementing such programs

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(viii); COMAR 14.01.04.05C(1)(d)(iii)
Methodology: Research and review
Data Sources: Manufacturer's website

Staff identified two patient access programs for Farxiga. The first program is the FARXIGA Savings Card.[64] The terms of use and eligibility for the program are expressed as follows:

> ELIGIBILITY: You may be eligible for this offer if you are insured by commercial insurance and your insurance does not cover the full cost of your prescription, or you are not insured and are responsible for the cost of your prescriptions. Patients who are enrolled in a state or federally funded prescription insurance program are not eligible for this offer. This includes patients enrolled in Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), Department of Defense (DOD) programs or TriCare, and patients who are Medicare eligible and enrolled in an employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees. If you are enrolled in a state or federally funded prescription insurance program, you may not use this savings card even if you elect to be processed as an uninsured (cash-paying) patient. This offer is not insurance, is restricted to residents of the United States and Puerto Rico, and to patients over 18 years of age.
>
> TERMS OF USE: Eligible commercially insured patients with a valid prescription for FARXIGA® (dapagliflozin) who present this savings card at participating pharmacies will pay as low as $0 per 30-day supply subject to a maximum savings of $175 per 30-day supply. If you pay cash for your prescription, AstraZeneca will pay up to the first $150, and you will be responsible for any remaining balance, for each monthly prescription. Other restrictions may apply. Patient is responsible for applicable taxes, if any. Non-transferable, limited to one per person, cannot be combined with any other offer. Void where prohibited by law, taxed or restricted. Patients, pharmacists, and prescribers cannot seek reimbursement from health insurance or any third party for any part of the benefit

[64] https://www.farxiga.com/savings-support/register

> received by the patient through this offer. AstraZeneca reserves the right to rescind, revoke, or amend this offer, eligibility and terms of use at any time without notice. This offer is not conditioned on any past, present or future purchase, including refills. Offer must be presented along with a valid prescription at the time of purchase. If you have any questions regarding this offer, please call 1-844-631-3978.[65]

The second program is called the "AZ&Me Prescription Savings Program."[66] According to the website:

> To receive support from the AZ&Me Prescription Savings Program, you will need to meet eligibility requirements.
>
> You must:
>
> Be a resident of the United States
> Be treated by a US-licensed healthcare practitioner
> Not have any commercial (private or employer-sponsored) insurance or government insurance other than Medicare, and
> Not be receiving any other medication payment assistance.

A reasonable search failed to disclose publicly available information concerning the dollar value of Farxiga-specific patient access programs.

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[65] Popup screen linked to "Subject to eligibility and monthly savings limit" at https://www.farxiga.com/savings-support/register#popup-1630592434947 (last checked May 1, 2025).
[66] https://www.azandmeapp.com/ (last checked May 1, 2025).

Factor 7.3: The average patient copay and other cost-sharing data for the prescription drug in the State

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(x); COMAR 14.01.04.05C(1)(f)(i)

Methodology: Aggregation of claims data to calculate average by out-of-pocket cost category

Data Sources: MCDB

For each NDC-11, the following tables provide the average out-of-pocket costs by payor type. Note that the MCDB includes these fields only for the commercial sector and not Medicare or Medicaid.

Table 21a. Farxiga Average Copays and Other Cost-Sharing

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Commercial (2023) Avg Deductible	Commercial (2023) Avg Copay	Commercial (2023) Avg Coinsurance	Commercial (2023) Avg Other Member Liability
66993-0457-30	Farxiga	10 MG	$8.57	$47.57	$11.63	$0.00
00310-6210-39	Farxiga	10 MG	$0.00	$16.23	$62.00	$26.15
00310-6210-30	Farxiga	10 MG	$66.01	$122.30	$51.77	$93.41
00310-6205-30	Farxiga	5 MG	$70.76	$93.32	$47.65	$77.15
66993-0456-30	Farxiga	5 MG	***	***	***	***

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients. ^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data. Blank spaces indicate that no data was provided.

Table 21b. Farxiga Average Copays and Other Cost-Sharing

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	State Local Gov (2023) Avg Deductible	State Local Gov (2023) Avg Copay	State Local Gov (2023) Avg Coinsurance	State Local Gov (2023) Avg Other Member Liability
66993-0457-30	Farxiga	10 MG	$10.00	$5.56	$0.00	$0.00
00310-6210-39	Farxiga	10 MG				
00310-6210-30	Farxiga	10 MG	$9.53	$99.02	$9.04	$5.65
00310-6205-30	Farxiga	5 MG	$6.67	$72.19	$8.24	$4.67
66993-0456-30	Farxiga	5 MG	***	***	***	***

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Factor 7.4: The average cost share

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(f)(ii)
Methodology: Aggregation of claims data to calculate average cost share (the average percentage of gross spending paid by patients)
Data Sources: MCDB

The table below shows the cost share for different types of payors. The table does not include Medicaid because the MCDB does not include out-of-pocket cost data for Medicaid. The cost share is the patient total out-of-pocket costs divided by gross spending, which yields the percentage of gross spending paid by the patient. The average cost share is, on average, the percentage of gross spending paid by patients.

Table 22. Farxiga Average Cost Share

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Commercial (2023) Avg. Cost Share	State Local Gov (2023) Avg. Cost Share	Medicare (2022) Avg. Cost Share
66993-0457-30	Farxiga	10 MG	5.37%	1.30%	
00310-6210-39	Farxiga	10 MG	6.05%		
00310-6210-30	Farxiga	10 MG	6.23%	2.73%	6.91%
00310-6205-30	Farxiga	5 MG	6.45%	2.55%	6.60%
66993-0456-30	Farxiga	5 MG	***	***	***

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Factor 7.5: The mean, median, and 90th percentile out-of-pocket costs per patient compared to State incomes

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(vi)
Methodology: Aggregation of claims data to determine distribution of out-of-pocket costs, research
Data Sources: MCDB, Maryland Manual On-line (derived from U.S. Census Bureau)

The table below shows out-of-pocket costs (average, median, and 90th percentile) by payor type.

Table 23. Farxiga Average Out-of-Pocket Costs

Drug Information		Commercial (2023) Statistics			State Local Gov (2023) Statistics			Medicare (2022) OOP Statistics		
National Drug Code (11-Digit)	Dosage Strength	Avg.	Median	90th Percentile	Avg.	Median	90th Percentile	Avg.	Median	90th Percentile
66993-0457-30	10 MG	$67.77	$0.00	$200.00	$15.56	$0.00	$90.00			
00310-6210-39	10 MG	$104.38	$14.00	$184.00						
00310-6210-30	10 MG	$333.48	$160.00	$840.00	$123.25	$60.00	$300.00	$353.70	$158.90	$1,080.51
00310-6205-30	5 MG	$288.87	$120.00	$756.00	$91.77	$40.00	$225.00	$303.36	$120.00	$1,008.33
66993-0456-30	5 MG	***	***	***	***	***	***			

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

The Maryland Manual On-line provides estimates of the Maryland median household income and per capita personal income based on data from the U.S. Census Bureau.[67] The Maryland Manual reports a 2023 median household income of $101,652 and a per capita personal income of $75,391. The Maryland Manual also provides per capita personal income for each county. In 2023, personal income per capita ranged from $37,345 in Somerset County to $100,044 in Montgomery County.

[67] https://msa.maryland.gov/msa/mdmanual/01glance/economy/html/income.html

Factor 7.6: An assessment of the impact of the prescription drug product's cost to access by priority populations and the impact on equity

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(vii)
Methodology: Analysis of claims data
Data Sources: MCDB

Given that the claims data did not include demographic information for the vast majority of patients, staff were unable to make a conclusive assessment. Due to the lack of data and information for this element, staff are unable to provide the Board with this data, information, and analyses for study.

If demographic information were available, staff anticipated using linear regression techniques to assess whether there is a statistically significant difference in spending and utilization between identified priority populations for each selected drug. The priority populations to be assessed are informed by the Agency for Healthcare Research and Quality (AHRQ) reporting of priority populations.[68]

Since staff were unable to conduct the Maryland-specific analysis, staff conducted a literature review to see if any studies addressed disparities at a national level. Staff identified one study concerning differences in utilization and another study that examined differences in out-of-pocket costs.

A study found that 10.8% of patients with diabetes and SGLT-2 inhibitor prescriptions were Black, compared to 11.9% of patients with diabetes and no SGLT-2 inhibitor prescription.[69] Meanwhile, 4.4% of patients with diabetes and SGLT-2 inhibitor prescriptions were Asian, compared to 4.8% of patients with diabetes and no SGLT-2 inhibitor prescription. In addition, 16.1% of patients with diabetes and SGLT-2 inhibitor prescriptions were Hispanic/Latino, compared to 15.0% of patients with diabetes and no SGLT-2 inhibitor prescription.

The same study also found that 24.8% of patients with diabetes and SGLT-2 inhibitor prescriptions were in zip codes with less than $50,000 in median household income, compared to 30.2% of patients with diabetes and no SGLT-2 inhibitor prescription.

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[68] The selection of priority populations informed by AHRQ's definitions. https://www.ahrq.gov/priority-populations/index.html (last checked April 30, 2025).
[69] Eberly LA, Yang L, Eneanya ND, et al. Association of Race/Ethnicity, Gender, and Socioeconomic Status With Sodium-Glucose Cotransporter 2 Inhibitor Use Among Patients With Diabetes in the US. *JAMA Netw Open.* 2021;4(4):e216139. doi:10.1001/jamanetworkopen.2021.6139

Meanwhile, 25.7% of patients with diabetes and SGLT-2 inhibitor prescriptions were in zip codes with greater than $100,000 in median household income, compared to 18.5% with diabetes and no SGLT-2 inhibitor prescription.

The study found that in multivariable analyses, being Black race (aOR, 0.83) and Asian race (aOR, 0.94) were independently associated with lower rates of SGLT2 inhibitor use compared with being White. Female gender was also independently associated with a lower rate of SGLT2 inhibitor use (aOR 0.84). Higher median household income was associated with a higher rate of SGLT2 inhibitor use.

A second study found that 19.4% of the low copay patients were Black, compared to 11.8% and 10.1% of the medium and high copay patients.[70] It also found that 20.7% of the low copay patients were Hispanic, compared to 15.7% and 13.4% of medium and high copay patients. Additionally, this study found that 44.8% of patients with low copays came from areas with median household incomes under $40,000, compared to 21.9% and 21.6% of medium and high copay patients. In comparison, 12.4% of low copay patients came from areas with median household income over $100,000, compared to 28.1% and 25.7% of medium and high copay patients.

[70] Essien UR, Singh B, Swabe G, et al. Association of Prescription Co-payment With Adherence to Glucagon-Like Peptide-1 Receptor Agonist and Sodium-Glucose Cotransporter-2 Inhibitor Therapies in Patients With Heart Failure and Diabetes. *JAMA Netw Open.* 2023;6(6):e2316290. doi:10.1001/jamanetworkopen.2023.16290

Factor 7.7: The costs to health plans based on patient access consistent with FDA-labeled indications or standard medical practice

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(vi); COMAR 14.01.04.05C(1)(d)(i)
Methodology: Aggregation of number of unique patients in claims data and calculation potential gross spending if all patients used a full year of treatment
Data Sources: FDA Databases and MCDB

The tables below summarize the projected spending if all patients used 365 days' worth of the prescription drug product. This data was calculated based on the number of patients using an NDC multiplied by the annual WAC (as estimated in other tables). This number may be an overestimate for total spending across all NDCs because a single patient may use multiple NDCs over the course of a year.

Table 24. Farxiga Cost Consistent with FDA Label

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected Commercial (2023) Gross Spending
66993-0457-30	Farxiga	10 MG	[redacted]
00310-6210-39	Farxiga	10 MG	[redacted]
00310-6210-30	Farxiga	10 MG	[redacted]
00310-6205-30	Farxiga	5 MG	[redacted]
66993-0456-30	Farxiga	5 MG	***
National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected State Local Gov. Emp. (2023) Gross Spending
66993-0457-30	Farxiga	10 MG	[redacted]
00310-6210-39	Farxiga	10 MG	
00310-6210-30	Farxiga	10 MG	[redacted]
00310-6205-30	Farxiga	5 MG	[redacted]
66993-0456-30	Farxiga	5 MG	***
National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected Medicaid (2022) Gross Spending
66993-0457-30	Farxiga	10 MG	
00310-6210-39	Farxiga	10 MG	
00310-6210-30	Farxiga	10 MG	[redacted]
00310-6205-30	Farxiga	5 MG	[redacted]
66993-0456-30	Farxiga	5 MG	

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected Medicare (2022) Gross Spending
66993-0457-30	Farxiga	10 MG	
00310-6210-39	Farxiga	10 MG	
00310-6210-30	Farxiga	10 MG	
00310-6205-30	Farxiga	5 MG	
66993-0456-30	Farxiga	5 MG	

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.

Blank spaces indicate that no data was provided.

Section 8: Other Information

Factor 8.1: Input from the Public

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xvii)
Methodology: Input received
Data Sources: Public

INITIAL 60-DAY COMMENT PERIOD

60-Day Written Comment: Notice Posted on 5/23/2024

In accordance with COMAR 14.01.04.05C(2)(a), the public may provide written comments concerning the prescription drug product within 60 days of the date the drug selected for a cost review study is posted on the Board's website. The 60-day public comment period for Farxiga began on May 23, 2024, and ended July 22, 2024. *See* Exhibit 6A.

WRITTEN COMMENT REQUEST

Written Comment Request: Posted 10/28/2024

In accordance with COMAR 14.01.01.05B(4), the Board requested public written comments for the cost review study process for Farxiga, Jardiance, Ozempic and Trulicity. Patient experience and clinician input regarding these drugs were of particular interest, but all comments were encouraged. Written comments were due by the close of business, Friday, November 8, 2024.

Written comments for Farxiga received in response to this request are attached as Exhibit 6B and are also available on the Board's website.[71]

JANUARY 2025 COMMENT SOLICITATION

Comment request posted and sent by listserv: January 15, 2025

Prior to the January 27, 2025, meeting, the Board invited public comment concerning Farxiga and Jardiance in connection with the cost review study. Notice was posted on the website and

[71] Faxiga Public Comment- Pages 1-2, 9
https://pdab.maryland.gov/Documents/comments/11.8.2024%20Cost%20Review%20Comment%20Packet_updated.pdf

sent via the Board listserv on January 15, 2025. Under COMAR 14.01.04.05D, the Board may consider oral public comment made at the Board meeting and written comments. The written comments received are located on the website[72] and in Exhibit 6C.

PUBLIC COMMENTS IN CONJUNCTION WITH BOARD MEETINGS TO DATE

The Board also received oral public comments regarding Farxiga/Jardiance during several Board meetings.

Board Meeting: January 27, 2025- Oral Comment

1. Dr. Janie Abernathy, Primary Care Provider, Agenda Item V

2. Lenoard Lucci, Consumer, Agenda Item V

3. Peter Maybarduk, Public Citizen, Agenda Item V

Board Meeting: March 24, 2025- Oral Comment

Dr. Alankrita Olson, Preventative Medicine Physician, Agenda Item IV

WRITTEN COMMENT REQUEST ON DRAFT DOSSIER

Written Comment Request: Posted 6/18/2025

The Board requested comment on the drug, the dossier, whether use of the drug has created an affordability challenge for the State health care system or high out-of-pocket costs for patients, and, if so, how. Written comments were due by the close of business, Thursday, July 3, 2025.

Written comments for Farxiga received in response to this request are attached as Exhibit 6D and are also available on the Board's website

[72] Comments in Response to Additional Solicitation- https://pdab.maryland.gov/Documents/comments/2025/Written%20Comment%20Packet%201.27%20Board%20Meeting%20%281%29.pdf

Factor 8.2: Analysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xiii)
Methodology: Research
Data Sources: Review of FDA. DEA, and State regulations

Staff did not identify any other regulatory or compliance issue that would provide additional context for the market related to this prescription drug product.

Factor 8.3: Input from state and local governmental entities and the entities' contractors such as health plans and plan administrators

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xiv)
Methodology: Outreach to state and local governmental entities
Data Sources: State and Governmental Entities

Although Board staff reached out to state and local government entities, staff did not receive input for the cost review study of Farxiga.

For future Cost Review Studies, staff will continue to work with state and local governments to develop data and mechanisms to support this factor.

Factor 8.4: Information and analyses submitted by an entity under Regulation .04 of this chapter.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05.C(1)(g)(xviii)
Methodology: Request for Information
Data Sources: Manufacturer, health plans, PBMS, wholesalers as applicable

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as Exhibit 2 to the dossier. Under COMAR 14.01.04.05C(1)(g)(xviii), the Board may consider the "[i]nformation and analyses submitted by an entity under Regulation .04 of this chapter."

In accordance with Health-General Article § 21-2C-09 and COMAR 14.01.04.05E, the Board only considers certain categories of information and data if the Board is first unable to make an affordability challenge determination based on the other data and information provided. If the Board is unable to make an affordability determination, the Board may then consider that information. In compliance with these requirements, Board staff redacted the information that may be considered at the second step from the submitted documents provided to the Board as exhibits to the dossier. If the Board is unable to make an affordability challenge determination, staff will provide the Board with unredacted copies of the exhibits that contain the information that may be considered at the second step.

The Board received comment letters concerning the dossier (see exhibit 6), regarding authorized generics. In accordance with COMAR 14.01.04.05C(1)(g)(xvi), staff may perform analyses and research in response to information "submitted by an entity under Regulation .04 of this chapter, or through any public comment or public input procedure." See also COMAR14.01.04.04.B(1)(m) ("[i]nformation concerning all authorized generics as defined by 42 CFR §447.502 for the prescription drug product"). Information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential and proprietary information and is not subject to disclosure.

Historical pricing information for these NDCs are included in exhibit 1.

Table 25. Authorized Generic Prices- WAC and AWP Pricing

National Drug Code	WAC Unit Price	Est. WAC per Year	AWP Unit Price	Est. AWP per Year
50090-7056-00 (5 MG)			[redacted]	[redacted]
50090-7057-00 (10 MG)			[redacted]	[redacted]
66993-0456-30 (5 MG)	[redacted]	[redacted]	[redacted]	[redacted]
66993-0457-30 (10 MG)	[redacted]	[redacted]	[redacted]	[redacted]

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

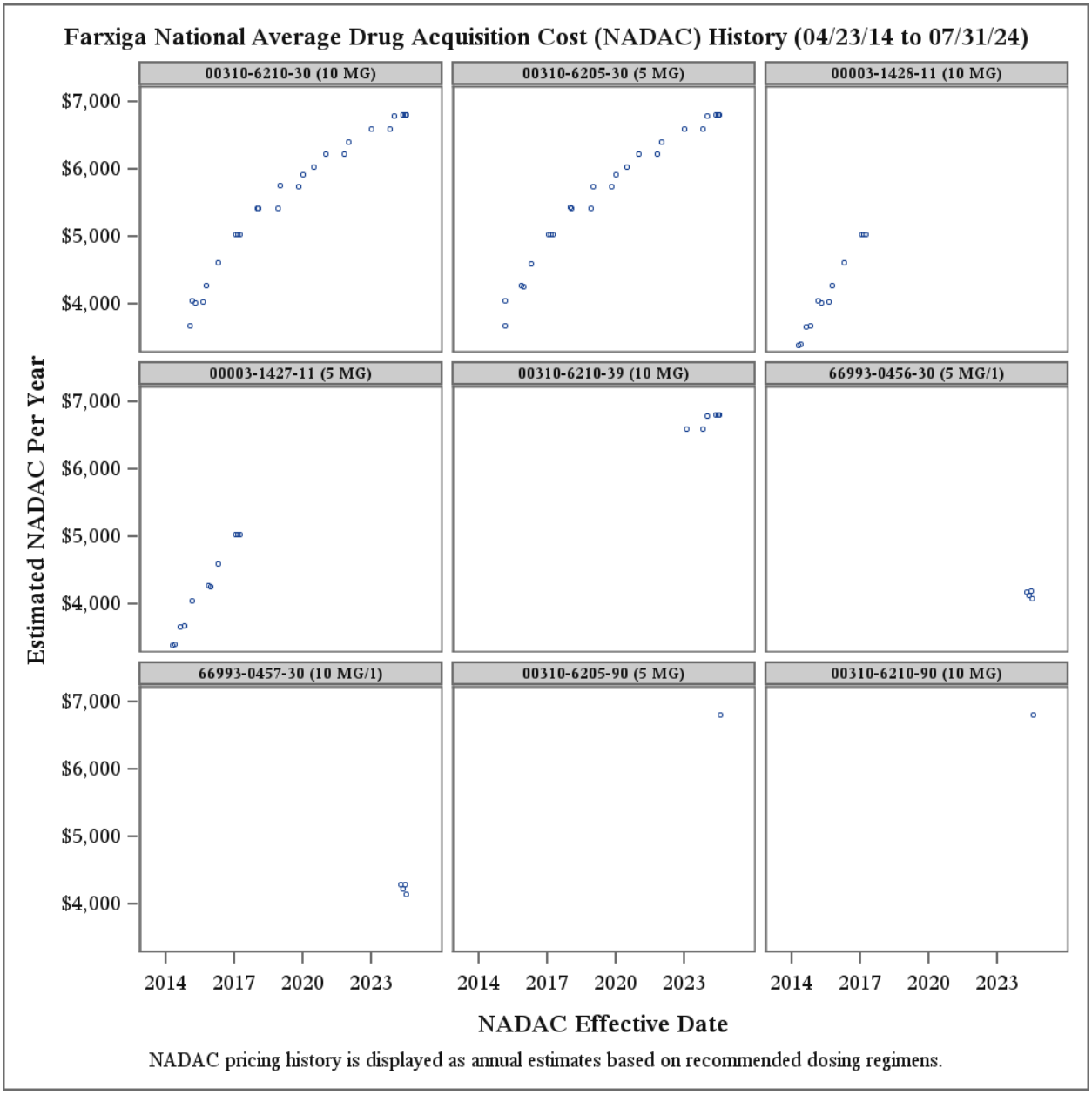
Table of Exhibits

Exhibit 1_REDACTED		Pricing History_REDACTED (PDF)
Exhibit 2		RFI Submissions **(NON-PUBLIC--TRADE SECRET, CONFIDENTIAL, AND PROPRIETARY)**
Exhibit 3_REDACTED		FARXIGA Therapeutic Alternative Pricing_REDACTED (Excel Document)
Exhibit 4		Farxiga Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)
Exhibit 5		
	Exhibit 5A	Farxiga Summary of Cost Effectiveness Analyses
	Exhibit 5B	Farxiga Summary of Comparative Effectiveness Research
Exhibit 6		
	Exhibit 6A	Written Comments (60-day COMAR 14.01.04.05C(2)) (PDF)
	Exhibit 6B	Written Comments (Request October 28, 2024) (PDF)
	Exhibit 6C	Written Comments (Request January 27, 2025) (PDF)
	Exhibit 6D	Written Comments (Request June 18, 2025) (PDF)

In accordance with Health-General Article §§ 21-2c-10 and 21-2c-03, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. The documents contained in Exhibit 2 are, therefore, not available to the public.

Exhibit 1-
Farxiga Pricing History_REDACTED

Historical National Average Drug Acquisition Cost (NADAC) Graph


Farxiga National Average Drug Acquisition Cost (NADAC) History (04/23/14 to 07/31/24)
00310-6210-30 (10 MG)
00310-6205-30 (5 MG)
00003-1428-11 (10 MG)
00003-1427-11 (5 MG)
00310-6210-39 (10 MG)
66993-0456-30 (5 MG/1)
66993-0457-30 (10 MG/1)
00310-6205-90 (5 MG)
00310-6210-90 (10 MG)
Estimated NADAC Per Year
$7,000
$6,000
$5,000
$4,000
2014
2017
2020
2023
NADAC Effective Date
NADAC pricing history is displayed as annual estimates based on recommended dosing regimens.

Historical Wholesale Acquisition Cost (WAC) Graphs by NDC

Historical Average Wholesale Price Graphs by NDC

DOSSIER EXHIBIT 2

- Exhibit 2 RFI Submissions (NON-PUBLIC--TRADE SECRET, CONFIDENTIAL, AND PROPRIETARY)

DOSSIER EXHIBITS 3-5 Attached Separately

- Exhibit 3 Farxiga Therapeutic Alternative Pricing_REDACTED (Excel Document) -
- Exhibit 4 Farxiga Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)
- Exhibit 5
  - Exhibit 5A Farxiga Summary of Cost Effectiveness Analyses
  - Exhibit 5B Farxiga Summary of Comparative Effectiveness Research

Exhibit 6A-

Written Comments

(60-day COMAR 14.01.04.05C(2))

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

1111 North Charles Street • Baltimore, MD 21201 • 410.837.2050 • chasebrexton.org

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

1111 North Charles Street • Baltimore, MD 21201 • 410.837.2050 • chasebrexton.org

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

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

Exhibit 6B-

Written Comments

(Request October 28, 2024)

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

November 8, 2024

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

RE: Public Comments on Drugs Subject to Cost Review (Farxiga)

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.

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.

Ensure Patients Will Benefit from Cost Reviews

UPLs fail to address many of the underlying causes and complicated factors that result in higher prescription drug costs for patients. There are also no current mechanisms in place to guarantee that payers who benefit from UPLs will pass along savings to 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 for patients and what will be the state or the broader healthcare system.

Enact Patient Protections

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 appreciate the board's recognition that this could be a consequence of UPL implementation; however, we are disappointed that the board only intends to monitor for these changes after the UPL has been implemented.

Instead, we urge the board to work with the state legislature to put in place safeguards for patients prior to moving forward with UPL policies to protect patients from increased utilization management, compromised access to drugs under review, and other unintended consequences of the board's actions.

Focus on Patient Experiences and Perspectives

Finally, we continue to urge the board to ensure that patient experiences are a critical focus of the process to identify the appropriate policy remedy. Rather than immediately proceeding to a UPL, the board should instead take the opportunity to seek broad patient input to better understand the source and reasons for affordability challenges.

We urge that the board utilize the cost review process to gather more in-depth input from patients in the form of roundtables or focus groups. 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.

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 of the policy review process.

We look forward to continuing to engage with staff as cost reviews proceed. We invite any and all opportunities to speak directly with any board member who would be interested in more detailed perspectives from our national network of patient organizations and allied groups.

Sincerely,

Tiffany Westrich-Robertson
Ensuring Access through Collaborative Health (EACH) Coalition

Exhibit 6C-

Written Comments

(Request January 27, 2025)

EACH PIC COALITION

January 22, 2025

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

RE: Public Comments on Drugs Subject to Cost Review (Farxiga)

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

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 coalition participants, 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.

Ensure Patients Will Benefit from Cost Reviews

UPLs fail to address many of the underlying causes and complicated factors that result in higher prescription drug costs for patients. There are also no current mechanisms in place to guarantee that payers who benefit from UPLs will pass along savings to 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 for patients and what will be the state or the broader healthcare system.

Enact Patient Protections

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 appreciate the board's recognition that this could be a consequence of UPL implementation; however, we are disappointed that the board only intends to monitor for these types of changes after the UPL has been implemented.

Instead, we urge the board to work with the state legislature to put in place safeguards for patients prior to moving forward with UPL policies to protect patients from increased utilization

management, compromised access to drugs under review, and other unintended consequences of the board's actions.

Focus on Patient Experiences and Perspectives

Finally, we continue to urge the board to ensure that patient experiences are a critical focus of the process to identify the appropriate policy remedy. Rather than immediately proceeding to a UPL, the board should instead take the opportunity to gather more in-depth input from patients to better understand the source and reasons for affordability challenges.

We invite the board to engage with our coalition participants who can serve as a direct conduit to understanding and incorporating patient and caregiver perspectives and who understand the life cycle of disease from the lens of prevention, diagnosis, and disease management.

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 of the policy review process.

We look forward to continuing to engage with staff as cost reviews proceed. We invite any and all opportunities to speak directly with any board member who would be interested in more detailed perspectives from our national network of patient organizations and allied groups (EACH) and patients and caregivers (PIC).

Sincerely,

Tiffany Westrich-Robertson
Ensuring Access through Collaborative Health (EACH) Coalition and Patient Inclusion Council (PIC)

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Farxiga

Maryland is working to support affordability through its Prescription Drug Affordability Board, while advocates press for the expansion of this authority to help more residents. Among the drugs up for review by the PDAB is Farxiga (dapagliflozin). Farxiga is manufactured by AstraZeneca and is used to treat diabetes, heart failure, and chronic kidney disease.

Farxiga has brought in more than $20 billion in revenue for AstraZeneca. As AstraZeneca reaped huge profits by charging Americans ten times more than it charges comparable countries, the company spent billions on self-enriching activities like executive compensation and dividends (a way publicly traded companies return cash to investors).

AstraZeneca has generated over $20.9 billion in sales revenue from Farxiga since its launch in 2014.

- Revenues obtained by AstraZeneca through Farxiga sales are nearly **30 times** the median cost for research and development of a new drug estimated by experts.

AstraZeneca charges Americans the highest price in the world for Farxiga.

- Farxiga's list price is $582 for a 30-day supply — this is 10.8 times higher than the average price across comparable countries ($54), according to a recent analysis.

AstraZeneca ripping us off is even more egregious considering significant taxpayer contributions to research prior to the approval of Farxiga, including $437.3 million[1] in NIH funding for basic and applied research.[2]

AstraZeneca uses predatory patenting tactics to expand monopoly protections over Farxiga. This staves off generic competition — a proven way to lower prices — keeping prices higher, longer.

- According to Public Citizen research, the patent protection for some of the more recent indications of Farxiga related to heart failure expires as late as 2040 — almost 14 years after the patent covering the drug substance expires and 26 years after the drug's initial approval.

AstraZeneca spends huge sums on payouts to executives and shareholders, rather than R&D.

- In 2023 alone, AstraZeneca spent $4.5 billion paying dividends and maintaining its exorbitant executive compensation.

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[1] Zhou et al. identified PubMed publications related to the drug target or the drug and subsequently identified NIH grants associated with the publications. Basic research funding was totaled through the date of approval of a first-in-class product associated with that target (in the case of Farxiga and Jardiance (which both target SGLT2), the first-in-class drug approval was Invokana (canagliflozin) in 2013). Thus, the funding total applies to multiple drugs.
See, https://www.ineteconomics.org/uploads/papers/WP_219-Federal-spending-on-drugs-Ledley-et-al-final.pdf

[2] NIH support for biomedical research is largely focused on basic research (the foundational research on biological targets for drug action that drug development is based upon). A smaller proportion goes toward applied research (research associated with later-stage development of a drug). See, https://www.bmj.com/content/367/bmj.l5766

Exhibit 6D-

Written Comments

(Request June 18, 2025)

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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
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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*
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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
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

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.

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 Farxiga, 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

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

APPENDIX B-
July 28, 2025
Farxiga Resolutions

CORRECTED RESOLUTION 2025-01
OF THE
PRESCRIPTION DRUG AFFORDABILITY BOARD
PRELIMINARY DETERMINATION COST REVIEW STUDY OF FARXIGA
July 28, 2025

WHEREAS, the Prescription Drug Affordability Board (Board) is authorized to conduct a cost review study of selected prescription drug products; and

WHEREAS, the Board selected Farxiga for study; and

WHEREAS, the Board has considered the data, analyses, and information assembled by staff in the dossier organized, in part, by regulatory factor; and

WHEREAS, the Board has considered the public oral and written comments received to date as part of the cost review process; and

WHEREAS, the Board considered, discussed and deliberated concerning the proprietary, trade secret and confidential information and data in closed session; and

WHEREAS, the Board may preliminarily determine whether use of the prescription drug product has led to an affordability challenge to the State health care system or high out-of-pocket costs for patients; and

WHEREAS, the Board may identify the circumstances under which the prescription drug product has or will lead to an affordability challenge to the State health care system or high out-of-pocket costs to patients; and

WHEREAS, upon consideration and deliberation of the proprietary, trade secret and confidential information in closed session, the Board voted to make a preliminary determination and identified two circumstances relying on confidential and proprietary data under which the prescription drug product has led to an affordability challenge; and

WHEREAS, the Board hereby ratifies the closed session vote, determination, and the identified circumstance as set forth below;

It is hereby

RESOLVED that:

The Board makes a preliminary determination that use of Farxiga:

Has created an affordability challenge for the State health care system; and

That the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice.

The circumstances under which the prescription drug product has led to an affordability challenge include:

(1) the percentage change in WAC over time is substantially larger than the percentage change in inflation (rate of increase in inflation) (closed session);

(2) at 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors (closed session); and

(3) total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments (public session).

Be it **FURTHER RESOLVED** that:

In accordance with COMAR 14.01.04.05F(2), the Board's preliminary determination is non-final and subject to revision and modification; and

Any circumstance is a sufficient and independent basis for the preliminary affordability challenge determination.

Be it **FUTHER RESOLVED**, that the Executive Director and staff, are authorized, directed, and empowered to draft a cost review study report in accordance with this resolution and the regulations, to be published as a draft for public comment, subject to a final determination and approval of a final report.

I, Van T. Mitchell, CERTIFY that the foregoing Resolution was adopted by the Board at a duly held meeting on July 28, 2025 by unanimous vote of a quorum of the Board.

_____