Farxiga
Cost Review Study

PDAB Meeting

July 28, 2025

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

History and Input on the Dossier

- **Draft Sections of Dossier Posted for May 19, 2025 Board Meeting**
  - **Received feedback from Board**
- **Draft Dossier for Public Comment**
  - **Posted for Comment: June 18, 2025**
  - **Comments Due: July 3, 2025**
- **Final Dossier for Consideration**
  - **Posted: July 18, 2025**

Farxiga Dossier Comments

- **PDAB staff received a total of 6 comments on the Farxiga dossier for the comment period ending on July 3, 2025. Four comments were provided by organizations and two comments were provided by pharmaceutical companies.**
- **Feedback Themes Included:**
  - Technical Changes
  - Process and Deadlines
  - Upper Payment Limit Concerns
  - Support for Upper Payment Limits
  - Metrics, Data Evaluation and Methodology Concerns
  - Affordability Concerns and Payment Design
  - Therapeutic Alternative Interchangeability

Incorporated Changes

- **PDAB staff posted a Final Dossier on July 18, 2025 that incorporated changes from the June 18th version. These changes included:**
  - General Formatting and Copy Editing
  - Updated Government website links
  - Updated information on authorized generics

Dossier Overview

- Section 1: Background
- Section 2: Clinical Information
- Section 3: Regulatory Approval and Market Context
- Section 4: Utilization of Drug Product Under Review
- Section 5: Pricing Information and Rebates
- Section 6: Therapeutic Alternatives, Cost Comparisons, and Health Economics Outcomes and Research (HEOR)
- Section 7: Cost-Sharing and Insurance Benefit Design
- Section 8: Other Information

Dossier Overview

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)
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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.

Section 1: Background

Section 1: Background

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

Section 2: Clinical Information

Factor 2.1: Clinical information- FDA indications

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

Factor 2.1: Clinical information- Information concerning standard medical practice

Place in Therapy for Diabetes Mellitus Type 2

- SGLT2 inhibitors are a preferred drug class in the treatment of Type 2 DM. SGLT2 inhibitors are typically considered as a first therapy option for Type 2 DM first line therapy given the overall safety (low risk of hypoglycemia), effectiveness in lowering blood sugar, and CKD, CVD, HF benefits/protection. GLP1-agonists have demonstrated similar outcomes, and are an alternative first-like therapy. Metformin, a biguanide, is also considered first line therapy with effectiveness in lowering blood sugar, low hypoglycemia risk, and potential CVD benefit; but has not demonstrated benefit in HF or progression of CKD. Jardiance, Farxiga and Invokana (canagliflozin) are the preferred choices in this class for medical professionals given their proven benefits for HF, CVD, and CKD.

Place in Therapy for Heart Failure

- SGLT2 inhibitors, specifically Jardiance, Farxiga, or Inpefa (sotagliflozin), are recommended to be taken by all symptomatic HF patients.

Place in Therapy for Chronic Kidney Disease

- To lower the risk of CKD progression and acute kidney injury and improve cardiovascular outcomes, SGLT2i inhibitors (equal weight preference to Jardiance, Farxiga and canagliflozin) are recommended by major guidelines for adult CKD patients with DM Type 2, HF and/or albuminuria ≥200mg/g and suggested for adult CKD patients with an eGFR of 20 to 45 ml/min/1.73m2.

All Pricing, Spending and Utilization Data is Consistent with the labeling approved by the FDA or standard medical practice.

Factor 2.2: The disease burden of the condition that is treated by the prescription drug product- Type 2 Diabetes Mellitus (DM)

Prevalence

- In the United States (US), 38.4 million (11.6%) people have diagnosed or undiagnosed diabetes mellitus (DM).1,2 Type 2 DM accounts for 90-95% of all diagnosed cases of diabetes.
- In Maryland, the total age-adjusted percentage of adults aged 18 years or older with diagnosed diabetes was 10.5% in 2022.

Incidence

- In 2021, 1.2 million adults were diagnosed with diabetes (rate of 5.9 per 1000 people).1,2 Worth noting, 98 million adults, more than 1 in 3 people, have prediabetes (38% of adult US population). In individuals 65 years or older, 48.8% have prediabetes.
- In Maryland, the age-adjusted rate of adults aged 18 years or older with newly diagnosed diabetes was 7.8 per 1000 in 2022.

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. 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.

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.
- In Maryland in 2021, total and per patient medical costs attributable to diabetes were $6.506 billion and $11,909, respectively.

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).

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). Including diabetes as a contributing cause of death, the rate increases to 120.3 per 100,000 people (399,401 death certificates)
- 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.

Factor 2.2: The disease burden of the condition that is treated by the prescription drug product- Heart Failure (HF)

Prevalence

- Based on NHANES 2017-2020, approximately 6.7 million US adults have HF (overall population rate of 1.9-2.6%). 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.
- 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).

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).

Disease Severity

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

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.
- 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).

Factor 2.2: The disease burden of the condition that is treated by the prescription drug product- Heart Failure (HF)

Morbidity

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

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

Factor 2.2: The disease burden of the condition that is treated by the prescription drug product- Chronic Kidney Disease (CKD)

Prevalence

- Based on data from 2017 - March 2020, 35.5million (14%) US adults have CKD2,4 About 1 in 3 people with diabetes and 1 in 5 people with high blood pressure have kidney disease.

Incidence

- There are approximately 360 new dialysis starts daily.
- 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.

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.

Cost of Illness/Financial Impact

- Medicare beneficiaries with CKD cost $87.2 billion in 2019.
- 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.
- 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 with those without CKD ($13,604).

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).
- 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.

Section 3: Regulatory Approval and Market Context

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

- The U.S. Food and Drug Administration (FDA) approved Farxiga on January 8, 2014
- 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)."
- 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."
- 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."
- On June 12, 2024, the FDA expanded Farxiga's diabetes indication to children ages 10 and above

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

- Farxiga is not in shortage

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

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.

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

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	***	***	***

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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

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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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

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			

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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

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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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

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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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

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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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

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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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

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

- 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

- WAC and AWP are redacted as proprietary information
- Exhibit 1 reflects pricing history for Farxiga.

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

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

- Net price and net sales are redacted as proprietary information

Factor 5.3: Information estimating manufacturer net price and net sales amounts of the prescription drug product under review

- 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.
  - Using this information, staff calculated the expected price concession, discount, and rebate for Medicare Plans in Maryland.
- Calculations the price concession, rebate, and discounts as a percentage of WAC are redacted as proprietary data
- Farxiga Medicare Maximum Fair Price (MFP) per Unit: $6.05

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

- Exhibit 2 contains information responsive to this element
- Documents are available to the Board, but not the public, as exhibits to the dossier.

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

- Exhibit 2 contains information responsive to this element
- Documents are available to the Board, but not the public, as exhibits to the dossier.

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

- WAC and AWP are redacted as proprietary information
- Exhibit 3_REDACTED FARXIGA Therapeutic Alternative Pricing_REDACTED (Excel Document)

Factor 6.1: NADAC, SAAC, ASP, and FSS at which each therapeutic alternative has been sold in the State- SGLT-2s

	Estimated NADAC	Estimated SAAC	Estimated FSS	Medicare Negotiated Price
Bexagliflozin (Brenzavvy)				
Canagliflozin (Invokana)	$6998.95	$7045.40	6656.99	
Dapagliflozin (Farxiga)	$6802.61	$6751.69	$5668.08	$2142
Empagliflozin (Jardiance)	$7134.66	$7068.73	$5284.47	$2364
Ertugliflozin (Steglatro)	$4178.80	$4182.46	$3818.75	

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

- The average price concession, discount, or rebate the manufacturer provides or is expected to provide redacted as proprietary information
- Exhibit 3_REDACTED FARXIGA Therapeutic Alternative Pricing_REDACTED (Excel Document)

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

- Exhibit 4 (Farxiga Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)

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

- Exhibit 5A Farxiga Summary of Cost Effectiveness Analyses
- General Findings
  - Increased costs compared to older antidiabetic drugs driven by higher drug prices and longer average life and offset by reduced other medical expenditures
  - Lower costs compared to GLP-1 drugs driven by lower drug prices, impact on other medical spending depends on sub-groups

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.

- Exhibit 5A Farxiga Summary of Cost Effectiveness Analyses and Exhibit 5B Farxiga Summary of Comparative Effectiveness Research
  - Increased effectiveness compared to older therapies
  - Compared across SGLT2 class
    - Varied results in different subgroups
  - SGLT2s vs GLP-1s, generally GLP-1s more effective, but SGLT2s more effective in certain subgroups

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

- Farxiga is not a generic drug product.

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

- 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

- Analyses 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:
  - Without controlling for other factors, researchers 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
  - Researchers found that increased copays were associated with more prescription days covered

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

- Staff identified two patient access programs for Farxiga. The first program is the FARXIGA Savings Card.
- A reasonable search failed to disclose publicly available information concerning the dollar value of Farxiga-specific patient access programs.

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

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	***	***	***	***

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

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

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

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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Blank spaces indicate that no data was provided.

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

- Claims data did not include demographic information for the vast majority of patients
  - Staff were unable to make a conclusive assessment
- Literature Review:
  - 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.
  - 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.
  - 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.
  - 19.4% of the low copay patients were Black, compared to 11.8% and 10.1% of the medium and high copay patients.
  - 20.7% ofthe low copay patients were Hispanic, compared to 15.7% and 13.4% of medium and high copay patients.
  - 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.
  - 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.

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

- This data was calculated based on the number of patients using an NDC multiplied by the annual WAC, which is redacted as proprietary information.

Section 8: Other Information

Factor 8.1: Input from the Public

- Staff received comments during the following comment periods:
  - INITIAL 60-DAY COMMENT PERIOD
    - 60-Day Written Comment: Notice Posted on 5/23/2024
  - WRITTEN COMMENT REQUEST
    - Written Comment Request: Posted 10/28/2024
  - JANUARY 2025 COMMENT SOLICITATION
    - Comment request posted and sent by listserv: January 15, 2025
  - PUBLIC COMMENTS IN CONJUNCTION WITH BOARD MEETINGS TO DATE
    - Board Meeting: January 27, 2025- Oral Comment
    - Board Meeting: March 24, 2025- Oral Comment
  - WRITTEN COMMENT REQUEST ON DRAFT DOSSIER
    - Written Comment Request: Posted 6/18/2025

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

- 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

- Board staff did not receive input from state and local government entities for the cost review study of Farxiga.

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

- Documents received in response to the request for information are available to the Board, but not the public, as Exhibit 2 to the dossier.
- 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 regarding authorized generics for Farxiga. Staff conducted additional analyses related to these comments.

MARYLAND
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