Farxiga (dapagliflozin)-
Dossier

Maryland Prescription Drug Affordability Board

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MARYLAND
Prescription Drug Affordability Board

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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]

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
50090-7057-00	Farxiga	Dapagliflozin	10 MG
55154-6933-08	Farxiga	Dapagliflozin	10 MG
63629-3253-01	Farxiga	Dapagliflozin	10 MG
66993-0457-30	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
50090-7056-00	Farxiga	Dapagliflozin	5 MG/1

[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

55154-6932-08	Farxiga	Dapagliflozin	5 MG/1
66993-0456-30	Farxiga	Dapagliflozin	5 MG/1

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.[3]

[3] In accordance with COMAR 14.01.04.05C(1)(g)(xvi), to the extent that some of these NDCs represent authorized generics, 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.

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)[4]

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

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

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

body to make sufficient (or any) insulin, such as in Type 1 DM, or resistance to insulin, as found in Type 2 DM.[5]

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.[6,7]

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, sulfonlyurea, etc).[3] The AACE similarly considers patient-specific factors and explicitly prefers SGLT2 inhibitors (or GLP1 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.[8,9]

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]

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[5] 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.

[6] 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.

[7] 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.

[8] 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.

[9] 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.

- This recommendation is independent of the patient's use of other medications (unless specifically unable to use with a particular medication) or 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 GLP1 agonists 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) or 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) or glycemic control.
- Equally weighted recommendation for GLP1 agonists 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 a first-line therapy 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. GLP-1 agonists have demonstrated similar outcomes and are an alternative first-line therapy. 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.[10]

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.[7,11]

Per ACC/AHA guidelines, SGLT2 inhibitors, specifically Jardiance and Farxiga, are recommended for all patients with symptomatic HFpEF.[7,12] 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, or Inpefa, are recommended for all symptomatic HF patients.

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.[13] Kidney function is measured through estimated glomerular filtration rate (eGFR) and the loss of protein in the form of albumin in the urine.

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[10] 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.

[11] 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.

[12] 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.

[13]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.

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 to treat 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 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/1.73m^2.

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 on various dimensions.

Type 2 Diabetes Mellitus (DM)

Prevalence

- In the United States (US), 38.4 million (11.6%) people have diagnosed or undiagnosed diabetes mellitus (DM).[14,15] 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.[16]

Incidence

- In 2021, 1.2 million adults were diagnosed with diabetes (rate of 5.9 per 1000 people).[11,12] More than 1 in 3 people, or 98 million adults, have prediabetes (38% of adult US population).[11,12] In individuals 65 years or older, 48.8% have prediabetes.[12]
- In Maryland, the age-adjusted rate of adults aged 18 years or older with newly diagnosed diabetes was 7.8 per 1000 in 2022.[13]

Disease Severity

- Diabetes is classified into categories including the following: Type 1 (immune destruction of insulin-producing pancreatic cells); Type 2 (non-immune progressive

[14] 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 . Available from: https://www.cdc.gov/diabetes/images/library/socialmedia/diabetesintheus_print.pdf.
[15] 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. Available from: https://www.cdc.gov/diabetes/php/data-research/index.html.
[16] United States Diabetes Surveillance System [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention. 2000. Available from: https://gis.cdc.gov/grasp/diabetes/diabetesatlas-surveillance.html#.

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.[17] 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.[18]

Comorbid Disease

- Based on 2017-2020 data for persons in the United States aged 18 years or older with diagnosed diabetes, 39.2% had chronic kidney disease (CKD, stages 1-4) and 15.7% had moderate to severe kidney disease (stages 3 and 4).[7]
- Based on global data from 2007-2017, 32.2% of persons with Type 2 Diabetes Mellitus have cardiovascular disease (CVD). In this report, 13% and 46% of the studies analyzed were from North America and Europe, respectively.[8]
- Type 2 Diabetes Mellitus contributes to the development and worsening of CKD and CVD. A 2018 study of >500,000 US adults with Type 2 Diabetes Mellitus found that <10% had no associated cardiovascular or kidney disorder. These disease states can initiate and perpetuate each other, leading to increased morbidity and mortality.[9]

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.[12]
- In Maryland, for calendar year 2021, total and per-patient medical costs attributable to diabetes were $6.506 billion and $11,909, respectively.[19]
- In the same jurisdiction and year, diabetes-attributable total and per-person productivity losses due to morbidity were $3.4 billion and $6,224, respectively.[16]

Morbidity

[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#.

[18] 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.

[19] 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.

- In 2020, approximately 16.8 million emergency department visits in the US were reported with diabetes as a 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).[12]

Table 1. Number and rate of hospitalizations per 1,000 adults aged 18 years or older with diabetes for selected causes, United States, 2019-2020[12]

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).[12]
- 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.[12]

Mortality

- Diabetes was the 8th leading cause of death in the US in 2021, based on 103,294 death certificates listing diabetes as an underlying cause (a rate of 31.1 per 100,000 people).[12] Including diabetes as a contributing cause of death, the rate increased to 120.3 per 100,000 people (399,401 death certificates).[12]
- 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.[13]

Heart Failure (HF)

Prevalence

- Based on National Health and Nutrition Examination Survey (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.[20]
- Within Maryland, the 2016 age adjusted prevalence of heart failure is approximately 1100 per 100,000 persons. Relative to other states, Maryland's prevalence is moderately elevated (prevalence range 700-1300 per 100,000 persons).[17,21]

Incidence

- A variation in incidence rates reported in studies is surmised to be due to differences in data sources, population demographics, 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).[17]

Disease Severity

- Heart failure severity is categorized by the AHA/ACC into stages A, B, C and D. The following table defines each stage.[18] Stages A & B represent those individuals without signs or symptoms of heart failure but either are at risk for or have pre-heart failure. Stages C & D represent individuals with symptomatic heart failure. Stage D represents more severe symptoms that interfere with activities of daily living.[22]

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[20] Bozkurt B, Ahmad T, Alexander KM, 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.

[21] 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.

[22] 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 3. Stages of HF[19]

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, the 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 approximately$244 for every US adult.[23]
- 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).[20]

Morbidity

- In 2019, there were 8,054,000 physician office visits in the US 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.[20]

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. Accordingly, mortality from HF is underestimated. The reported absolute

[23] 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 deaths with HF as an underlying cause of death was 85,855, whereas the total number of cardiovascular deaths was 928,741 deaths in the US by 2020. By including any mention of HF on a death certificate, HF was a contributing cause in 415,922 deaths in the US in 2020.[17]

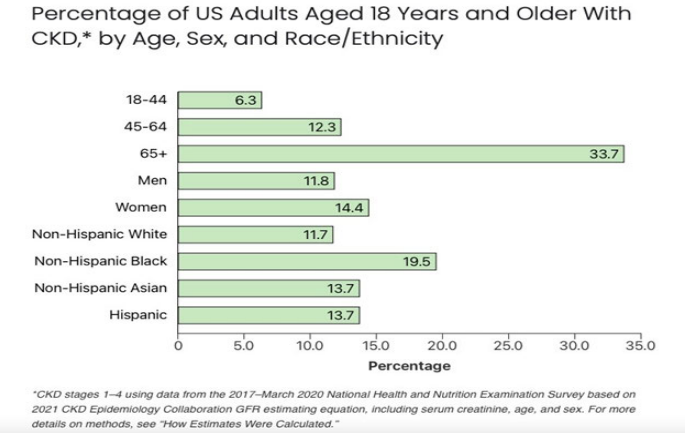
- In 2022, heart failure was mentioned on 457,212 death certificates (and responsible for 13.9% of all causes of death).[24]
- HF is associated with a loss of 15 years of median survival for adults aged 65–90 years of age compared with the general US population.[17]
- The 1-year HF mortality rate is approximately 30%, increasing to approximately 40% at 5 years.[25]

Chronic Kidney Disease (CKD)

Prevalence

- Based on data from 2017 through March 2020, 35.5 million US adults (14%) have CKD.[12,14] 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 and Older with CKD*, by Age, Sex and Race/Ethnicity[26]



[24] 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. Available from: https://www.cdc.gov/heart-disease/about/heart-failure.html.

[25] 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.

[26] 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. Available from: https://www.cdc.gov/kidney-disease/php/data-research/index.html.

Incidence

- There are approximately 360 new dialysis starts per day.[23]
- 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 living without treatment.[16]

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 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).[27]

Table 4. Percentage by eGFR and ACR, 2017-March, 2020[24]

Percentage | Number of Persons | Publications

(a) Percentage by eGFR and ACR, 2017-March, 2020

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

Cost of illness/Financial Impact

- Medicare beneficiaries with CKD cost $87.2 billion in 2019.[23]
- Medicare spending for beneficiaries with CKD (not including end-stage kidney disease) ages 66 or older was nearly $77 billion in 2021, representing 24.1% of Medicare spending in this age group.[28]

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[27] United States Renal Data System. 2024 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024. Available from: https://usrds-adr.niddk.nih.gov/2024/chronic-kidney-disease/3-morbidity-and-mortality-in-patients-with-ckd.

[28] 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

- 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).[25]

Table 5. Per person per year Medicare FFS Spending among older adults with CKD, by CKD stage overall and by patient characteristics, 2022[24]

	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

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)

Health and Human Services; 2023. Available from: https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

Figure 2. All-cause hospitalization rates in older adults, Medicare FFS, 2012-2022, by CKD status, adjusted for demographics and comorbidities[24]

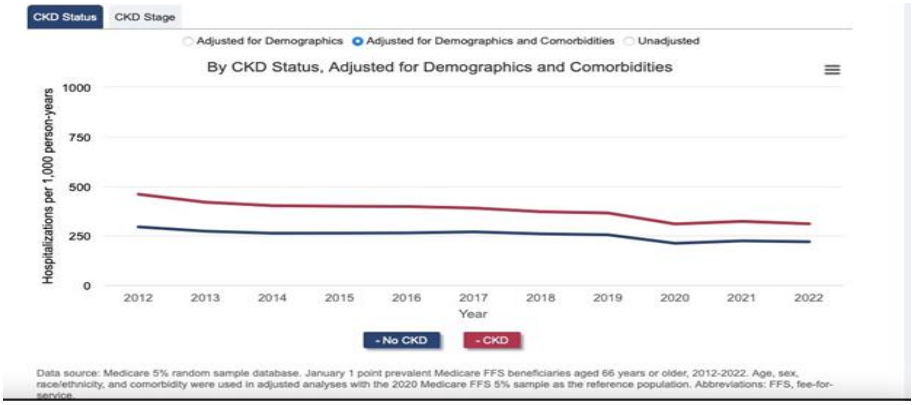
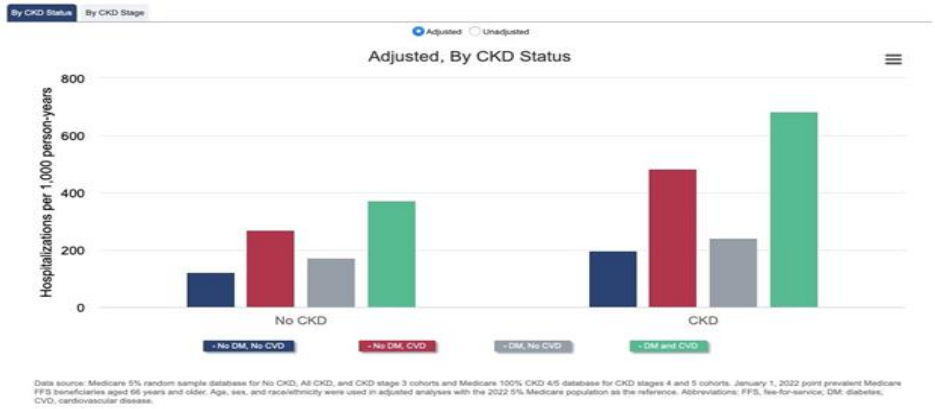


Figure 3. All-cause hospitalization rates in older adults, by presence of diabetes mellitus and cardiovascular disease, Medicare FFS, 2022, Adjusted by CKD Status[24]



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).[25]
- 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 person-years, respectively.[24]

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.[29] 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?"[30]

After receiving additional information, the FDA approved Farxiga in 2014. At the time of approval, Farxiga was the second SGLT-2 inhibitor approved.[31] 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."[32]

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

[29] Drugs@FDA Search
[30] http://web.archive.org/web/20161023221930/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM268726.pdf
[31] Drugs@FDA Search
[32] 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.[33]

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."[34]

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.[35]

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)."[36]

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."[37]

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."[38]

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[33] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/202293Orig1s000ltr.pdf
[34] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202293s018lbl.pdf
[35] https://www.astrazeneca.com/media-centre/press-releases/2019/update-on-us-regulatory-decision-for-farxiga-in-type-1-diabetes-15072019.html#
[36] https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293s020lbl.pdf
[37] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202293s024lbl.pdf
[38] 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.[39] This fulfilled a Pediatric Research Equity Act (PREA) requirement.[40] They have no outstanding PREA requirements.[41]

The FDA granted Farxiga Fast Track Designation in the US for heart failure following acute myocardial infarction.[42] The FDA granted Farxiga Breakthrough Therapy Designation for chronic kidney disease.[43] The FDA granted Farxiga Priority Review for the treatment of patients with chronic kidney disease.[44]

[39] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/202293s031lbl.pdf
[40] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/202293Orig1s031,205649Orig1s022ltr.pdf
[41] https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm
[42] 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#
[43] https://www.astrazeneca.com/media-centre/press-releases/2020/farxiga-granted-breakthrough-therapy-designation-in-us-for-chronic-kidney-disease.html#
[44] 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.[45]

[45] 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.[46] 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.

[46] "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 6. 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.[47] 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."[48]

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.[49] 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."[50]

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

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

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

[49] 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#

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

ingredient in Farxiga (dapagliflozin). Qternmet XR was approved on May 2, 2019.[51] 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."[52]

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.

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

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

Qtern

Table 7a. 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 7b. 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 8a. 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.

^^^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. 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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^^^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 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[53], the following tables provide the gross spending and number of patients by payor type.

[53] In accordance with COMAR 14.01.04.05C(1)(g)(xvi), to the extent that some of these NDCs represent authorized generics, 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").

Table 9a. 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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Blank spaces indicate that no data was provided.

Table 9b. 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/1	***	***	***

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Blank spaces indicate that no data was provided.

Table 9c. 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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Blank spaces indicate that no data was provided.

Table 9d. 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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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.[54]

[54] In accordance with COMAR 14.01.04.05C(1)(g)(xvi), to the extent that some of these NDCs represent authorized generics, 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").

Table 10a. 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 10b. 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 10c. 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 10d. 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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Blank spaces indicate that no data was provided.

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 for 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 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 11b. 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)	[redacted]	[redacted]	[redacted]	[redacted]
00003-1428-11 (10 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00310-6205-30 (5 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00310-6205-90 (5 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00310-6205-95 (5 MG)				
00310-6210-30 (10 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00310-6210-39 (10 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00310-6210-90 (10 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00310-6210-95 (10 MG)				
50090-3481-00 (10 MG)			[redacted]	[redacted]
50090-3482-00 (5 MG)			[redacted]	[redacted]
50090-7056-00 (5 MG/1)			[redacted]	[redacted]
50090-7057-00 (10 MG/1)			[redacted]	[redacted]

55154-6932-08 (5 MG/1)	[redacted]	[redacted]	[redacted]	[redacted]
55154-6933-08 (10 MG/1)	[redacted]	[redacted]	[redacted]	[redacted]
66993-0456-30 (5 MG/1)	[redacted]	[redacted]	[redacted]	[redacted]
66993-0457-30 (10 MG/1)	[redacted]	[redacted]	[redacted]	[redacted]

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Blank spaces indicate that no data was provided.

Table 11a. 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/1)						
50090-7057-00 (10 MG/1)						
55154-6932-08 (5 MG/1)						
55154-6933-08 (10 MG/1)						
66993-0456-30 (5 MG/1)	$11.17	$4,078.40			$12.55	$4,581.97
66993-0457-30 (10 MG/1)	$11.37	$4,149.78			$12.55	$4,581.97

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Exhibit 4 (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.

Table 12. Farxiga Net WAC and and Net Spending Estimates

Drug Information			Annual Price or Sales After SSR Application [redacted]			
National Drug Code	Strength	SSR Rebate	Est. WAC per Year	Commercial (2023) Estimated Net Spend [redacted]	State Local Govt Emp (2023) Estimated Net Spend	Medicare (2022) Estimated Net Spend
00310-6210-30	10 MG	[redacted]	[redacted]	[redacted]		
00310-6205-30	5 MG	[redacted]	[redacted]	[redacted]		
66993-0457-30	10 MG/1	[redacted]	[redacted]	[redacted]	[redacted]	
00310-6210-39	10 MG	[redacted]	[redacted]	[redacted]		
66993-0456-30	5 MG/1	[redacted]	[redacted]	***	***	
00310-6210-90	10 MG	[redacted]	[redacted]			
55154-6933-08	10 MG/1	[redacted]	[redacted]			
00003-1427-11	5 MG	[redacted]	[redacted]			
00310-6205-90	5 MG	[redacted]	[redacted]			
55154-6932-08	5 MG/1	[redacted]	[redacted]			
00003-1428-11	10 MG	[redacted]	[redacted]			

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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 13. 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	50090-7057-00	.		
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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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 5 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 5 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)) addresses 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)) addresses 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 1_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 1_REDACTED contains the information specified above for non-insulin therapeutic alternatives.

Sheet 2 of Exhibit1_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 Exhibit1_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 2 (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). 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. In total, staff reviewed ten articles with varying results. The results varied because the assumptions about the cost of Farxiga, the use of Farxiga for different indications, and the comparators also varied. The results of these studies are summarized below.

Studies Concerning Type 2 Diabetes

One study found that over one year, the total costs (medical and pharmacy) for dapagliflozin (Farxiga)[60] were $2,701 less than glucagon-like peptide-1 receptor agonists and $795 less than dipeptidyl peptidase-4 inhibitors. Dapagliflozin (Farxiga) had $1,848

[60] 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.

higher total costs compared to thiazolidinediones (a class of therapeutic alternatives) and $2,161 higher total cost than sulfonylureas (a class of therapeutic alternatives).[61]

A second study found that over a 30-year horizon, canagliflozin 300 mg saved $13,991 compared to dapagliflozin 10 mg as an add-on to metformin.[62]

Another study compared the use of empagliflozin as an add on to the standard of care to dapagliflozin as an add on to the standard of care for patients with type 2 diabetes and cardiovascular risk. It found that empagliflozin yielded $27,539 more in costs.[63]

Studies Concerning Heart Failure

A study found that compared to the standard of care for patients who have heart failure with reduced ejection fraction (HFrEF), dapagliflozin resulted in $38,212 in additional discounted lifetime costs. Discounting is the process of converting a value received in a future time period to an equivalent value received immediately. This is based on the idea that there is a time value of money so future money is not worth the same amount as present money.[64]

An additional study found that dapagliflozin was projected to add $42,800 in lifetime costs if added to guideline-directed medical therapy for heart failure with reduced ejection fraction.[65]

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[61] Chakravarty, A., Rastogi, M., Dhankhar, P., & Bell, K. F. (2018). Comparison of costs and outcomes of dapagliflozin with other glucose-lowering therapy classes added to metformin using a short-term cost-effectiveness model in the US setting. Journal of Medical Economics, 21(5), 497–509. https://doi.org/10.1080/13696998.2018.1434182

[62] Neslusan C, Teschemaker A, Willis M, Johansen P, Vo L. Cost-Effectiveness Analysis of Canagliflozin 300 mg Versus Dapagliflozin 10 mg Added to Metformin in Patients with Type 2 Diabetes in the United States. Diabetes Ther. 2018 Apr;9(2):565-581. doi: 10.1007/s13300-018-0371-y. Epub 2018 Feb 6. PMID: 29411292; PMCID: PMC6104269.

[63] Reifsnider OS, Kansal AR, Gandhi PK, Cragin L, Brand SB, Pfarr E, Fahrbach K, Ustyugova A. Cost-effectiveness of empagliflozin versus canagliflozin, dapagliflozin, or standard of care in patients with type 2 diabetes and established cardiovascular disease. BMJ Open Diabetes Res Care. 2021 May; 9(1):e001313. doi: 10.1136/bmjdrc-2020-001313. PMID: 33941549; PMCID: PMC8098979.

[64] Parizo JT, Goldhaber-Fiebert JD, Salomon JA, Khush KK, Spertus JA, Heidenreich PA, Sandhu AT. Cost-effectiveness of Dapagliflozin for Treatment of Patients With Heart Failure With Reduced Ejection Fraction. JAMA Cardiol. 2021 Aug 1;6(8):926-935. doi: 10.1001/jamacardio.2021.1437. PMID: 34037681; PMCID: PMC8156166.

[65] Isaza N, Calvachi P, Raber I, Liu CL, Bellows BK, Hernandez I, Shen C, Gavin MC, Garan AR, Kazi DS. Cost-effectiveness of Dapagliflozin for the Treatment of Heart

Another study found that adding an SGLT-2 inhibitor (empagliflozin or dapagliflozin) resulted in an increase in lifetime direct healthcare spending of $26,312 for patients with heart failure with preserved ejection fraction.[66]

According to another study, “Dapagliflozin-SoC [dapagliflozin in combination with the standard of care] cost more $5,524 more…than empagliflozin-SoC” for patients with heart failure with preserved ejection fraction.”[67]

Another study found that “the incremental expected lifetime cost of treating patients with dapagliflozin vs empagliflozin was $37,684.”[68]

Another study used pricing based on “Big-4” and federal supply schedule prices. The big four represents pricing available to certain federal agencies and the federal supply schedule price represents the price for the federal government generally, the guideline-directed medical therapy incurs $123,872 in costs, compared to $154,402 in costs if an SGLT2 is added to the guideline-directed medical therapy, $166,870 if an ARNi is added to the guideline-directed medical therapy, and $204,139 if both an ANRi and an SGLT2 are added to guideline-directed medical therapy.[69]

Failure With Reduced Ejection Fraction. JAMA Netw Open. 2021 Jul 1;4(7):e2114501. doi: 10.1001/jamanetworkopen.2021.14501. PMID: 34313742; PMCID: PMC8317009.

[66] Cohen LP, Isaza N, Hernandez I, Lewis GD, Ho JE, Fonarow GC, Kazi DS, Bellows BK. Cost-effectiveness of Sodium-Glucose Cotransporter-2 Inhibitors for the Treatment of Heart Failure With Preserved Ejection Fraction. JAMA Cardiol. 2023 May 1;8(5):419-428. doi: 10.1001/jamacardio.2023.0077. PMID: 36870047; PMCID: PMC9985815.

[67] Nguyen BN, Mital S, Bugden S, Nguyen HV. Cost-effectiveness of dapagliflozin and empagliflozin for treatment of heart failure with reduced ejection fraction. Int J Cardiol. 2023 Apr 1;376:83-89. doi: 10.1016/j.ijcard.2023.01.080. Epub 2023 Feb 2. PMID: 36736672.

[68] Nechi RN, Rane A, Karaye RM, Ndikumukiza C, Alsahali S, Jatau AI, Zoni CR, Alanzi A, Karaye IM, Yunusa I. Cost-Effectiveness of Dapagliflozin vs Empagliflozin for Treating Heart Failure With Reduced Ejection Fraction in the United States. Clin Ther. 2023 Jul;45(7):627-632. doi: 10.1016/j.clinthera.2023.05.002. Epub 2023 Jun 1. PMID: 37270374.

[69] Yan BW, Spahillari A, Pandya A. Cost-Effectiveness of Quadruple Therapy in Management of Heart Failure With Reduced Ejection Fraction in the United States. Circ Cardiovasc Qual Outcomes. 2023 Jun;16(6):e009793. doi: 10.1161/CIRCOUTCOMES.122.009793. Epub 2023 Jun 6. PMID: 37278232.

Studies Concerning Chronic Kidney Disease

In one study, dapagliflozin plus standard care increased lifetime costs from $245,900 to $324,8900 for patients with non-diabetic chronic kidney disease.[70]

For diabetic nephropathy, another study found that "the standard of care was the less costly treatment with a lifetime cost of $106,150.25 as compared with dapagliflozin, which costs $110,689.25."[71]

[70] Tisdale RL, Cusick MM, Aluri KZ, Handley TJ, Joyner AKC, Salomon JA, Chertow GM, Goldhaber-Fiebert JD, Owens DK. Cost-Effectiveness of Dapagliflozin for Non-diabetic Chronic Kidney Disease. J Gen Intern Med. 2022 Oct;37(13):3380-3387. doi: 10.1007/s11606-021-07311-5. Epub 2022 Feb 8. PMID: 35137296; PMCID: PMC9551016.

[71] Abegaz TM, Diaby V, Sherbeny F, Ali AA. Cost Effectiveness of Dapagliflozin Added to Standard of Care for the Management of Diabetic Nephropathy in the USA. Clin Drug Investig. 2022 Jun;42(6):501-511. doi: 10.1007/s40261-022-01160-8. Epub 2022 May 25. PMID: 35614298.

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; and 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.

Summary of Cost-Effectiveness Literature

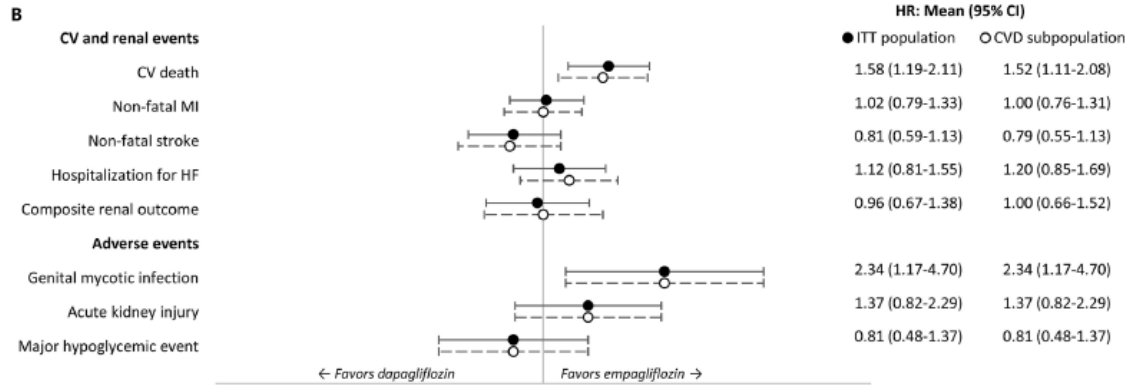
Studies Concerning Type 2 Diabetes

One study compared dapagliflozin to GLP-1 receptor agonists, dipeptidyl peptidase-4 inhibitors, sulphonylureas, and thiazolidinediones. In particular, the study examined the impact of using dapagliflozin compared to those other therapies on A1c (a measure of blood glucose levels), weight, systolic blood pressure, hypoglycemia rate (hypoglycemia patient proportion per patient-year). The study found that use of dapagliflozin resulted in 0.41% higher A1c, 0.5 kg lower weight, and 1.48 mmHg lower systolic blood pressure compared to GLP-1 receptor agonists. It also found that use of dapagliflozin resulted in 0.11% lower A1c, 2.6 kg lower weight, 2.20 mmHg lower systolic blood pressure, and 1.29 percentage points lower hypoglycemia rate compared to dipeptidyl peptidase-4 inhibitors. According to the study, the use of dapagliflozin resulted in 0.02% lower A1c, 4.8 kg lower weight, and 1.29 percentage points lower hypoglycemia rate compared to thiazolidinediones. The use of dapagliflozin resulted in 0.00% lower A1c, 4.7 kg lower

weight, 5.10 mmHg lower systolic blood pressure, and 25.65 percentage points lower hypoglycemia rate compared to dipeptidyl peptidase-4 inhibitors.[72]

A second study found that over a 30-year horizon, compare dapagliflozin with canagliflozin 300 mg in terms of A1c, systolic blood pressure, body mass index, total cholesterol levels, LDL cholesterol, HDL cholesterol, triglycerides, and adverse events. The study found that canagliflozin reduced A1c by 0.79 and dapagliflozin reduced A1c by 0.41. Canagliflozin reduced systolic blood pressure by 5.4 mmHg and dapagliflozin reduced it by 3.7 mmHg. Canagliflozin reduced BMI by 0.8 and dapagliflozin reduced BMI by 0.7. [73]

Another examined the effectiveness of empagliflozin compared to dapagliflozin in patients with cardiovascular disease and type 2 diabetes. The study focused on cardiovascular outcomes. The figure below from the study summarizes the results.[74]



[72] Chakravarty, A., Rastogi, M., Dhankhar, P., & Bell, K. F. (2018). Comparison of costs and outcomes of dapagliflozin with other glucose-lowering therapy classes added to metformin using a short-term cost-effectiveness model in the US setting. Journal of Medical Economics, 21(5), 497–509. https://doi.org/10.1080/13696998.2018.1434182

[73] Neslusan C, Teschemaker A, Willis M, Johansen P, Vo L. Cost-Effectiveness Analysis of Canagliflozin 300 mg Versus Dapagliflozin 10 mg Added to Metformin in Patients with Type 2 Diabetes in the United States. Diabetes Ther. 2018 Apr;9(2):565-581. doi: 10.1007/s13300-018-0371-y. Epub 2018 Feb 6. PMID: 29411292; PMCID: PMC6104269.

[74] Reifsnider OS, Kansal AR, Gandhi PK, Cragin L, Brand SB, Pfarr E, Fahrbach K, Ustyugova A. Cost-effectiveness of empagliflozin versus canagliflozin, dapagliflozin, or standard of care in patients with type 2 diabetes and established cardiovascular disease. BMJ Open Diabetes Res Care. 2021 May;9(1):e001313. doi: 10.1136/bmjdrc-2020-001313. PMID: 33941549; PMCID: PMC8098979.

Studies Concerning Heart Failure

A study found that compared to the standard of care for patients who have heart failure with reduced ejection fraction (HFrEF), dapagliflozin produced a monthly heart failure rate ratio of 0.71 and a cardiovascular death of 0.83.[75]

An additional study found that dapagliflozin had hazard ratios of 0.63 for patients without diabetes and 0.76 for patients with diabetes for heart failure hospitalizations compared to guideline-directed medical therapy. They also found hazard ratios of 0.88 and 0.78 for death from any cause.[76]

Another study found that adding an SGLT-2 inhibitor (empagliflozin or dapagliflozin) had hazard ratios of 0.74 and 0.88 for hospitalization and cardiovascular death compared to standard of care.[77]

According to another study, dapagliflozin had a hazard ratio of heart failure hospitalization of 0.70 while empagliflozin had a hazard ration of 0.69 compared to standard of care. Meanwhile the two drugs had hazard ratios of 0.82 and 0.92 for cardiovascular death."[78]

Another study found that empagliflozin produced 3.395 quality adjusted life-years (QALYs) while dapagliflozin produced 4.776 QALYs. QALYs are a measure of disease burden that attempt to aggregate the quality and quantity of life in a single measure."[79]

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[75] Parizo JT, Goldhaber-Fiebert JD, Salomon JA, Khush KK, Spertus JA, Heidenreich PA, Sandhu AT. Cost-effectiveness of Dapagliflozin for Treatment of Patients With Heart Failure With Reduced Ejection Fraction. JAMA Cardiol. 2021 Aug 1;6(8):926-935. doi: 10.1001/jamacardio.2021.1437. PMID: 34037681; PMCID: PMC8156166.

[76] Isaza N, Calvachi P, Raber I, Liu CL, Bellows BK, Hernandez I, Shen C, Gavin MC, Garan AR, Kazi DS. Cost-effectiveness of Dapagliflozin for the Treatment of Heart Failure With Reduced Ejection Fraction. JAMA Netw Open. 2021 Jul 1;4(7):e2114501. doi: 10.1001/jamanetworkopen.2021.14501. PMID: 34313742; PMCID: PMC8317009.

[77] Cohen LP, Isaza N, Hernandez I, Lewis GD, Ho JE, Fonarow GC, Kazi DS, Bellows BK. Cost-effectiveness of Sodium-Glucose Cotransporter-2 Inhibitors for the Treatment of Heart Failure With Preserved Ejection Fraction. JAMA Cardiol. 2023 May 1;8(5):419-428. doi: 10.1001/jamacardio.2023.0077. PMID: 36870047; PMCID: PMC9985815.

[78] Nguyen BN, Mital S, Bugden S, Nguyen HV. Cost-effectiveness of dapagliflozin and empagliflozin for treatment of heart failure with reduced ejection fraction. Int J Cardiol. 2023 Apr 1;376:83-89. doi: 10.1016/j.ijcard.2023.01.080. Epub 2023 Feb 2. PMID: 36736672.

[79] Nechi RN, Rane A, Karaye RM, Ndikumukiza C, Alsahali S, Jatau AI, Zoni CR, Alanzi A, Karaye IM, Yunusa I. Cost-Effectiveness of Dapagliflozin vs Empagliflozin for Treating Heart Failure With Reduced Ejection Fraction in the United States. Clin

The last study found that lifetime expected heart failure admissions were 2.45 for guideline-directed medical therapy, 1.86 when an SGLT2 is added, 2.17 when an ARNI (angiotensin receptor/neprilysin inhibitor which is a combination of sacubitril and valsartan) is added, and 1.64 when both an SGLT2 and ARNI are added. In addition, life expectancy was 9.25 years under guideline-directed medical therapy, 10.12 when an SGLT2 is added, 10.35 when an ARNI added, and 11.26 when both are added.[80]

Studies Concerning Chronic Kidney Disease

In one study, dapagliflozin had a hazard ratio or 0.51 for chronic kidney disease progression and 0.52 for all-cause mortality.[81]

For diabetic nephropathy, adding dapagliflozin to standard of care produced an additional 0.2 quality adjusted life years on average."[82]

Ther. 2023 Jul;45(7):627-632. doi: 10.1016/j.clinthera.2023.05.002. Epub 2023 Jun 1. PMID: 37270374.

[80] Yan BW, Spahillari A, Pandya A. Cost-Effectiveness of Quadruple Therapy in Management of Heart Failure With Reduced Ejection Fraction in the United States. Circ Cardiovasc Qual Outcomes. 2023 Jun;16(6):e009793. doi: 10.1161/CIRCOUTCOMES.122.009793. Epub 2023 Jun 6. PMID: 37278232.

[81] Tisdale RL, Cusick MM, Aluri KZ, Handley TJ, Joyner AKC, Salomon JA, Chertow GM, Goldhaber-Fiebert JD, Owens DK. Cost-Effectiveness of Dapagliflozin for Non-diabetic Chronic Kidney Disease. J Gen Intern Med. 2022 Oct;37(13):3380-3387. doi: 10.1007/s11606-021-07311-5. Epub 2022 Feb 8. PMID: 35137296; PMCID: PMC9551016.

[82] Abegaz TM, Diaby V, Sherbeny F, Ali AA. Cost Effectiveness of Dapagliflozin Added to Standard of Care for the Management of Diabetic Nephropathy in the USA. Clin Drug Investig. 2022 Jun;42(6):501-511. doi: 10.1007/s40261-022-01160-8. Epub 2022 May 25. PMID: 35614298.

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)
Data Sources: MCDB

The following analysis estimates the impact on patient access resulting from the cost of 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.

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
β_4 = Interaction Term – Continuous User*Avg Copay
β_5 = Interaction Term – Continuous User*Avg Coinsurance

Results

Data Characteristics

Table 14. 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 15. 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 16. 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 17. 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 18. Model Statistics.			
Root MSE	0.28072	**R-Square**	0.0106
Dependent Mean	0.73214	**Adj R-Sq**	0.0101
Coeff Var	38.34276		

Table 9. 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.

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.[83] 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

[83] 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.[84]

The second program is called the "AZ&Me Prescription Savings Program."[85] 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.

[84] 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).
[85] 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 and Medicaid.

Table 20. 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/1	$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/1	***	***	***	***

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/1	$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/1	***	***	***	***

*** 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.

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 21. 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/1	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/1	***	***	***

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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 22. 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/1	$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/1	***	***	***	***	***	***			

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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.[86] 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.

[86] 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

Because 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 is 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.[87]

[87] The selection of priority populations informed by AHRQ's definitions. https://www.ahrq.gov/priority-populations/index.html (last checked April 30, 2025).

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 23. 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/1	[redacted]
00310-6210-39	Farxiga	10 MG	
00310-6210-30	Farxiga	10 MG	
00310-6205-30	Farxiga	5 MG	
66993-0456-30	Farxiga	5 MG/1	***

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected State Local Gov. Emp. (2023) Gross Spending
66993-0457-30	Farxiga	10 MG/1	[redacted]
00310-6210-39	Farxiga	10 MG	
00310-6210-30	Farxiga	10 MG	
00310-6205-30	Farxiga	5 MG	
66993-0456-30	Farxiga	5 MG/1	***

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected Medicaid (2023) Gross Spending
66993-0457-30	Farxiga	10 MG/1	
00310-6210-39	Farxiga	10 MG	
00310-6210-30	Farxiga	10 MG	[redacted]
00310-6205-30	Farxiga	5 MG	
66993-0456-30	Farxiga	5 MG/1	

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected Medicare (2023) Gross Spending
66993-0457-30	Farxiga	10 MG/1	
00310-6210-39	Farxiga	10 MG	
00310-6210-30	Farxiga	10 MG	[redacted]
00310-6205-30	Farxiga	5 MG	
66993-0456-30	Farxiga	5 MG/1	

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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 3A.

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 3B and are also available on the Board website.[88]

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

[88] 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 listserve 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[89] and in Exhibit 3C.

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

[89] 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 5 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.

Table of Exhibits

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 5 are, therefore, not available to the public.