Jardiance (empaglifozin)-Dossier

Maryland Prescription Drug Affordability Board

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MARYLAND
Prescription Drug Affordability Board

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Cost Review Study Dossier - Jardiance (empaglifozin)

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 Jardiance (proprietary name) and empaglifozin (non-proprietary name).[1] The NDC-11 codes were identified by staff through searches on the RxNorm database.[2]

Table 1. NDC List

National Drug Code	Proprietary Name	Non-Proprietary Name	Dosage-Strength
00597-0152-07	Jardiance	Empagliflozin	10 MG
00597-0152-30	Jardiance	Empagliflozin	10 MG
00597-0152-37	Jardiance	Empagliflozin	10 MG
00597-0152-90	Jardiance	Empagliflozin	10 MG
50090-4492-00	Jardiance	Empagliflozin	10 MG
50090-4492-01	Jardiance	Empagliflozin	10 MG
00597-0152-70	Jardiance	Empagliflozin	10 MG/1
70518-1986-00	Jardiance	Empagliflozin	10 MG/1
50090-6452-00	Jardiance	Empagliflozin	10 MG/1
55154-0411-08	Jardiance	Empagliflozin	10 MG/1
00597-0153-07	Jardiance	Empagliflozin	25 MG
00597-0153-30	Jardiance	Empagliflozin	25 MG
00597-0153-37	Jardiance	Empagliflozin	25 MG
00597-0153-90	Jardiance	Empagliflozin	25 MG
50090-4384-00	Jardiance	Empagliflozin	25 MG
50090-4384-01	Jardiance	Empagliflozin	25 MG
71610-0177-09	Jardiance	Empagliflozin	25 MG
71610-0177-15	Jardiance	Empagliflozin	25 MG
71610-0177-30	Jardiance	Empagliflozin	25 MG
71610-0177-42	Jardiance	Empagliflozin	25 MG
71610-0177-45	Jardiance	Empagliflozin	25 MG
00597-0153-70	Jardiance	Empagliflozin	25 MG/1
70518-2447-00	Jardiance	Empagliflozin	25 MG/1
50090-6457-00	Jardiance	Empagliflozin	25 MG/1
55154-0412-08	Jardiance	Empagliflozin	25 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 Jardiance is referred to as empagliflozin.
[2] https://www.nlm.nih.gov/research/umls/rxnorm/index.html

Section 2: Clinical Information

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

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

Table 2. Jardiance (empagliflozin): FDA approved indications and associated dosing regimen(s)[3]

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.	10mg (1 tablet) by mouth once daily in the morning with or without food 25mg (1 tablet) by mouth once daily in the morning with or without food, if further glycemic control is needed Not recommended for eGFR < 30 mL/min/1.73 m2
To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.	10mg (1 tablet) by mouth once daily in the morning with or without food No renal adjustment needed for reduced renal function
To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.	10mg (1 tablet) by mouth once daily in the morning with or without food No renal adjustment needed for reduced renal function
To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression	10mg (1 tablet) by mouth once daily in the morning with or without food No renal adjustment needed for reduced renal function

[3] Jardiance. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc.; 2023 Sept. Package Insert. NDC 0597-0152-30.

Standard Medical Practice Recommendations

Jardiance (empagliflozin) Place in Therapy for Diabetes Mellitus Type 2

Diabetes mellitus (DM) describes a group of chronic metabolic disorders of blood sugar, where the body both underuses and overproduces sugar resulting in high blood sugar. Underuse of blood sugar may be caused by either an inability of the body to make sufficient (or any) insulin, such as in Type 1 DM, or resistance to insulin as found in Type 2 DM.[4]

Jardiance, along with other medications in the SGLT2 inhibitor class, are recommended by the American Diabetes Association (ADA) and the American Association of Clinical Endocrinology (AACE) as one of the seven medication class options which may be used to lower blood sugar in *patients with Type 2 DM*.[5,6] 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 sugar, dosing frequency, etc. For treatment of glycemic control only, use of Jardiance, is equal to other therapeutic options indicated for Type 2 DM (such as insulin, metformin, GLP-1, sulfonlyurea, etc).[7] The AACE similarly considers patient specific factors and explicitly prefers SGLT2i (or GLP1 agonists) for patients with overweight or obesity or at risk of low blood sugar.[8] These guideline recommendations are in line with other major society guidelines, including the American College of

[4] 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.
[5] American Diabetes Association Professional Practice Committee; 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2025. Diabetes Care January 2025; 48 (Supplement_1): S181–S206. https://doi.org/10.2337/dc25-S009.
[6] 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.
[7] American Diabetes Association Professional Practice Committee; 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2025. Diabetes Care 1 January 2025; 48 (Supplement_1): S181–S206. https://doi.org/10.2337/dc25-S009.
[8] Samson, Susan L. et al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update. Endocrine Practice, Volume 29, Issue 5, 305 – 340.

Physicians and the National Kidney Foundation Kidney Disease Improving Global Outcomes.[9,10]

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, high cholesterol), the ADA and AACE recommend the use of SGLT2 inhibitors with proven benefit (Jardiance or Invokana [canagliflozin]) as first line therapy.[11,12]

- 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 [dulaglutide], Victoza [liraglutide], Ozempic [semaglutide]).[13],[14]

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 sugars and reduction of HF-related symptoms as first line therapy (Farxiga, Jardiance, Invokana [canagliflozin] or Steglatro [ertugliflozin]).[15],[16]

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

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

[11] 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.

[12] 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.

[13] 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.

[14] 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.

[15] 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.

[16] 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.

- 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 sugars and slowing progression of CKD (Farxiga, Jardiance, Invokana [canagliflozin]) 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 [dulaglutide], Victoza [liraglutide], Ozempic [semaglutide]).[17],[18]

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

Jardiance (empagliflozin) Place in Therapy for Heart Failure

Heart failure (HF) is a complex, symptomatic, 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 and HFpEF. HFrEF (Heart Failure with Reduced Ejection Fraction) occurs when the heart muscle is weak and HFpEF (Heart Failure with Preserved Ejection Fraction) occurs when the heart muscle is stiff. Guideline medication recommendations are different for HFrEF vs. HFpEF.[19]

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[17] 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.
[18] 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.
[19] 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

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.[20,21]

Per ACC/AHA guidelines, SGLT2 inhibitors, specifically Jardiance, are recommended for all patients with symptomatic HFpEF.[22,23] Sotagliflozin, while mentioned due to clinical trial benefits, was not recommended as it was not FDA approved at the time of the publication date. It is now FDA approved and available for use.

Clinical use in HF Takeaway: SGLT2 inhibitors, specifically Jardiance, Farxiga, or Inpefa (sotagliflozin), are recommended to be taken by all symptomatic HF patients.

Jardiance® (empagliflozin) Place in Therapy for Chronic Kidney Disease

Chronic Kidney Disease (CKD) encompasses abnormalities of kidney function or structure present for at least 3 months. This carries health implications as the kidneys are unable to filter blood as well as they should.[24] Kidney function is measured through

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Guidelines. JACC. 2022 May, 79 (17) e263–e421. https://doi.org/10.1016/j.jacc.2021.12.012.

[20] 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.

[21] Maddox TM, Januzzi JL Jr, Allen LA, Breathett K, Brouse S, Butler J, Davis LL, Fonarow GC, Ibrahim NE, Lindenfeld J, Masoudi FA, Motiwala SR, Oliveros E, Walsh MN, Wasserman A, Yancy CW, Youmans QR. 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.

[22] 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.

[23] Kittleson MM, Panjrath GS, Amancherla K, Davis LL, Deswal A, Dixon DL, Januzzi JL Jr, Yancy CW. 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.

[24] 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.

estimated glomerular filtration rate (eGFR) and the loss of protein in the form of albumin in the urine.

The Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend SGLT2 inhibitors for all adult patients with (a) 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.[25]

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.[26]

The KDIGO guidelines do not recommend or specify any particular drug within the SGLT 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 (sotagliflozin) and Invokana (canagliflozin).[27]

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

[25] 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.

[26] 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.

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

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

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

Jardiance 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 diagnoses or undiagnosed diabetes mellitus (DM).[28,29] Type 2 DM accounts for 90-95% of all diagnosed cases of diabetes.[28]
- In Maryland, the total age-adjusted percentage of adults aged 18 years or older with diagnosed diabetes was 10.5% in 2022.[30]

Incidence

- In 2021, 1.2 million adults were diagnosed with diabetes (rate of 5.9 per 1000 people).[28, 29] Worth noting, 98 million adults, more than 1 in 3 people, have prediabetes (38% of adult US population).[28,29] In individuals 65 years or older, 48.8% have prediabetes.[29]
- In Maryland, the age-adjusted rate of adults aged 18 years or older with newly diagnosed diabetes was 7.8 per 1000 in 2022.[30]

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

Disease Severity

- Diabetes is classified into categories, including Type 1 (immune destruction of insulin producing pancreatic cells), Type 2 (non-immune progressive loss of insulin secretion, frequently with an inability of the body to use available insulin), gestational (diagnosed in 2nd or 3rd trimester of pregnancy and not present pre-pregnancy) and other causes.[31] 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.[32]

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.[28]
- In Maryland in 2021, total and per patient medical costs attributable to diabetes were $6.506 billion and $11,909, respectively.[33]
    - In Maryland in 2021, diabetes-attributable total and per-person productivity losses due to morbidity were $3.4 billion and $6,224, respectively.[33]

Morbidity

- In 2020, about 16.8 million emergency department visits were reported with diabetes as any listed diagnosis among adults aged 18 years or older. Of these, 267,000 were for hyperglycemic crisis (11.4 per 1,000 adults with diabetes) and 202,000 were for hypoglycemia (8.6 per 1,000 adults with diabetes).[29]

[31] 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.
[32] 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.
[33] A. Khavjou, Olga; Sun, Minglu; R. D'Angelo, Sophia; J. Neuwahl, Simon; J. Hoerger, Thomas; Cho, Pyone; et al. (2024). Economic Costs Attributed to Diagnosed Diabetes in Each US State and the District of Columbia, 2021. American Diabetes Association. Figure. https://doi.org/10.2337/figshare.26351743.v1.

Table 3. Number and rate of hospitalizations per 1,000 adults aged 18 years or older with diabetes for selected causes, United States, 2019-2020[29]

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).[29]
- 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.[29]

Mortality

- Diabetes was the 8th leading cause of death in the US in 2021, based on 103,294 death certificates with diabetes as underlying cause (rate of 31.1 per 100,000 people).[29] Including diabetes as a contributing cause of death, the rate increases to 120.3 per 100,000 people (399,401 death certificates).[29]
- 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.[30]

Heart Failure (HF)

Prevalence

- The overall population rate of heart failure is 1.9-2.8%. Based on NHANES 2017-2020, approximately 6.7 million US adults have HF. Prevalence progressively increases with each decade of life; individuals over age 65 have a 4-fold higher prevalence of HF (8-9.1%) vs. those under 65 years.[34]
- Within Maryland, the 2016 age adjusted prevalence of heart failure is approximately 1100 per 100,000 persons. Relative to other states, MD prevalence is moderately elevated (prevalence range 700-1300 per 100,000 persons).[35,36]

Incidence

- A variation in incidence rates reported in studies is surmised to be due to differences in data sources, population demographics and composition, HF ascertainment methodology, and periodic differences. The inclusion of HFpEF also influences results as it becomes the dominant phenotype, attributed to increasing prevalence of underlying risk factors for HF (including diabetes and obesity).[35]

Disease Severity

- Heart failure severity is categorized into stages A, B, C and D by the AHA/ACC. The following table defines each stage.[36] Stages A & B represent those individuals without signs or symptoms of heart failure but either at risk for or with pre-heart failure. Stages C & D represent individuals with symptomatic heart failure, Stage D representing more severe symptoms interfering with activities of daily living.[37]

[34]Bozkurt B, Ahmad T, et.al. WRITING COMMITTEE MEMBERS. HF STATS 2024: Heart Failure Epidemiology and Outcomes Statistics An Updated 2024 Report from the Heart Failure Society of America. J Card Fail. 2025 Jan;31(1):66-116. doi: 10.1016/j.cardfail.2024.07.001. Epub 2024 Sep 24.

[35] Bozkurt B, Ahmad T. et. al. Writing Committee Members. Heart Failure Epidemiology and Outcomes Statistics: A Report of the Heart Failure Society of America. J Card Fail. 2023 Oct;29(10):1412-1451. https://doi.org/10.1016/j.cardfail.2023.07.006.

[36] 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.

[37] Heidenreich PA, Bozkurt B, et.al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145:e895–e1032. https://doi.org/10.1161/CIR.0000000000001063.

Table 4. Stages of HF[23]

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

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

Cost of illness/Financial Impact

- In 2012, total cost for HF was estimated to be $30.7 billion (2010 dollars), of which more than two-thirds was attributable to direct medical costs. Projections suggest that by 2030 the total cost of HF will increase by 127% to $69.8 billion, amounting to ~$244 for every US adult.[38]
- 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).[38]

Morbidity

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

[38] 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.

Mortality

- One-third of all cardiovascular deaths are usually attributable to HF, however coding guidelines consider HF as a mediator rather than the underlying cause of death. Therefore, mortality from HF is underestimated. The reported absolute number of deaths with HF as an underlying cause of death was 85,855, whereas the total number of cardiovascular deaths were 928,741 deaths in the US by 2020. By including any mention of HF on death certificates, HF was a contributing cause in 415,922 deaths in the US in 2020.[35]
- In 2022, heart failure was mentioned on 457,212 death certificates (and responsible for 13.9% of all causes of death).[39]
- 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.[35]
- The 1-year HF mortality rate is approximately 30%, increasing to approximately 40% at 5 years.[40]

Chronic Kidney Disease (CKD)

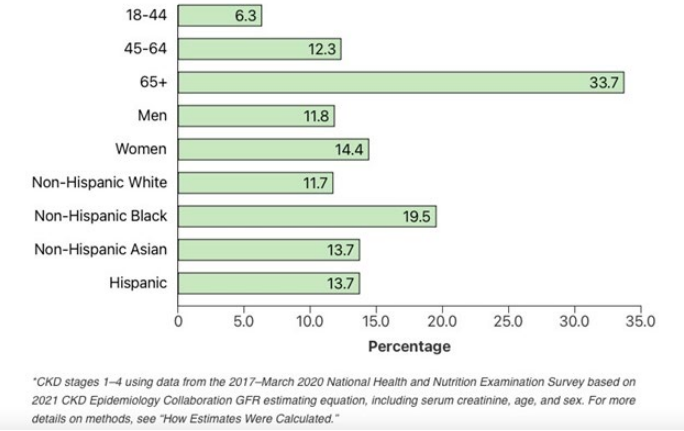
Prevalence

- Based on data from 2017 - March 2020, 35.5million (14%) US adults have CKD[29,31] About 1 in 3 people with diabetes and 1 in 5 people with high blood pressure have kidney disease.[29]

[39] Centers for Disease Control and Prevention. About Heart Failure [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2024 [cited 2025 Jan 4]. Available from: https://www.cdc.gov/heart-disease/about/heart-failure.html.

[40] 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.

Figure 1. Percentage of US Adults Aged 18 years and Older with CKD*, by Age, Sex and Race/Ethnicity[41]



Incidence

- There are approximately 360 new dialysis starts daily.[41]
- Incidence rates are not available for new diagnoses of CKD, however it is estimated that 1 in 3 US adults is at risk for CKD. This estimate is based on the prevalence of diabetes, hypertension (high blood pressure) and obesity in the population and without treatment.[42]

Disease Severity

- CKD severity is based on estimated glomerular filtration rate (eGFR), a calculation to estimate how well an individual's kidneys filter blood, and albumin to creatinine ratio (ACR), a measure of protein found in the urine. Lower eGFR values and higher albuminuria levels (ACR) correspond to reduced kidney function. In the following table, eGFR categories G1-G5, are equivalent to Stages 1-5 in subsequent table(s).[42]

[41] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2023 [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2023 [cited 2025 Jan 2]. Available from: https://www.cdc.gov/kidney-disease/php/data-research/index.html.
[42] National Kidney Foundation. Kidney Disease: Fact Sheet, Fast Facts 2024 update [Internet]. New York, NY: National Kidney Foundation; 2025 [cited 2025 Jan 4]. Available from: https://www.kidney.org/about/kidney-disease-fact-sheet.

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

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

Cost of illness/Financial Impact

- Medicare beneficiaries with CKD cost $87.2 billion in 2019.[41]
- Medicare spending for beneficiaries with CKD (not including ESKD) ages 66 or older was nearly $77 billion in 2021, representing 24.1% of Medicare spending in this age group.[43]
- 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).[43]

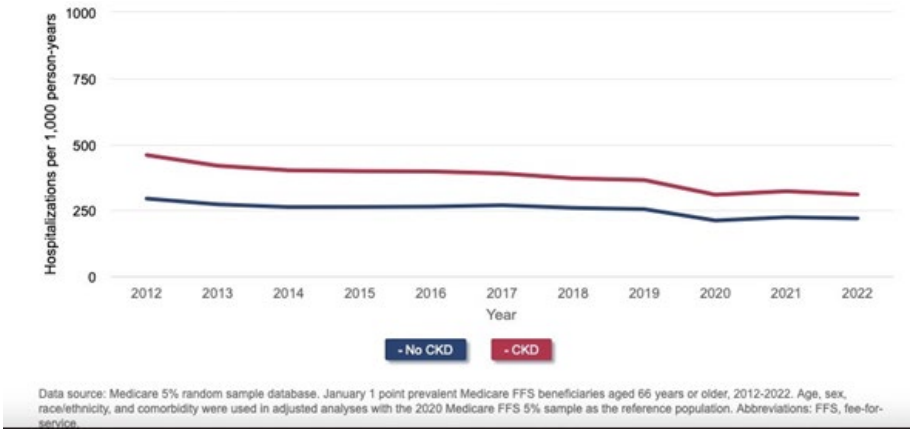
[43] National Institute of Diabetes and Digestive and Kidney Diseases. Kidney Disease Statistics for the United States [Internet]. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, US Department of Health and Human Services; 2023 [cited 2025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

Table 6. Per person per year Medicare FFS Spending among older adults with CKD, by CKD stage overall and by patient characteristics, 2022[42]

	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

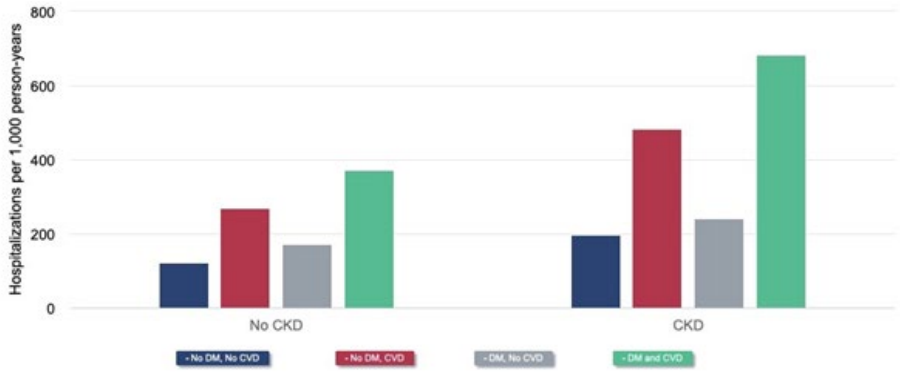
Data source: Medicare 5% FFS sample. Point prevalent individuals aged ≥66 years on January 1, 2022 with CKD and Medicare Parts A, B, & D coverage in 2021 (ESRD excluded)

Figure 2. All-cause hospitalization rates in older adults, Medicare FFS, 2012-2022, by CKD status, adjusted for demographics and comobidities[42]



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

Figure 3. All-cause hospitalization rates in older adults, by presence of diabetes mellitus and cardiovascular disease, Medicare FFS, 2022, Adjusted by CKD Status[42]



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

Mortality

- In 2021, the demographic-adjusted mortality rate was more than twice as high among Medicare beneficiaries ages 66 years or older with CKD (101.8 per 1,000 person-years) than among those without CKD (46.3 per 1,000 person-years).[43]
- Specifically in Maryland, all-cause mortality in older adults in 2022 in persons without CKD vs. All stages of CKD was 39.4 vs 114.5 per 1,000 PY, respectively.[42]

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") initially approved Jardiance on August 1, 2014. Because the FDA found that the drug was not the first in its class and the safety profile is similar to other drugs approved for this indication, Jardiance was not referred to an advisory committee prior to approval.[44] Since then, the FDA has approved 24 supplemental applications.[45] Nine of the 24 supplements relate to new efficacy data, including four for new indications and one for a new patient population.[46] FDA approved the original application under the stand review pathway. Jardiance received Fast Track designation for chronic kidney disease[47] and for improving outcomes after a heart attack.[48] Jardiance received Breakthrough Therapy designation for heart failure with preserved ejection fraction.[49] FDA review Jardiance under Priority Review for adults with heart failure independent of left ventricular ejection fraction.[50]

Jardiance was originally approved as "an adjunct to diet and exercise to improve glycemic control in . . . adults with type 2 diabetes mellitus." FDA approved with the post-market commitment to conduct:

> "A randomized, double-blind, placebo-controlled trial evaluating the effect of empagliflozin on the incidence of major adverse cardiovascular events (MACE)

[44] FDA Summary Review: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.pdf
[45] https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/summary-supplemental-applications-proposing-labeling-changes-approved-drugs-and-biological-products
[46] Drugs@FDA New Drug Application (NDA): 204629
[47] https://www.boehringer-ingelheim.com/us/media/press-releases/fda-grants-fast-track-jardiance-empagliflozin-ckd-boehringer-ingelheim-us
[48] https://investor.lilly.com/news-releases/news-release-details/us-fda-grants-fast-track-designation-jardiancer-empagliflozin
[49] https://investor.lilly.com/news-releases/news-release-details/fda-grants-jardiancer-breakthrough-therapy-designation-heart
[50] https://investor.lilly.com/news-releases/news-release-details/us-fda-accepts-supplemental-new-drug-application-and-grants

> in patients with type 2 diabetes mellitus… .The long-term effects of empagliflozin on the incidence of liver toxicity, bone fractures, nephrotoxicity/acute kidney injury, breast cancer, bladder cancer, lung cancer, melanoma, complicated genital infections, complicated urinary tract infections/pyelonephritis/urosepsis, serious events related to hypovolemia and serious hypersensitivity reactions should also be assessed. Estimated glomerular filtration rate (eGFR) should also be monitored over time to assess for worsening renal function."[51]

The sponsor used the data generated by this post-marketing commitment to receive FDA approval on a second indication, "to reduce the risk of cardiovascular death in adult patients with type 2" on December 2, 2016.[52] On June 28, 2016, in a 12-11 vote, the committee recommended that the drug be approved for this condition.[53]

The sponsors submitted a supplemental application for Type I diabetes. In November 2019 the FDA held an advisory committee meeting on the application. The committee voted 14-2 that the benefits do not outweigh the risks. In March 2020, the FDA issued a complete response letter advising that the application was not approved.

On August 18, 2021, the FDA approved Jardiance for a new indication to "reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure and reduced ejection fraction." This was based on a new clinical trial related to this indication.[54]

On February 24, 2022, the FDA broadened the indication by changing it to "reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure."[55]

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[51] FDA Summary Review: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.pdf
[52] FDA Label December 2, 2016 https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf
[53] June 28, 2016: Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee https://www.fda.gov/advisory-committees/endocrinologic-and-metabolic-drugs-advisory-committee/june-28-2016-meeting-endocrinologic-and-metabolic-drugs-advisory-committee
[54] FDA Label August 18, 2021 https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s026lbl.pdf
[55] FDA Label February 24, 2022 https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s033lbl.pdf

On June 20, 2023, the FDA expanded the diabetes indication to include children 10 and older.[56]

On September 21, 2023, FDA approved Jardiance "to reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression."[57]

[56] FDA Label June 20, 2023
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s042lbl.pdf
[57] FDA Label September 21, 2023
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf

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

Jardiance is not in shortage.

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

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

Jardiance currently has 11 listed in the orange book. Some of the patents have pediatric study extensions and any dates reflect those extensions. The first listed patent is set to expire on 10/15/2027. This patent is designated as the drug substance patent and the drug product patent and thus is often referred to as the "primary patent." The next patent expires on 02/01/2029. This patent is also listed as a drug substance patent. The last listed patent is set to expire on 12/11/2034. The last patent submitted to be listed in the orange book was submitted on 11/12/2024.

Table 7. Patent Listing Table

Patent Number	DS Patent[1]	DP Patent[2]	Patent Use Code	Submission Date	Original Patent Expiration	Patent Extension Expiration[3]	Listed for 10 MG	Listed for 25 MG
7713938	Yes	Yes		8/15/2014	4/15/2027	10/15/2027	Yes	Yes
7579449	Yes	No		8/15/2014	8/1/2028	2/1/2029	Yes	Yes
8551957	No	No	U-1651	3/14/2016	10/14/2029	4/14/2030	Yes	Yes
12115179	No	No	U-4023	11/12/2024	2/11/2030		Yes	Yes
11833166	No	No	U-3776 U-3777	1/3/2024	4/3/2034		Yes	Yes
11666590	No	No	U-3691	10/3/2023	4/3/2034		Yes	No
10258637	No	No	U-2290	4/30/2019	4/3/2034	10/3/2034	Yes	Yes
11090323	No	No	U-3191	8/20/2021	4/3/2034	10/3/2034	Yes	Yes
11813275	No	No	U-3759 U-3760	12/13/2023	4/3/2034		Yes	No
9949997	No	No	U-2292	5/15/2018	5/17/2034	11/17/2034	Yes	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.

The exclusivities in the orange book relate to post-initial approval labeling changes to add new patient populations and indications. One of the listed exclusivities expired on 08/18/2024. The next exclusivity is set to expire on 08/24/2025. The last one expires on 09/21/2026.

Additional

Glyxambi (Empagliflozin; Linagliptin) is a fixed-dose combination product in which one of the active ingredients is the same as Jardiance. Glyxambi was originally approved on January 30, 2015.[19] The FDA label states that GLYXAMBI is a combination of empagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor and linagliptin, 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. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.

Synjardy (Empagliflozin; Metformin Hydrochloride) is a fixed-dose combination product in which one of the active ingredients is the same as Jardiance.[20] Synjardy was originally

approved on August 26, 2015. The FDA label states that SYNJARDY is a combination of empagliflozin, 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.

Synjardy XR (Empagliflozin; Metformin Hydrochloride) is a fixed-dose combination product in which one of the active ingredients is the same as Jardiance.[21] Synjardy XR was originally approved on December 9, 2016. The FDA label states that SYNJARDY XR is a combination of empagliflozin, a SGLT2 inhibitor and metformin HCl, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Trijardy XR (Empagliflozin; Linagliptin; Metformin Hydrochloride) is a fixed-dose combination product in which one of the active ingredients is the same as Jardiance.[22] Trijardy XR was originally approved on January 27, 2020. TRIJARDY XR is a combination of empagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride (HCl), a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.

Glyxambi

Table 7a. Glyxambi 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
00597-0182-30	Glyxambi	10-5 MG	139	$651,168.00	12	$30,916.00
00597-0182-39	Glyxambi	10-5 MG	14	$53,992.00	***	***
00597-0182-90	Glyxambi	10-5 MG	70	$356,197.00	***	***
00597-0164-30	Glyxambi	25-5 MG	231	$1,098,237.00	21	$107,990.00
00597-0164-39	Glyxambi	25-5 MG	40	$110,703.00	***	***
00597-0164-90	Glyxambi	25-5 MG	187	$870,410.00	17	$67,385.00

Table 7b. Glyxambi 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
00597-0182-30	Glyxambi	10-5 MG	***	***	75	$301,365.65
00597-0182-39	Glyxambi	10-5 MG			***	***
00597-0182-90	Glyxambi	10-5 MG			25	$91,630.32
00597-0164-30	Glyxambi	25-5 MG	***	***	112	$463,090.66
00597-0164-39	Glyxambi	25-5 MG	***	***	***	***
00597-0164-90	Glyxambi	25-5 MG	***	***	52	$189,512.18

Synjardy

Table 8a. Synjardy 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
00597-0168-18	Synjardy	12.5-1000 MG	253	$1,243,388.00	22	$106,511.00
00597-0168-60	Synjardy	12.5-1000 MG	297	$1,268,567.00	19	$67,866.00
00597-0180-18	Synjardy	12.5-500 MG	45	$197,346.00	***	***
00597-0180-60	Synjardy	12.5-500 MG	75	$194,347.00	***	***
00597-0175-18	Synjardy	5-1000 MG	95	$430,509.00	***	***
00597-0175-60	Synjardy	5-1000 MG	143	$542,799.00	***	***
00597-0159-18	Synjardy	5-500 MG	56	$222,744.00	***	***
00597-0159-60	Synjardy	5-500 MG	106	$430,167.00	***	***

Table 8b. Synjardy 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
00597-0168-18	Synjardy	12.5-1000 MG	24	$61,666.40	58	$206,347.85
00597-0168-60	Synjardy	12.5-1000 MG	62	$225,489.29	95	$359,380.81
00597-0180-18	Synjardy	12.5-500 MG	***	***	20	$53,791.04
00597-0180-60	Synjardy	12.5-500 MG	***	***	34	$118,549.82
00597-0175-18	Synjardy	5-1000 MG	13	$27,085.04	33	$122,645.49
00597-0175-60	Synjardy	5-1000 MG	27	$82,068.44	58	$195,893.47
00597-0159-18	Synjardy	5-500 MG	***	***	14	$60,751.91
00597-0159-60	Synjardy	5-500 MG	12	$40,350.54	35	$126,522.04

Synjardy XR

Table 9a. Synjardy 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
00597-0280-73	Synjardy XR	10-1000 MG	267	$1,388,626.00	18	$86,151.00
00597-0280-90	Synjardy XR	10-1000 MG	186	$953,157.00	14	$72,255.00
00597-0300-45	Synjardy XR	12.5-1000 MG	748	$3,244,973.00	52	$172,563.00
00597-0300-93	Synjardy XR	12.5-1000 MG	498	$2,174,408.00	42	$173,623.00
00597-0295-78	Synjardy XR	25-1000 MG	351	$1,780,021.00	34	$162,257.00
00597-0295-88	Synjardy XR	25-1000 MG	338	$1,610,028.00	22	$76,004.00
00597-0290-59	Synjardy XR	5-1000 MG	138	$596,956.00	12	$41,152.00
00597-0290-74	Synjardy XR	5-1000 MG	175	$623,073.00	14	$37,661.00

Table 9b. Synjardy 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
00597-0280-73	Synjardy XR	10-1000 MG	21	$77,088.42	95	$458,123.51
00597-0280-90	Synjardy XR	10-1000 MG	13	$47,616.50	31	$108,036.27
00597-0300-45	Synjardy XR	12.5-1000 MG	79	$285,467.23	201	$780,513.72
00597-0300-93	Synjardy XR	12.5-1000 MG	20	$44,085.99	65	$211,166.65
00597-0295-78	Synjardy XR	25-1000 MG	***	***	81	$331,079.54
00597-0295-88	Synjardy XR	25-1000 MG	35	$135,157.49	99	$399,191.62
00597-0290-59	Synjardy XR	5-1000 MG	***	***	32	$105,339.40
00597-0290-74	Synjardy XR	5-1000 MG	14	$51,575.04	74	$231,935.12

Trijardy XR

Table 10a. Trijardy 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
00597-0380-13	Trijardy XR	10-5-1000 MG	38	$177,032.00	***	***
00597-0380-68	Trijardy XR	10-5-1000 MG	17	$69,371.00	***	***
00597-0385-77	Trijardy XR	12.5-2.5-1000 MG	62	$257,725.00	***	***
00597-0385-86	Trijardy XR	12.5-2.5-1000 MG	62	$297,244.00	***	***
00597-0390-13	Trijardy XR	25-5-1000 MG	47	$130,077.00	***	***
00597-0390-71	Trijardy XR	25-5-1000 MG	86	$373,742.00	***	***
00597-0395-23	Trijardy XR	5-2.5-1000 MG	22	$56,026.00	***	***
00597-0395-82	Trijardy XR	5-2.5-1000 MG	43	$192,142.00	***	***

Table 10b. Trijardy 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
00597-0380-13	Trijardy XR	10-5-1000 MG	***	***	14	$57,140.04
00597-0380-68	Trijardy XR	10-5-1000 MG			***	***
00597-0385-77	Trijardy XR	12.5-2.5-1000 MG			27	$85,898.55
00597-0385-86	Trijardy XR	12.5-2.5-1000 MG	***	***	19	$65,783.69
00597-0390-13	Trijardy XR	25-5-1000 MG	***	***	***	***
00597-0390-71	Trijardy XR	25-5-1000 MG	***	***	23	$97,417.32
00597-0395-23	Trijardy XR	5-2.5-1000 MG			***	***
00597-0395-82	Trijardy XR	5-2.5-1000 MG	***	***	14	$46,382.17

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

[58] 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 11a. Jardiance 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
00597-0152-90	Jardiance	10 MG	$19,412,368.00	5,267	0.1937%
00597-0152-30	Jardiance	10 MG	$95,989,130.00	21,512	0.9578%
00597-0153-90	Jardiance	25 MG	$25,175,084.00	8,729	0.2512%
00597-0153-30	Jardiance	25 MG	$91,863,771.69	19,505	0.9167%
71610-0177-45	Jardiance	25 MG	***	***	***
00597-0153-37	Jardiance	25 MG	$130,950.00	56	0.0013%
71610-0177-15	Jardiance	25 MG	***	***	***
00597-0152-37	Jardiance	10 MG	$97,556.00	41	0.0010%
71610-0177-42	Jardiance	25 MG	***	***	***

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Blank spaces indicate that no data was provided.

Table 11b. Jardiance 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
00597-0152-90	Jardiance	10 MG	$897,155.00	253	0.1308%
00597-0152-30	Jardiance	10 MG	$4,629,223.00	1,199	0.6750%
00597-0153-90	Jardiance	25 MG	$1,699,246.00	683	0.2478%
00597-0153-30	Jardiance	25 MG	$5,578,432.00	1,417	0.8135%
71610-0177-45	Jardiance	25 MG			
00597-0153-37	Jardiance	25 MG	***	***	***
71610-0177-15	Jardiance	25 MG			
00597-0152-37	Jardiance	10 MG	***	***	***
71610-0177-42	Jardiance	25 MG	***	***	***

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Blank spaces indicate that no data was provided.

Table 11c. Jardiance 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
00597-0152-90	Jardiance	10 MG	$800,953.23	398	0.0438%
00597-0152-30	Jardiance	10 MG	$7,527,001.06	2,472	0.4112%
00597-0153-90	Jardiance	25 MG	$1,431,274.74	644	0.0782%
00597-0153-30	Jardiance	25 MG	$8,067,144.09	2,264	0.4408%
71610-0177-45	Jardiance	25 MG			
00597-0153-37	Jardiance	25 MG	$53,659.64	35	0.0029%
71610-0177-15	Jardiance	25 MG			
00597-0152-37	Jardiance	10 MG	***	***	***
71610-0177-42	Jardiance	25 MG			

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Blank spaces indicate that no data was provided.

Table 11d. Jardiance 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
00597-0152-90	Jardiance	10 MG	$9,046,979.24	2,670	0.2501%
00597-0152-30	Jardiance	10 MG	$33,109,658.90	9,408	0.9154%
00597-0153-90	Jardiance	25 MG	$10,649,412.98	3,308	0.2944%
00597-0153-30	Jardiance	25 MG	$27,321,027.82	6,987	0.7553%
71610-0177-45	Jardiance	25 MG			
00597-0153-37	Jardiance	25 MG	$205,842.53	84	0.0057%
71610-0177-15	Jardiance	25 MG			
00597-0152-37	Jardiance	10 MG	$29,951.14	13	0.0008%
71610-0177-42	Jardiance	25 MG			

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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.[59]

[59] 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 12a. Jardiance 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
00597-0152-90	Jardiance	10 MG	$6,734,943.00	53.13%	1,468	4,464	232,121
00597-0152-30	Jardiance	10 MG	$43,639,967.00	83.36%	6,219	23,259	1,169,266
00597-0153-90	Jardiance	25 MG	$9,083,009.00	56.44%	2,737	8,591	466,131
00597-0153-30	Jardiance	25 MG	$36,972,705.69	67.36%	4,784	18,394	1,006,498
71610-0177-45	Jardiance	25 MG	***	***	***	***	***
00597-0153-37	Jardiance	25 MG	$-334,436.00	-71.86%	-161	-270	-23,093
71610-0177-15	Jardiance	25 MG	***	***	***	***	***
00597-0152-37	Jardiance	10 MG	$65,683.00	206.08%	21	27	1,021
71610-0177-42	Jardiance	25 MG	***	***	***	***	***

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Blank spaces indicate that no data was provided.

Table 12b. Jardiance 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
00597-0152-90	Jardiance	10 MG	$135,963.00	17.86%	31	20	2,861
00597-0152-30	Jardiance	10 MG	$1,112,013.00	31.62%	216	772	23,436
00597-0153-90	Jardiance	25 MG	$551,040.00	47.99%	217	556	34,002
00597-0153-30	Jardiance	25 MG	$1,350,249.00	31.93%	271	980	35,801
71610-0177-45	Jardiance	25 MG					
00597-0153-37	Jardiance	25 MG	***	***	***	***	***
71610-0177-15	Jardiance	25 MG					
00597-0152-37	Jardiance	10 MG	***	***	***	***	***
71610-0177-42	Jardiance	25 MG	***	***	***	***	***

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Blank spaces indicate that no data was provided.

Table 12c. Jardiance 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
00597-0152-90	Jardiance	10 MG	$371,634.12	86.56%	161	304	19,569
00597-0152-30	Jardiance	10 MG	$2,336,215.87	45.01%	555	1,286	115,530
00597-0153-90	Jardiance	25 MG	$547,296.48	61.91%	168	390	27,383
00597-0153-30	Jardiance	25 MG	$2,288,870.84	39.61%	398	1,184	109,099
71610-0177-45	Jardiance	25 MG	.	.	.	.	.
00597-0153-37	Jardiance	25 MG	$-186,901.59	-77.69%	-93	-164	-10,687
71610-0177-15	Jardiance	25 MG					
00597-0152-37	Jardiance	10 MG	***	***	***	***	***
71610-0177-42	Jardiance	25 MG					

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Blank spaces indicate that no data was provided.

Table 12d. Jardiance 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
00597-0152-90	Jardiance	10 MG	$3,752,479.02	70.88%	1,041	3,376	181,987
00597-0152-30	Jardiance	10 MG	$13,406,839.60	68.05%	3,433	12,179	629,319
00597-0153-90	Jardiance	25 MG	$4,034,846.60	61.00%	1,063	3,861	222,738
00597-0153-30	Jardiance	25 MG	$10,696,257.95	64.34%	2,161	8,278	504,384
71610-0177-45	Jardiance	25 MG					
00597-0153-37	Jardiance	25 MG	$-755,288.68	-78.58%	-315	-628	-41,040
71610-0177-15	Jardiance	25 MG					
00597-0152-37	Jardiance	10 MG	$1,087.23	3.77%	-4	-3	-45
71610-0177-42	Jardiance	25 MG					

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

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

Staff conducted research to understand the impact of the utilization and spending on the prescription drug product on public budgets and to compare spending on the prescription drug product to relevant benchmarks. The utilization and spending data is captured for Commercial, State and Local Government Employee, and Medicaid 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.[60] The SAAC is provided by Myers and Stauffer, a contractor of the State of Maryland.[61] The ASP is publicly available from the Centers for Medicare and Medicaid Services.[62] The FSS is publicly available from the U.S. Department of Veterans Affairs.[63] 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.

[60] https://www.medicaid.gov/medicaid/nadac
[61] https://myersandstauffer.com/client-portal/maryland/maryland-pharmacy/
[62] https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files
[63] https://www.va.gov/opal/nac/fss/pharmprices.asp

Table 13a. Jardiance WAC and AWP Pricing

National Drug Code	WAC Unit Price	Est. WAC per Year	AWP Unit Price	Est. AWP per Year
00597-0152-07 (10 MG)				
00597-0152-30 (10 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00597-0152-37 (10 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00597-0152-90 (10 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00597-0153-07 (25 MG)				
00597-0153-30 (25 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00597-0153-37 (25 MG)	[redacted]	[redacted]	[redacted]	[redacted]
00597-0153-90 (25 MG)	[redacted]	[redacted]	[redacted]	[redacted]
50090-4384-00 (25 MG)			[redacted]	[redacted]
50090-4384-01 (25 MG)			[redacted]	[redacted]
50090-4492-00 (10 MG)			[redacted]	[redacted]
50090-4492-01 (10 MG)			[redacted]	[redacted]
50090-6452-00 (10 MG/1)			[redacted]	[redacted]

50090-6457-00 (25 MG/1)			[redacted]	[redacted]
55154-0411-08 (10 MG/1)			[redacted]	[redacted]
55154-0412-08 (25 MG/1)			[redacted]	[redacted]
71610-0177-09 (25 MG)			[redacted]	[redacted]
71610-0177-15 (25 MG)			[redacted]	[redacted]
71610-0177-30 (25 MG)			[redacted]	[redacted]
71610-0177-42 (25 MG)			[redacted]	[redacted]
71610-0177-45 (25 MG)			[redacted]	[redacted]

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Blank spaces indicate that no data was provided.

Table 13b. Jardiance 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
00597-0152-07 (10 MG)			$19.37	$7,068.62		
00597-0152-30 (10 MG)	$19.55	$7,134.66	$19.37	$7,068.62	$14.48	$5,284.47
00597-0152-37 (10 MG)	$19.55	$7,134.66	$19.37	$7,068.62	$14.48	$5,284.47
00597-0152-90 (10 MG)	$19.55	$7,134.66	$19.37	$7,068.62	$14.48	$5,284.47
00597-0153-07 (25 MG)			$19.37	$7,068.74		
00597-0153-30 (25 MG)	$19.54	$7,133.61	$19.37	$7,068.74	$14.48	$5,284.47
00597-0153-37 (25 MG)	$19.54	$7,133.61	$19.37	$7,068.74	$14.48	$5,284.47
00597-0153-90 (25 MG)	$19.54	$7,133.61	$19.37	$7,068.74	$14.48	$5,284.47
50090-4384-00 (25 MG)						

50090-4384-01 (25 MG)						
50090-4492-00 (10 MG)						
50090-4492-01 (10 MG)						
50090-6452-00 (10 MG/1)						
50090-6457-00 (25 MG/1)						
55154-0411-08 (10 MG/1)						
55154-0412-08 (25 MG/1)						
71610-0177-09 (25 MG)						
71610-0177-15 (25 MG)						
71610-0177-30 (25 MG)						
71610-0177-42 (25 MG)						

71610-0177-45 (25 MG)						

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Exhibit 5 (attached) reflects pricing history for Jardiance.

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 14. Jardiance Net WAC and Net Spending Estimates

Drug Information			Annual Price or Sales After SSR Application [redacted]			
National Drug Code	Strength	SSR Rebate	Est. WAC per Yr	Commercial (2023) Gross Spend	State Local Govt Emp (2023) Gross Spend	Medicare (2022) Gross Spend
00597-0152-30	10 MG	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00597-0153-30	25 MG	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00597-0153-90	25 MG	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00597-0152-90	10 MG	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00597-0153-37	25 MG	[redacted]	[redacted]	[redacted]	***	[redacted]
00597-0152-37	10 MG	[redacted]	[redacted]	[redacted]	***	[redacted]
71610-0177-42	25 MG	[redacted]		***	***	
71610-0177-45	25 MG	[redacted]		***		
71610-0177-15	25 MG	[redacted]		***		
55154-0411-08	10 MG/1	[redacted]	[redacted]			
55154-0412-08	25 MG/1	[redacted]	[redacted]			

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

Blank spaces indicate that no data was provided.

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

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

Under the Medicare Drug Price Negotiation Program authorized by the Inflation Reduction Act of 2022 (P.L. 117-169), beginning January 1,2026, Jardiance is subject to a negotiated Maximum Fair Price (MFP) for the Medicare program.[64] 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.

[64] 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 15. Jardiance Price Concessions for Medicare under MFP

Drug	National Drug Code	WAC Unit Per Unit	MFP Per Unit	Price Concession As A Percent of WAC
Jardinance	00597-0152-07			
Jardinance	00597-0152-30	[redacted]	$6.79	[redacted]
Jardinance	00597-0152-37	[redacted]	$6.79	[redacted]
Jardinance	00597-0152-90	[redacted]	$6.79	[redacted]
Jardinance	00597-0153-07			
Jardinance	00597-0153-30	[redacted]	$6.79	[redacted]
Jardinance	00597-0153-37	[redacted]	$6.79	[redacted]
Jardinance	00597-0153-90	[redacted]	$6.79	[redacted]
Jardinance	50090-4384-00			
Jardinance	50090-4384-01			
Jardinance	50090-4492-00			
Jardinance	50090-4492-01			
Jardinance	50090-6452-00			
Jardinance	50090-6457-00			
Jardinance	55154-0411-08	[redacted]		
Jardinance	55154-0412-08	[redacted]		
Jardinance	71610-0177-09			
Jardinance	71610-0177-15			
Jardinance	71610-0177-30			
Jardinance	71610-0177-42			
Jardinance	71610-0177-45			

*** 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.

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 "JARDIANCE 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 (Jardiance 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 Jardiance. Staff used the Tufts Medical Center's Center for the Evaluation of Value and Risk in Health's Cost Effectiveness Analysis Registry to identify potential analyses.[65] Staff searched for articles containing dapagliflozin in the United States. In total, staff reviewed ten articles with varying results.

The majority of the literature assesses the cost of the drug over a lifetime which necessarily includes the assessment of three components: (1) the incremental impact of the cost of the drug product; (2) the reductions in healthcare spending due to the drug product improving health (offsets); and (3) additional healthcare costs incurred from living longer. The results varied because the assumptions about the cost of Jardiance, the use of Jardiance for different indications, and the comparators also varied. The results of these studies are summarized in Exhibit 4A.

[65] CEA Registry. Tufts Medical Center. https://cear.tuftsmedicalcenter.org/. Search conducted on February 6, 2025.

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.

Staff reviewed literature from two different sources. First, staff reviewed the same articles identified in Factor 6.4. In addition, staff reviewed literature identified by the Center for Medicare and Medicaid Services for the Medicare Drug Price Negotiation Program. In explaining, the resulting Maximum Fair Price, CMS published a list studies they considered during the process.[66] Staff reviewed this list for relevant Comparative Effectiveness Research. See Exhibit 4A and 4B for a summary of the literature.

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

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

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

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

Section 7: Cost-Sharing and Insurance Benefit Design

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

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

MCDB Analysis

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. In the second analysis, we examined how increases in copayment impact the number of prescriptions a patient has in a year. Some patients had previously began using Jardiance. Meanwhile, others begin Jardiance during the year. As a result, we attempted to see if the impact differed for new patients compared to pre-existing patients using an interaction term.

Methods

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

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

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

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

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

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

where

Y_i = Normalized 30 Day Equivalent

β_0 = Intercept

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

Results

Data Characteristics

Table 16. 2023 Commercial Pharmacy Claims Characteristics for Jardiance Analysis		
	Patient Count	**Claim Count**
Total Population[48]		
Counts	46,942	181,625
Eligible Patients (≥ 11 months of pharmacy coverage)		
Counts	40,750	151,012
Final Summary File for Eligible Claims		
Counts	23,970	84,497

Jardiance

Table 17. Jardiance Out-of-Pocket Frequency Analysis

COIN_FLAG	COPAY_FLAG	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	0	20682	24.48	20682	24.48
0	1	53991	63.90	74673	88.37
1	0	9170	10.85	83843	99.23
1	1	654	0.77	84497	100.00

Among eligible commercial claims for Jardiance, we see copay is used most often (64%) as part of the insurance benefit design. The use of coinsurance as part of the benefit design, either by itself or in conjunction with coinsurance payments, are only observed in about 12% of claims.

Regression Analysis

Table 18. Summary statistics for regression variables

	N	NMiss	Min	Max	Mean	Std
Normalized 30 Day Equivalent	23970	0	0.08	1.00	0.72	0.28
Continuous User Indicator	23970	0	0.00	1.00	0.47	0.50
Average Coinsurance	23970	0	0.00	2754.00	12.86	59.25
Average Copay	23970	0	0.00	600.00	35.84	42.51
Continuous User*Avg. Coinsurance	23970	0	0.00	2198.50	5.63	33.61
Continuous User*Avg. Copay	23970	0	0.00	600.00	16.42	32.44

The average copay per beneficiary ($36) is significantly higher than the average copay ($12).

Table 19. Analysis of Variance					
Source	**DF**	**Sum of Squares**	**Mean Square**	**F Value**	**Pr > F**
Model	5	12.40769	2.48154	31.46	<.0001
Error	23964	1890.44203	0.07889		
Corrected Total	23969	1902.84972			

Table 20. Model Statistics.			
Root MSE	0.28087	**R-Square**	0.0065
Dependent Mean	0.72463	**Adj R-Sq**	0.0063
Coeff Var	38.76030		

Table 21. Parameter Estimates						
Variable	**Label**	**DF**	**Parameter Estimate**	**Standard Error**	**t Value**	**Pr > |t|**
Intercept	Intercept	1	0.70246	0.00332	211.35	<.0001
AVG_COPAY	Average Copay	1	0.00034941	0.00005641	6.19	<.0001
AVG_COIN	Average Coinsurance	1	-0.00009190	0.00003734	-2.46	0.0139
CONT_USER	Continuous User Indicator	1	0.02717	0.00496	5.47	<.0001
INTX_COIN	Continuous User*Avg. Coinsurance	1	-0.00023670	0.00006712	-3.53	0.0004
INTX_COPAY	Continuous User*Avg. Copay	1	-0.00003680	0.00008794	-0.42	0.6756

The results above suggest that about 0.6% of the variation in a commercial patient's normalized 30 day equivalent can be explained by average copay per claim per beneficiary and the average coinsurance per claim per beneficiary, while controlling for whether a patient is a continuous user, the interaction between continuous user and average coinsurance/copay, and other confounding factors controlled for by the intercept. Generally, unit decreases in a patient's average coinsurance/copayment per claim minimally increase the patient's normalized 30-day equivalent ratio and are statistically significant.

Literature Review

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

The first article examined the relationship between copayments and utilization in a database of commercial insurance and Medicare Part D plans associated with Medicare Advantage.[67] They categorized patients into three groups based on their copay levels: low (less than $10), medium (between $10 and $50), and high (greater than $50). They then examined the proportion of days covered by prescriptions. They examined the relationship between the copayment categories and the probability of having more than 80% of the prescription days covered in a year. Without controlling for other factors, they found that 77% of patients with low copayment levels had more than 80% of prescription days covered. In comparison, 72% of those with medium and 72% of those with high copayments had 80% covered. Controlling for demographic, clinical, and socioeconomic factors, the authors found that the odds ratio for those with medium copayments was 0.67 and those with high copayments was 0.68 compared to the low copayment group.

The second article examined adherence during the first year of SGLT2 inhibitor use in Medicare beneficiaries.[68] In this study, they found that increased copays were associated with more prescription days covered.

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

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

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

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

Staff identified two patient access programs for Jardiance.

We identified two programs for Jardiance. The first program is the Jardiance Savings Card.[49] This card can allow patients to pay as little as $10 a month a prescription. The terms and conditions state that:

> Patients who meet the eligibility criteria may pay as little as $10/month with a maximum savings up to $175 per 30-day supply. Benefits not to exceed program expiration on December 31, 2025. In Massachusetts and California, the validity of this voucher and its use are subject to state law. Other state restrictions may apply. One card per patient, not transferable, and may not be used in combination with any other discount, coupon, rebate, free trial, or similar offer.
>
> Card not accepted in Veterans Affairs pharmacies. Program is not health insurance. You must present this card to the pharmacist with your JARDIANCE prescription to participate. Only valid for commercially insured patients in the 50 United States, DC, and Puerto Rico whose insurance policy provides coverage for JARDIANCE who are not reimbursed for the entire cost of the prescription. Offer not valid for patients without commercial coverage or patients whose prescriptions for JARDIANCE are eligible to be reimbursed, in whole or in part, by any governmental program such as Medicaid, Medicare, Medigap, the Retiree Drug Subsidy Program, VA, DOD, TRICARE®, or any state patient or pharmaceutical assistance program and where prohibited by law. Offer not valid for prescriptions for JARDIANCE that are eligible to be reimbursed, in whole or in part, by any state employee health plans where prohibited by law. Offer may change at any time, without notice. Offer is intended to comply with all applicable laws and regulations, including, without limitation, the federal Anti-Kickback Statute, its implementing regulations, and related guidance interpreting the federal

> Anti-Kickback Statute. The selling, purchasing, trading, or counterfeiting of the offer is prohibited by law. The offer has no cash value.
> Insurance plans, PBMs and other third-party companies are prohibited from enrolling or assisting in the enrollment of patients in the PROGRAM. The patient, or his/her legal representative, must personally enroll in the Program in order to be eligible for program benefits. The value of the Program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles.
>
> By enrolling in the Program, you agree that this program is intended solely for the benefit of you, the patient. Some insurance plans have established programs referred to as 'accumulator adjustment' or 'co-pay maximizer' programs which requires you to enroll in a manufacturer copay assistance program. An accumulator adjustment program is one in which payments made by you that are subsidized by manufacturer assistance do not count toward your deductibles and other out-of-pocket cost sharing limitations. Co-pay maximizers are programs in which the amount of your out-of-pocket costs is increased to reflect the availability of support offered by a manufacturer assistance program. Except where prohibited by applicable state law, if your insurance company, health plan or other company implements either an accumulator adjustment or co-pay maximizer program, you will not be eligible for, and agree not to use, the Program because these programs are inconsistent with our agreed intent that this program is solely for your benefit. Since you may be unaware whether you are subject to a co- pay maximizer program when you enroll in the co-pay assistance program, if Boehringer Ingelheim suspects or is made aware that you are subject to one of these programs, we reserve the right to discontinue copay assistance at any time.

The second program was Boehringer Cares Patient Assistance Program. According to their website:

> The Boehringer Ingelheim Cares Foundation Patient Assistance Program (Boehringer Cares) is provided by the Boehringer Ingelheim Cares Foundation, an independent nonprofit organization that seeks to help eligible patients receive medicines for free.
>
> The Program provides Boehringer Ingelheim medicines free of charge to U.S. patients who meet our program eligibility requirements.[50] Our goal is to invest our resources to help the most patients with the greatest need, including senior citizens and families with limited incomes.

You may be eligible for the Boehringer Cares Patient Assistance Program if all terms below are met:

- You reside in the U.S. or a U.S. territory and are being treated as an outpatient by a U.S. licensed health care provider.
- You are uninsured or have Medicare Part D coverage (please refer to the application as some products vary)
- Your total household income before taxes and deductions is at or below our annual income limit (% of Federal Poverty Level (FPL)).

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

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 22. Jardiance 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
00597-0152-90	Jardiance	10 MG	$37.37	$81.46	$30.54	$61.07
00597-0152-30	Jardiance	10 MG	$77.23	$89.91	$45.71	$71.21
00597-0153-90	Jardiance	25 MG	$26.48	$112.57	$23.59	$38.47
00597-0153-30	Jardiance	25 MG	$77.61	$114.07	$42.33	$62.20
71610-0177-45	Jardiance	25 MG	***	***	***	***
00597-0153-37	Jardiance	25 MG	$24.73	$42.14	$27.05	$44.89
71610-0177-15	Jardiance	25 MG	***	***	***	***

00597-0152-37	Jardiance	10 MG	$77.02	$38.73	$14.54	$40.24
71610-0177-42	Jardiance	25 MG	***	***	***	***

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
00597-0152-90	Jardiance	10 MG	$3.74	$65.88	$19.83	$11.11
00597-0152-30	Jardiance	10 MG	$3.35	$77.96	$10.01	$2.73
00597-0153-90	Jardiance	25 MG	$2.82	$68.00	$4.29	$0.92
00597-0153-30	Jardiance	25 MG	$5.72	$80.59	$8.07	$1.44
71610-0177-45	Jardiance	25 MG				
00597-0153-37	Jardiance	25 MG	***	***	***	***
71610-0177-15	Jardiance	25 MG				
00597-0152-37	Jardiance	10 MG	***	***	***	***
71610-0177-42	Jardiance	25 MG	***	***	***	***

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

Blank spaces indicate that no data was provided.

Factor 7.4: 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 23. Jardiance 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
00597-0152-90	Jardiance	10 MG	5.79%	2.83%	7.21%
00597-0152-30	Jardiance	10 MG	6.45%	2.40%	5.64%
00597-0153-90	Jardiance	25 MG	6.98%	3.07%	7.61%
00597-0153-30	Jardiance	25 MG	5.85%	2.41%	6.29%
71610-0177-45	Jardiance	25 MG	***		
00597-0153-37	Jardiance	25 MG	5.94%	***	6.12%
71610-0177-15	Jardiance	25 MG	***		
00597-0152-37	Jardiance	10 MG	7.17%	***	13.24%
71610-0177-42	Jardiance	25 MG	***	***	

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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 24. Jardiance 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
00597-0152-90	10 MG	$210.44	$80.00	$518.00	$100.55	$40.00	$210.00	$300.22	$80.00	$1,026.66
00597-0152-30	10 MG	$284.06	$100.00	$713.00	$94.05	$40.00	$240.00	$270.57	$59.10	$944.32
00597-0153-90	25 MG	$201.10	$90.00	$463.00	$76.02	$40.00	$184.00	$296.47	$104.78	$1,020.77
00597-0153-30	25 MG	$296.21	$130.00	$697.00	$95.82	$50.00	$240.00	$309.62	$87.33	$1,046.24
71610-0177-45	25 MG	***	***	***						
00597-0153-37	25 MG	$138.82	$47.50	$467.00	***	***	***	$192.37	$88.65	$590.87
71610-0177-15	25 MG	***	***	***						
00597-0152-37	10 MG	$170.54	$45.00	$324.00	***	***	***	$715.80	$1,078.06	$1,208.71
71610-0177-42	25 MG	***	***	***	***	***	***			

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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.[69] 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.

[69] 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.[70]

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

A study found that 10.8% of patients with diabetes and SGLT-2 inhibitor prescriptions were black compared to 11.9% of patients with diabetes and no SGLT-2 inhibitor prescription.[71] Meanwhile, 4.4% of patients with diabetes and SGLT-2 inhibitor prescriptions were Asian compared to 4.8% of patients with diabetes and no SGLT-2 inhibitor prescription. In addition, 16.1% of patients with diabetes and SGLT-2 inhibitor prescriptions were Hispanic/Latino compared to 15.0% of patients with diabetes and no SGLT-2 inhibitor prescription

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

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

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

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

A second study found that 19.4% of the low copay patients were black compared to 11.8% and 10.1% of the medium and high copay patients.[72] It also found 20.7% of the low copay patients were Hispanic compared to 15.7% and 13.4% of medium and high copay patients. It also found 44.8% of patients with low copays came from areas with median household incomes under $40,000, compared to 21.9% and 21.6% of medium and high copay patients. In comparison, 12.4% of low copay patients came from areas with median household income over $100,000 compared to 28.1% and 25.7% of medium and high income copay patients.

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.

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

Table 25. Jardiance Cost Consistent with FDA Label

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected Commercial (2023) Gross Spending
00597-0152-90	Jardiance	10 MG	[redacted]
00597-0152-30	Jardiance	10 MG	
00597-0153-90	Jardiance	25 MG	
00597-0153-30	Jardiance	25 MG	
71610-0177-45	Jardiance	25 MG	***
00597-0153-37	Jardiance	25 MG	[redacted]
71610-0177-15	Jardiance	25 MG	****
00597-0152-37	Jardiance	10 MG	[redacted]
71610-0177-42	Jardiance	25 MG	***

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected State Local Gov. Emp. (2023) Gross Spending
00597-0152-90	Jardiance	10 MG	[redacted]
00597-0152-30	Jardiance	10 MG	
00597-0153-90	Jardiance	25 MG	
00597-0153-30	Jardiance	25 MG	
71610-0177-45	Jardiance	25 MG	
00597-0153-37	Jardiance	25 MG	***
71610-0177-15	Jardiance	25 MG	
00597-0152-37	Jardiance	10 MG	***
71610-0177-42	Jardiance	25 MG	***

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected Medicaid (2022) Gross Spending
00597-0152-90	Jardiance	10 MG	[redacted]
00597-0152-30	Jardiance	10 MG	
00597-0153-90	Jardiance	25 MG	
00597-0153-30	Jardiance	25 MG	
71610-0177-45	Jardiance	25 MG	
00597-0153-37	Jardiance	25 MG	[redacted]
71610-0177-15	Jardiance	25 MG	
00597-0152-37	Jardiance	10 MG	***
71610-0177-42	Jardiance	25 MG	

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Projected Medicare (2022) Gross Spending
00597-0152-90	Jardiance	10 MG	[redacted]
00597-0152-30	Jardiance	10 MG	
00597-0153-90	Jardiance	25 MG	
00597-0153-30	Jardiance	25 MG	
71610-0177-45	Jardiance	25 MG	
00597-0153-37	Jardiance	25 MG	[redacted]
71610-0177-15	Jardiance	25 MG	
00597-0152-37	Jardiance	10 MG	[redacted]
71610-0177-42	Jardiance	25 MG	

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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 Jardiance 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 Jardiance received in response to this request are attached as Exhibit 3B and are also available on the Board website.[90]

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 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[91] 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

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 Jardiance.

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.