Jardiance (empaglifozin)-
DRAFT Cost Review Study Report

Maryland Prescription Drug Affordability Board

March 16, 2026

Version 1.0

MARYLAND
Prescription Drug Affordability Board

Van T. Mitchell
Board Chair

Gerard Anderson, Ph.D.
Member

Van T. Mitchell
Board Chair

Stephen Rockower, MD **Board**
Board Member

Julia Slejko, Ph.D.
Board Member

Georges Benjamin, M.D.
Board Member

For further information concerning this document, please contact:
Andrew York, Pharm.D., J.D.
Executive Director
16900 Science Drive, Suite 112-114
Bowie, MD 20715

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Table of Contents

Executive Summary.....1

Background.....3

I. Summary of Information Considered by the Board.....5

II. Summary of Deliberations.....11

III. Circumstances and Indicia Reflecting the Affordability Challenge and Preliminary Determination.....13

Appendix A. Dossier July 18, 2026 Jardiance Dossier

Exhibit 1- Pricing History_REDACTED (PDF)

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

Exhibit 3- Jardiance Therapeutic Alternative Pricing_REDACTED (Excel Document)

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

Exhibit 5

Exhibit 5A Jardiance Summary of Cost Effectiveness Analyses
Exhibit 5B Jardiance Summary of Comparative Effectiveness Research

Exhibit 6

Exhibit 6A Written Comments (60-day COMAR 14.01.04.05C(2)) (PDF)

Exhibit 6B Written Comments (Request October 28, 2024) (PDF)

Exhibit 6C Written Comments (Request January 27, 2025) (PDF)

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

Appendix B. Resolution 2025-02

Executive Summary

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

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

Jardiance is a drug used for patients with type 2 diabetes (T2DM), heart failure (HF), cardiovascular disease (CVD), and chronic kidney disease (CKD). These conditions are common and are of importance to public health. Clinical guidelines for these conditions recommend the use of Jardiance. Initially, Jardiance was approved for T2DM before getting additional indications. Generic versions of the product may enter the market in 2027, depending on resolution of patents other than primary patents. The use of Jardiance was spread across multiple NDCs, but when added together made up almost 2% of the gross drug spending in some market segments. On a list price basis, the data suggested that Jardiance had prices (not including rebates) in excess of $7,000 per year. However, rebates substantially reduced the average net price of the drug. Generally, the use of Jardiance was associated with higher spending but better health outcomes. Finally, the average out-of-pocket (OOP) for the most common NDC (00597-0153-30) was $95.82 for the full year of 2023 for state and local government beneficiaries and $296.21 for patients with commercial insurance.

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

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

Background

Established in 2019, the Maryland Prescription Drug Affordability Board ("Board") is an independent agency charged with "protecting State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drugs." Md. Code Ann., Health-Gen. ("HG") § 21-2C-02(b). The Board confers with, and receives input from, a 26-member appointed advisory Stakeholder Council composed of experts across the supply chain and stakeholder representatives.

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

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

In response to this selection, Board staff developed a dossier to provide the Board with information addressing the factors the Board may consider under COMAR 14.01.05. Board Staff conducted literature reviews, analyses of the MCDB, analyses of proprietary datasets, conducted a Request for Information (RFI) from manufacturers, wholesalers, PBMs, and payors. Staff also received public comments that are exhibits to the dossier. Staff presented iterations of the dossier to the board to get feedback and update the dossier On July 28, 2025, the Board, at their open in-person Board meeting, considered whether use of Jardiance has led or will lead to affordability challenges to the State health care system or high out-of-pocket costs for patients and whether that use was consistent with the labeling approved by the Food and Drug Administration (FDA) or standard medical practice.

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

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

In accordance with COMAR 14.01.04.05F, staff prepared a draft of the preliminary determination cost review report. The report summarizes the information considered by the Board in conducting the cost review study, the Board's deliberations, the circumstances or indicia reflecting the affordability challenge, and the Board's preliminary determination.

I. Summary of Information Considered by the Board

Introduction

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

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

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

Dossier Section 1: Background

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

Dossier Section 2: Clinical Information

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

This section contains information about the drug, including information about the diseases the drug treats, how it fits into clinical guidelines, the dosing of the drug, and the burden to society of the diseases treated by the drug.

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

SGLT2 inhibitors (the therapeutic class in which Jardiance is a member) are a preferred drug class in the treatment of Type 2 DM. SGLT2 inhibitors are typically considered as a first-line therapy

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

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

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

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

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

Dossier Section 3: Regulatory Approval and Market Context

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

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

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

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

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

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

According to patent data, Jardiance has a number of patents. The "primary patents" the drug substance and product patents, are set to expire in 2027, potentially opening up for the potential of generic entry. However, the manufacturer has other patents that may block generic entry if they are not invalidated by litigation or the generic firms have not developed a product that does not infringe on those patents.

The manufacturer has produced other products that contain the same active ingredient as Jardiance. These other products also treat T2DM. These products are fixed dose combination products with dapagliflozin and other antidiabetic drugs, such as metformin. All of these drug products are used much less frequently than Jardiance and thus do not tend to show a pattern of product hopping.

Dossier Section 4: Utilization of Drug Product Under Review

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

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

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

Section Four of the Dossier contains information on the utilization of the data. Board Staff provided the board with tables summarizing the count of patients, prescriptions, and units (pills). In the Dossier, Staff presented NDC level data by different types of insurance (Commercial, State and Local Government, Medicaid, and Medicare). While the information included a variety of NDCs, the utilization data was primarily concentrated in four NDCs, two reflecting 10 MG pills and the other two reflecting 25 MG pills. The use of Jardiance was spread across multiple NDCs, but when added together made up over 1.8% of the gross drug spending in some market segments.

Section 5: Pricing Information and Rebates

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

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

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

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

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

Section Five of the Dossier contains pricing information for Jardiance. Staff calculated the annual pricing measures based on a patient taking a pill every day for 365 days. Much of the data is

redacted from the public versions of the dossier except for publicly available prices such as NADAC, SAAC, and FFS. On a list price basis, the data suggested that the drugs under review had prices (not including rebates) in excess of $7,000 per year. The proprietary data found substantial rebates that reduced prices well below the listed prices. In comparison, the Medicare Negotiated Maximum Fair Price was under $2,400 per year.

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

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

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

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

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

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

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

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

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

Jardiance does not have any FDA approved therapeutic equivalent products. In terms of therapeutic alternatives, the Dossier contains pricing and utilization information for a variety of drugs used to treat diabetes. Some drugs were in the same therapeutic class while others were in different classes. The Dossier also contains information on published studies related to the incremental costs and incremental benefits of the drug.

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

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

Section 7: Cost-Sharing and Insurance Benefit Design

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

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

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

Factor 7.4: The average cost share

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

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

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

This section includes information regarding patient access and out-pocket-cost for Jardiance. This section contains analysis of data from the MCDB on out-of-pocket and cost sharing. In addition, this section contains information derived from published studies on how out-pocket-cost impacts access, information derived from published studies on use of Jardiance by priority populations, and information from the manufacturer website regarding patient assistance programs. The average out-of-pocket for the most common NDC (00597-0153-30) was $$95.82 for the full year of 2023 for state and local government beneficiaries and $296.21 for patients with commercial insurance.

Section 8: Other Information

Factor 8.1: Input from the Public

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

This section includes input from the public, information from the request for information (RFI), information from state and local government entities, and information on any other relevant

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

II. Summary of Deliberations

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

Closed Session

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

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

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

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

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

Public Deliberations

Citing factors 4.1 through 4.2 (utilization of drug product), a Board member observed that spending on Jardiance represents 1.8% of all prescription drug spend (10 mg and 25 mg strengths) for state and local government. (Table 12b). Citing this percentage as representing a significant portion of drug spending, the Board member proposed that this constitutes a circumstance under which use of Jardiance has created an affordability challenge.

Deliberation also included discussion on the following matters:

- Jardiance is an effective drug;

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

- Jardiance and Farxiga are competitors for many indications and the Board does not want to hinder access to these two drugs in the State of Maryland because they are good drugs;
- Because Jardiance is an effective drug, the Board did not discuss the pricing of therapeutic alternatives;
- Concern that a single product (Jardiance) represents so much drug spend; and
- Observation and concern regarding the limited utilization of Jardiance among Medicaid patients in the public data.

The Board also made observations about additional analyses and data that may be explored:

- The desire for additional data and analyzes on certain topics such as state spending over time;
- Discussion of possibility of improving data readability by consolidating NDC codes or using weighted average dose;
- Observation regarding the lack of public information on co-pay programs; and
- Discussion of Factor 7.1 and relationships with benefit design suggests possible additional analyses.

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

On July 28, 2025, the Board ratified the preliminary determination made and the two circumstances identified during the closed session, and the affordability determination and circumstance identified in open session, by adopting Resolution 2025-02 by unanimous roll call vote.

The Resolution 2025-02 reads, in pertinent part:

> **RESOLVED** that:
>
> The Board makes a preliminary determination that use of Jardiance:
>
> Has created an affordability challenge for the State health care system; and
>
> That the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice.
>
> The circumstances under which the prescription drug product has led to an affordability challenge include:
>
> (1) the percentage change in WAC over time is substantially larger than the percentage change in inflation (rate of increase in inflation) (closed session);
> (2) at 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors (closed session); and
> (3) total gross spending for Jardiance for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments (public session).
>
> Be it **FURTHER RESOLVED** that:
>
> In accordance with COMAR 14.01.04.05F(2), the Board's preliminary determination is non-final and subject to revision and modification; and
>
> Any circumstance is a sufficient and independent basis for the preliminary affordability challenge determination.

Resolution 2025-02 (Appendix B).

APPENDIX A-
July 23, 2025
Jardiance Dossier

APPENDIX A- CONTENTS

- Jardiance Dossier- updated 7/23/2025
- Exhibit 1 Pricing History_REDACTED (PDF)
- Exhibit 2 RFI Submissions (NON-PUBLIC--TRADE SECRET, CONFIDENTIAL, AND PROPRIETARY)
- Exhibit 3 Jardiance Therapeutic Alternative Pricing_REDACTED (Excel Document)
- Exhibit 4 Jardiance Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)
- Exhibit 5
  - Exhibit 5A Jardiance Summary of Cost Effectiveness Analyses
  - Exhibit 5B Jardiance Summary of Comparative Effectiveness Research
- Exhibit 6
  - Exhibit 6A Written Comments (60-day COMAR 14.01.04.05C(2)) (PDF)
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  - Exhibit 6D Written Comments (Request June 18, 2025) (PDF)

Jardiance (empaglifozin)-Dossier

Maryland Prescription Drug Affordability Board

July 23, 2025

Version 2.1

Van T. Mitchell
Board Chair

Gerard Anderson, Ph.D. MD **Board Member**

Van T. Mitchell **Board Chair**

Stephen Rockower, **Board Member**

Eberechukwu Onukwugha, MS, Ph.D.
Board Member

Joseph Levy, Ph.D.
Board Member

For further information concerning this document, please contact:
Andrew York, Pharm.D., J.D.
Executive Director
16900 Science Drive, Suite 112-114
Bowie, MD 20715

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Table of Contents

Factor 2.1: Clinical information, including FDA indications and doses and information concerning standard medical practice. 5

Factor 2.2: The disease burden of the condition that is treated by the prescription drug product 11

Section 3: Regulatory Approval and Market Context 21

Factor 3.1: Analysis of the prescription drug product's approval process 21

Factor 3.2: Analysis of the prescription drug product's shortage status 24

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 25

Section 4: Utilization of Drug Product Under Review 32

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 32

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 36

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 41

Section 5: Pricing Information and Rebates 42

Factor 5.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS 42

Factor 5.2: Information estimating manufacturer net price and net sales amounts of the prescription drug product under review 45

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 47

Section 6: Therapeutic Alternatives, Cost Comparisons, and Health Economics Outcomes and Research (HEOR) 51

Factor 6.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS at which each therapeutic alternative has been sold in the State 51

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 51

Factor 6.3: The utilization, costs, and out-of-pocket costs for therapeutic alternatives 53

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 54

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. 55

Factor 6.6: In the case of generic prescription drug products, the number of pharmaceutical manufacturers that produce the prescription drug product 56

Factor 6.7: The utilization and pricing of therapeutically equivalent drug products 57

Section 7: Cost-Sharing and Insurance Benefit Design 58

Factor 7.1: The estimated impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design 58

Jardiance 61

Table 18. Jardiance Out-of-Pocket Frequency Analysis 61

Regression Analysis 61

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 64

Factor 7.3: The average patient copay and other cost-sharing data for the prescription drug in the State 67

Factor 7.4: The average cost share 69

Factor 7.5: The mean, median, and 90th percentile out-of-pocket costs per patient compared to State incomes 70

Factor 7.7: The costs to health plans based on patient access consistent with FDA-labeled indications or standard medical practice 73

Section 8: Other Information 75

Factor 8.1: Input from the Public 75

Factor 8.2: Analysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product 77

Factor 8.3: Input from state and local governmental entities and the entities' contractors such as health plans and plan administrators 78

Factor 8.4: Information and analyses submitted by an entity under Regulation .04 of this chapter. 79

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] Some the NDCs included on this list are discontinued. Staff has included discontinued NDCs in the list because some factors include historical data that necessitates including data on discontinued NDCs.

Table 1. NDC List

National Drug Code	Proprietary Name	Non-Proprietary Name	Dosage-Strength
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
70518-1986-00	Jardiance	Empagliflozin	10 MG
50090-6452-00	Jardiance	Empagliflozin	10 MG
55154-0411-08	Jardiance	Empagliflozin	10 MG
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
70518-2447-00	Jardiance	Empagliflozin	25 MG
50090-6457-00	Jardiance	Empagliflozin	25 MG
55154-0412-08	Jardiance	Empagliflozin	25 MG

[1] The standard practice in published literature is to refer to drugs by the name of the molecule rather than the brand name of the drug. Staff has retained that convention. As a result, when discussing literature 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 glucose in which the body both underuses and overproduces glucose, resulting in high blood glucose. Underuse of blood glucose may be caused by either an inability of the body to make sufficient (or any) insulin, such as in Type 1 DM, or resistance to insulin as found in Type 2 DM.[4]

Jardiance is a member of the sodium-glucose transporter 2 (SGLT2) inhibitor class. This medication class is recommended by the American Diabetes Association (ADA) and the American Association of Clinical Endocrinology (AACE) as one of the seven medication class options 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 within the same line of therapy as other therapeutic options indicated for Type 2 DM (such as insulin, metformin, GLP-1 receptor agonists, sulfonlyureas, etc).[7] The AACE similarly considers patient specific factors and explicitly prefers SGLT2i (or GLP-1 receptor agonists) for patients who are overweight, obese, or at risk of low blood glucose.[8] These guideline recommendations are in line with other guidelines from major societies 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, and high cholesterol), the ADA and AACE recommend the use of SGLT2 inhibitors with proven benefit (Jardiance [empagliflozin] or Invokana [canagliflozin]) as first-line therapy.[11,12]

- This recommendation is independent of the patient's use of other medications (unless specifically unable to use with a particular medication) and glycemic control.
- Equally weighted recommendation for GLP-1 receptor agonists (GLP-1 RAs) 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 glucose and reduction of HF-related symptoms as first-line therapy (Farxiga, Jardiance, Invokana, 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) and glycemic control.
- There is no other first-line or alternative therapy for this patient population.

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

- This recommendation is independent of the patient's use of other medications (unless specifically unable to use with a particular medication) and glycemic control.
- Equally weighted recommendation for GLP-1 RAs with proven benefit (Trulicity, Victoza, Ozempic).[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 first-line therapy options for Type 2 DM first line therapy given the overall safety (low risk of hypoglycemia), effectiveness in lowering blood glucose, and benefits/protection for CKD, CVD, and HF. GLP-1 RAs have demonstrated similar outcomes and are alternative first-line therapy options. Metformin, a biguanide, is also considered first-line therapy with effectiveness in lowering blood glucose, low hypoglycemia risk, and potential CVD benefit but has not demonstrated benefit in HF or progression of CKD. Medical professionals prefer Jardiance, Farxiga and Invokana, given their proven benefits for HF, CVD, and CKD.

Jardiance (empagliflozin) Place in Therapy for Heart Failure

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

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 and Farxiga, 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 publication. It is now FDA-approved and available for use.

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

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.

[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.

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

Chronic Kidney Disease (CKD) encompasses abnormalities of kidney function or structure that are present for at least 3 months. This carries health implications because the kidneys are unable to filter blood as well as they should.[24] Kidney function is measured through estimated glomerular filtration rate (eGFR) and the loss of protein in the form of albumin in the urine.

The Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend SGLT2 inhibitors for all adult patients with (1) Type 2 DM, CKD, and eGFR ≥ 20 mL/min/1.73m^2; (2) all adult patients with CKD, urinary albumin ≥200mg/g, and eGFR ≥ 20 mL/min/1.73m^2; and (3) all adult patients with CKD and HF.[25]

The KDIGO guidelines also suggest treating all adult patients with an eGFR of 20 to 45 ml/min/1.73m^2 with an SGLT2 inhibitor.[26]

The KDIGO guidelines do not recommend or specify any particular drug within the SGLT2 inhibitor class. The guidelines, per a review of large randomized controlled trials in support of the overall recommendations/suggestions, mention evidence for Farxiga, Jardiance, Inpefa, and Invokana.[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 for Jardiance, Farxiga, and Invokana) are (1) recommended by major guidelines for adult CKD patients with DM Type 2, HF, and/or albuminuria ≥200mg/g; and (2) suggested for adult CKD patients with an eGFR of 20 to 45 ml/min/1.73m^2.

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[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.

[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 diagnosed 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] Notably, 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]

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[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]
- Based on global data from 2007-2017, 32.2% of persons with type 2 diabetes mellitus have cardiovascular disease (CVD). In this report , 13% and 46% of the studies analyzed were from North America and Europe, respectively.[34]

[34] Einarson TR, Acs A, Ludwig C, Panton UH. Prevalence of cardiovascular disease in type 2 diabetes: a systematic literature review of scientific evidence from across the world in 2007-2017. Cardiovasc Diabetol. 2018 Jun 8;17(1):83. doi: 10.1186/s12933-018-0728-6. PMID: 29884191; PMCID: PMC5994068.

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.[35]
- 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).[36,37]

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).[36]

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[35]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.

[36] 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.

[37] 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.

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 and B represent those individuals without signs or symptoms of heart failure but either at risk for or with pre-heart failure. Stages C and D represent individuals with symptomatic heart failure, Stage D representing more severe symptoms interfering with activities of daily living.[38]

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.[39]
- 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).[39]

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[38] 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.

[39] 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.

Morbidity

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

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 was 928,741 (deaths in the US by 2020). By including any mention of HF on death certificates, HF was a contributing cause in 415,922 deaths in the US in 2020.[36]
- In 2022, heart failure was mentioned on 457,212 death certificates (and responsible for 13.9% of all causes of death).[40]
- For adults aged 65-90 years, HF is associated with a loss of 15 years of median survival compared with the general US population.[36]
- The 1-year HF mortality rate is approximately 30%, increasing to approximately 40% at 5 years.[41]

Chronic Kidney Disease (CKD)

Prevalence

- Based on data from 2017 - March 2020, 35.5 million (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]

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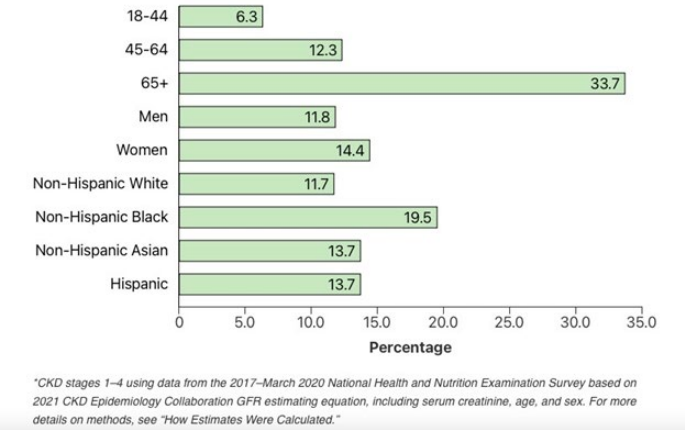
[40] Centers for Disease Control and Prevention. About Heart Failure [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2024 [cited 2025 Jan 4]. Available from: https://www.cdc.gov/heart-disease/about/heart-failure.html.

[41] 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[42]



Incidence

- There are approximately 360 new dialysis starts daily.[42]
- 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.[43]

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).[43]

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[42] 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.
[43] 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.[42]
- 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.[44]
- In 2021, annual per-person spending attributable to Medicare Parts A, B, and D was more than double for beneficiaries ages 66 or older with CKD ($28,162) compared to those without CKD ($13,604).[44]

[44] 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]

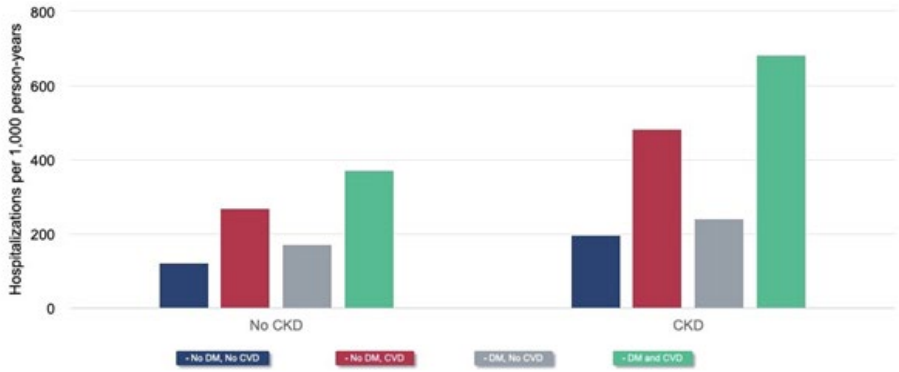
	All CKD	Stages 1-2	Stage 3	Stages 4-5
Patient counts	2,649,040	280,940	1,565,020	234,060
Patient years at risk	2,461,388	267,024	1,461,236	200,395
All patients	$28,116	$24,640	$27,327	$38,691
Age				
66-69	$27,795	$23,405	$27,676	$44,136
70-74	$26,330	$22,152	$26,102	$40,598
75-79	$27,705	$24,505	$26,821	$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 comorbidities[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).[44]
- 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.[43]

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.[45] 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.[46] Since then, the FDA has approved 24 supplemental applications.[47] Nine of the 24 supplements relate to new efficacy data, including four for new indications and one for a new patient population.[48] The FDA approved the original application under the standard review pathway. Jardiance received Fast Track designation for chronic kidney disease[49] and for improving outcomes after a heart attack.[50] Jardiance received Breakthrough Therapy designation for heart failure with preserved ejection fraction.[51] The FDA reviewed Jardiance under Priority Review for adults with heart failure independent of left ventricular ejection fraction.[52]

Jardiance was originally approved as "an adjunct to diet and exercise to improve glycemic control in . . . adults with type 2 diabetes mellitus."[53] The FDA approved Jardiance with the post-market commitment to conduct:

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[45] Drugs@FDA Search
[46] FDA Summary Review:
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.pdf
[47] https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/summary-supplemental-applications-proposing-labeling-changes-approved-drugs-and-biological-products
[48] Drugs@FDA New Drug Application (NDA): 204629
[49] https://www.boehringer-ingelheim.com/us/media/press-releases/fda-grants-fast-track-jardiance-empagliflozin-ckd-boehringer-ingelheim-us
[50] https://investor.lilly.com/news-releases/news-release-details/us-fda-grants-fast-track-designation-jardiancer-empagliflozin
[51] https://investor.lilly.com/news-releases/news-release-details/fda-grants-jardiancer-breakthrough-therapy-designation-heart
[52] https://investor.lilly.com/news-releases/news-release-details/us-fda-accepts-supplemental-new-drug-application-and-grants
[53] FDA Label August 1, 2024-
https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204629s000lbl.pdf

> "A randomized, double-blind, placebo-controlled trial evaluating the effect of empagliflozin on the incidence of major adverse cardiovascular events (MACE) 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."[54]

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 diabetes mellitus and established cardiovascular disease" on December 2, 2016.[55] On June 28, 2016, in a 12-11 vote, the advisory committee recommended that the drug be approved for this condition.[56]

The sponsors submitted a supplemental application for Type I diabetes. In November 2019, the FDA held an advisory committee meeting on the application.[57] 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.[58]

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

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[54] FDA Summary Review: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.pdf
[55] FDA Label December 2, 2016 https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf
[56] 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 also located at: https://wayback.archive-it.org/7993/20201221190544/https://www.fda.gov/advisory-committees/endocrinologic-and-metabolic-drugs-advisory-committee/2016-meeting-materials-endocrinologic-and-metabolic-drugs-advisory-committee in case the FDA archives the meeting information.
[57] https://wayback.archive-it.org/7993/20201224220015/https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-13-2019-meeting-endocrinologic-and-metabolic-drugs-advisory-committee-meeting-announcement
[58] https://investor.lilly.com/news-releases/news-release-details/us-fda-issues-complete-response-letter-empagliflozin-25-mg

and reduced ejection fraction."[59] This was based on a new clinical trial related to this indication.

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."[60]

On June 20, 2023, the FDA expanded the diabetes indication to include children ages 10 and older.[61]

On September 21, 2023, the 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."[62]

[59] FDA Label August 18, 2021 https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s026lbl.pdf
[60] FDA Label February 24, 2022 https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s033lbl.pdf
[61] FDA Label June 20, 2023 https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s042lbl.pdf
[62] 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.[63]

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

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

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

Patent and Exclusivity Data

Jardiance currently has 11 patents 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, 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 that in 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 that in Jardiance.[21] Synjardy XR was originally approved on December 9, 2016. The FDA label states that Synjardy XR is a combination of empagliflozin (an SGLT2 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.

Trijardy XR (empagliflozin/linagliptin/metformin hydrochloride) is a fixed-dose combination product in which one of the active ingredients is the same as that in 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 8a. 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

Table 8b. 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

Synjardy

Table 9a. 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

Table 9b. 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	***	***

Synjardy XR

Table 10a. 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

Table 10b. 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

Trijardy XR

Table 11a. 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

Table 11b. 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	***	***

Section 4: Utilization of Drug Product Under Review

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

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

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

Table 12a. 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 12b. 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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Table 12c. 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 12d. 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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Blank spaces indicate that no data was provided.

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

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

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

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

Table 13a. 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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Table 13b. 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 13c. 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 13d. 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 populations in Factor 4.1 “Pct Total Gross Spend” column in Tables 9a, 9b, and 9c.

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

In future Cost Review Studies, staff will continue to work with state and local governments, and other public budgets, to identify standardized data to support this analysis or develop other methods of conducting this analysis.

Section 5: Pricing Information and Rebates

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

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

This section covers various drug pricing metrics, including the Wholesale Acquisition Cost (WAC), Average Wholesale Price (AWP), National Average Drug Acquisition Cost (NADAC), State Average Acquisition Cost (SAAC), Average Sales Price (ASP), and Federal Supply Schedule (FSS) price. The WAC and AWP are proprietary and commercially licensed from UpToDate (MediSpan). The NADAC is publicly available from the Centers for Medicare and Medicaid Services.[64] The SAAC is provided by Myers and Stauffer, a contractor of the State of Maryland.[65] The ASP is publicly available from the Centers for Medicare and Medicaid Services.[66] The FSS is publicly available from the U.S. Department of Veterans Affairs.[67] 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.

[64] https://www.medicaid.gov/medicaid/nadac
[65] https://myersandstauffer.com/client-portal/maryland/maryland-pharmacy/
[66] https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files
[67] https://www.va.gov/opal/nac/fss/pharmprices.asp

Table 14a. 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)			[redacted]	[redacted]
50090-6457-00 (25 MG)			[redacted]	[redacted]
55154-0411-08 (10 MG)			[redacted]	[redacted]
55154-0412-08 (25 MG)			[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 14b. 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)						
50090-6457-00 (25 MG)						
55154-0411-08 (10 MG)						
55154-0412-08 (25 MG)						
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 1 (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.

[redacted]

Table 15. Jardiance Net WAC and Net Spending Estimates

Drug Information		Annual Price or Sales After SSR Application [redacted]				
National Drug Code	Strength	SSR Rebate	Est. Net Price 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]
00597-0153-30	25 MG	[redacted]		[redacted]	[redacted]	[redacted]
00597-0153-90	25 MG	[redacted]		[redacted]	[redacted]	[redacted]
00597-0152-90	10 MG	[redacted]		[redacted]	[redacted]	[redacted]
00597-0153-37	25 MG	[redacted]		[redacted]	***	[redacted]
00597-0152-37	10 MG	[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	[redacted]				
55154-0412-08	25 MG	[redacted]				

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Blank spaces indicate that no data was provided.

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

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

Under the Medicare Drug Price Negotiation Program authorized by the Inflation Reduction Act of 2022 (P.L. 117-169), beginning January 1,2026, Jardiance is subject to a negotiated Maximum Fair Price (MFP) for the Medicare program.[68] 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.

[68] 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 16. 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
Jardiance	00597-0152-07			
Jardiance	00597-0152-30	[redacted]	$6.79	[redacted]
Jardiance	00597-0152-37	[redacted]	$6.79	[redacted]
Jardiance	00597-0152-90	[redacted]	$6.79	[redacted]
Jardiance	00597-0153-07			
Jardiance	00597-0153-30	[redacted]	$6.79	[redacted]
Jardiance	00597-0153-37	[redacted]	$6.79	[redacted]
Jardiance	00597-0153-90	[redacted]	$6.79	[redacted]
Jardiance	50090-4384-00			
Jardiance	50090-4384-01			
Jardiance	50090-4492-00			
Jardiance	50090-4492-01			
Jardiance	50090-6452-00			
Jardiance	50090-6457-00			
Jardiance	55154-0411-08	[redacted]		
Jardiance	55154-0412-08	[redacted]		
Jardiance	71610-0177-09			
Jardiance	71610-0177-15			
Jardiance	71610-0177-30			
Jardiance	71610-0177-42			
Jardiance	71610-0177-45			

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Blank spaces indicate that no data was provided.

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

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

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

Exhibit 2 contains information responsive to this element.

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

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

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

Exhibit 2 contains information responsive to this element.

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

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

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

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

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

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

Methodology: Calculation using equation

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

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

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

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

[redacted]

Staff developed the attached supplemental excel document (Exhibit 3_REDACTED "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 3_REDACTED contains the information specified above for non-insulin therapeutic alternatives.

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

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

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

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

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

Staff developed the attached supplemental excel document Exhibit 4 (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 (empagliflozin). 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.[69] Staff searched for articles containing empagliflozin in the United States. In total, staff reviewed ten articles with varying results.

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

[69] 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; comparative effectiveness research compares different healthcare interventions or therapies to determine clinical effectiveness, benefits, and safety.

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

Staff reviewed literature from two different sources. First, staff reviewed the same articles identified in Factor 6.4. In addition, staff reviewed literature identified by the Centers for Medicare and Medicaid Services for the Medicare Drug Price Negotiation Program. In explaining, the resulting Maximum Fair Price, CMS published a list of studies that it considered during the process.[70] Staff reviewed this list for relevant Comparative Effectiveness Research. See Exhibits 5A and 5B for a summary of the literature.

[70] 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 the prescription drug product under study relative to insurance benefit design. Two items may be of particular interest to the Board: (a) the distribution of coinsurance/copayment utilization among claims for the drug under study; and (b) whether increases or decreases in a patient's average copay/coinsurance per claim impact their utilization of the drug. In the second analysis, we examined how increases in copayment impact the number of prescriptions a patient has in a year. Some patients had previously begun using Jardiance. Meanwhile, others began 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 17. 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 18. 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, is only observed in about 12% of claims.

Regression Analysis

Table 19. 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 coinsurance ($13).

Table 20. 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 21. Model Statistics.

Root MSE	0.28087	**R-Square**	0.0065
Dependent Mean	0.72463	**Adj R-Sq**	0.0063
Coeff Var	38.76030		

Table 22. 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 analysis above suggests that while there are statistically significant relationships between average copays and coinsurance and the number of prescriptions people use in a year, any impact is small.

Literature Review

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

The first article examined the relationship between copayments and utilization in a database of commercial insurance and Medicare Part D plans associated with Medicare Advantage.[71] The researchers categorized patients into three groups based on their copay levels: low (less than $10), medium (between $10 and $50), and high (greater than $50). They then examined the proportion of days covered by prescriptions. The researchers examined the relationship between the copayment categories and the probability of having more than 80% of the prescription days covered in a year. Without controlling for other factors, they found that 77% of patients with low copayment levels had more than 80% of prescription days covered. In comparison, 72% of those with medium and 72% of those with high copayments had 80% covered. Controlling for demographic, clinical, and socioeconomic factors, the authors found that the odds ratio for those

[71] 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

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.[72] In this study, researchers found that increased copays were associated with more prescription days covered.

[72] 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. The first program is the Jardiance Savings Card.[49] This card can allow patients to pay as little as $10 a month per 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 copayments, 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 'copay 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. Copay 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 copay 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 copay 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 its 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 or Medicaid.

Table 23a. 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	***	***	***	***

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

Table 23b. Jardiance Average Copays and Other Cost-Sharing

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	State Local Gov (2023) Avg Deductible	State Local Gov (2023) Avg Copay	State Local Gov (2023) Avg Coinsurance	State Local Gov (2023) Avg Other Member Liability
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	***	***	***	***

*** 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 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 24. 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	***	***	

*** 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 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 25. 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.[73] 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.

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

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

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

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

If demographic information were available, staff anticipated using linear regression techniques to assess whether there is a statistically significant difference in spending and utilization between identified priority populations for each selected drug. The priority populations to be assessed are informed by the Agency for Healthcare Research and Quality (AHRQ) reporting of priority populations.[74]

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

A study found that 10.8% of patients with diabetes and SGLT-2 inhibitor prescriptions were Black, compared to 11.9% of patients with diabetes and no SGLT-2 inhibitor prescription.[75] 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,

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[74] The selection of priority populations informed by AHRQ's definitions. https://www.ahrq.gov/priority-populations/index.html (last checked April 30, 2025).
[75] 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

compared to 30.2% of patients with diabetes and no SGLT-2 inhibitor prescription. 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.[76] It also found that 20.7% of the low copay patients were Hispanic, compared to 15.7% and 13.4% of medium and high copay patients. Additionally, this study found that 44.8% of patients with low copays came from areas with median household incomes under $40,000, compared to 21.9% and 21.6% of medium and high copay patients. In comparison, 12.4% of low copay patients came from areas with median household income over $100,000, compared to 28.1% and 25.7% of medium and high copay patients.

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

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

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

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

Table 26. 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	[redacted]
00597-0153-90	Jardiance	25 MG	[redacted]
00597-0153-30	Jardiance	25 MG	[redacted]
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	[redacted]
00597-0153-90	Jardiance	25 MG	[redacted]
00597-0153-30	Jardiance	25 MG	[redacted]
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	[redacted]
00597-0153-90	Jardiance	25 MG	[redacted]
00597-0153-30	Jardiance	25 MG	[redacted]
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	[redacted]
00597-0153-90	Jardiance	25 MG	[redacted]
00597-0153-30	Jardiance	25 MG	[redacted]
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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Blank spaces indicate that no data was provided.

Section 8: Other Information

Factor 8.1: Input from the Public

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

INITIAL 60-DAY COMMENT PERIOD

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

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

WRITTEN COMMENT REQUEST

Written Comment Request: Posted 10/28/2024

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

Written comments for Jardiance received in response to this request are attached as Exhibit 6B and are also available on the Board's 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 listserv on January 15, 2025. Under COMAR 14.01.04.05D, the Board may consider oral public comment made at the Board meeting and written comments. The written comments received are located on the website[91] and in Exhibit 6C.

PUBLIC COMMENTS IN CONJUNCTION WITH BOARD MEETINGS TO DATE

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

Board Meeting: January 27, 2025- Oral Comment

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

2. Lenoard Lucci, Consumer, Agenda Item V

3. Peter Maybarduk, Public Citizen, Agenda Item V

Board Meeting: March 24, 2025- Oral Comment

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

WRITTEN COMMENT REQUEST ON DRAFT DOSSIER

Written Comment Request: Posted 6/18/2025

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

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

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 2 to the dossier. Under COMAR 14.01.04.05C(1)(g)(xviii), the Board may consider the "[i]nformation and analyses submitted by an entity under Regulation .04 of this chapter."

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

Table of Exhibits

Exhibit 1_REDACTED Pricing History_REDACTED (PDF)

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

Exhibit 3_REDACTED JARDIANCE Therapeutic Alternative Pricing_REDACTED (Excel Document)

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

Exhibit 5

- Exhibit 5A Jardiance Summary of Cost Effectiveness Analyses
- Exhibit 5B Jardiance Summary of Comparative Effectiveness Research

Exhibit 6

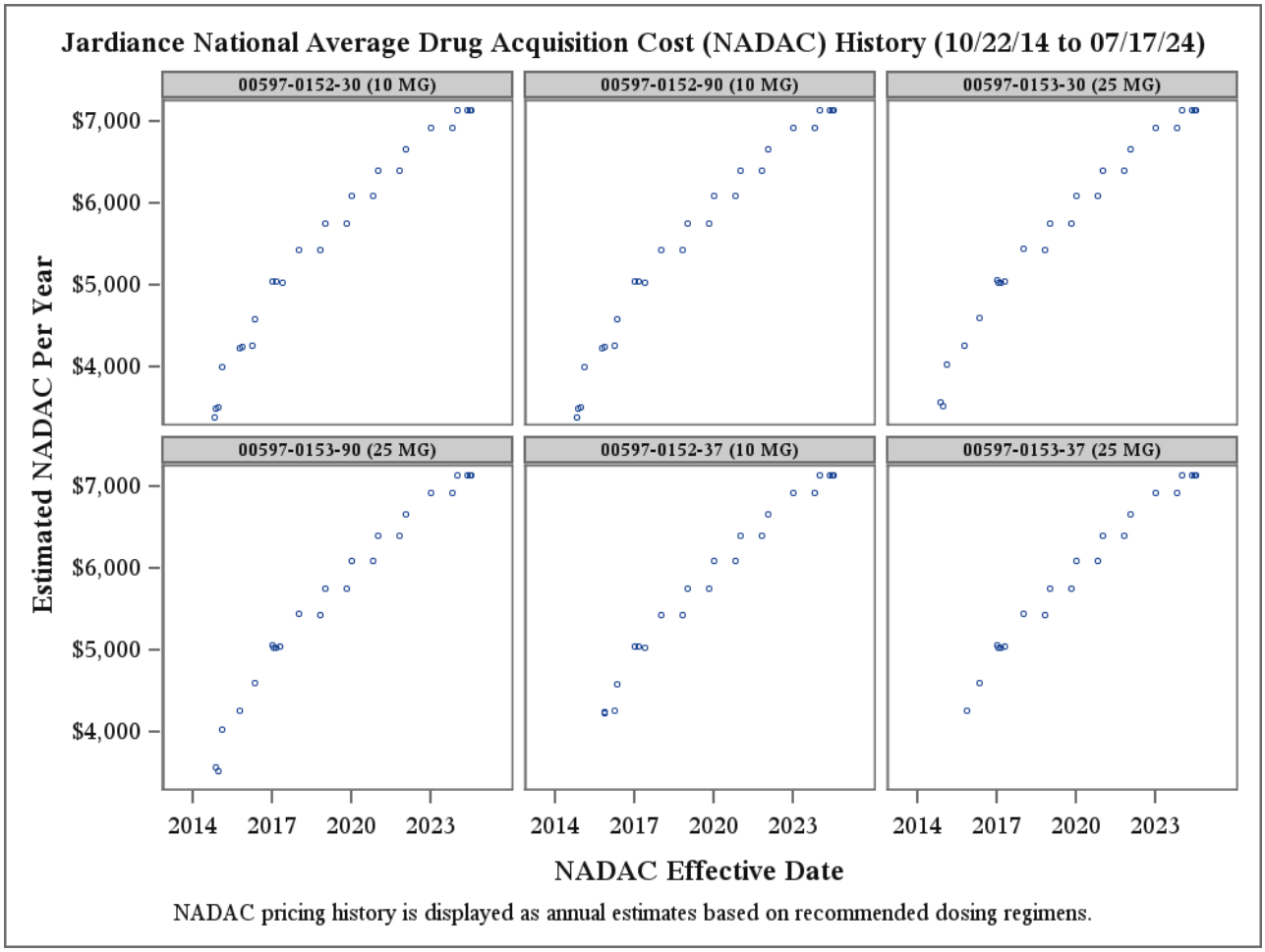
- Exhibit 6A Written Comments (60-day COMAR 14.01.04.05C(2)) (PDF)
- Exhibit 6B Written Comments (Request October 28, 2024) (PDF)
- Exhibit 6C Written Comments (Request January 27, 2025) (PDF)
- Exhibit 6D Written Comments (Request June 18, 2025) (PDF)

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

Exhibit 1-
Jardiance Pricing History_REDACTED

v.2.0
2025.07.18.1400

Historical National Average Drug Acquisition Cost (NADAC) Graph


Jardiance National Average Drug Acquisition Cost (NADAC) History (10/22/14 to 07/17/24)
00597-0152-30 (10 MG)
00597-0152-90 (10 MG)
00597-0153-30 (25 MG)
00597-0153-90 (25 MG)
00597-0152-37 (10 MG)
00597-0153-37 (25 MG)
Estimated NADAC Per Year
$7,000
$6,000
$5,000
$4,000
2014
2017
2020
2023
NADAC Effective Date
NADAC pricing history is displayed as annual estimates based on recommended dosing regimens.

v.2.0
2025.07.18.1400

Historical Wholesale Acquisition Cost (WAC) Graphs by NDC

v.2.0
2025.07.18.1400

Historical Average Wholesale Price Graphs by NDC

DOSSIER EXHIBIT 2

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

DOSSIER EXHIBITS 3-5 Attached Separately

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

Exhibit 6A-

Written Comments

(60-day COMAR 14.01.04.05C(2))

Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

Board Selected Drugs: Jardiance, Ozempic, Trulicity and Farxiga

1 message

Patrick Mutch <pmutch@chasebrexton.org> Fri, Jul 19, 2024 at 6:37 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>
Cc: [redacted]
>

Dear Members of PDAB,

As President and Chief Executive Officer of Chase Brexton Health Care, I am expressing our concerns focused on the several of latest diabetes medications under review, Jardiance, Ozempic, Trulicity and Farxiga. We rely on these medications to manage the complex healthcare needs of the over 4,700 diabetic patients, most of whom are underserved patients from marginalized communities.

Chase Brexton Health Care is a Federally Qualified Health Center (FQHC) non-profit organization with five centers in Baltimore City, Columbia, Glen Burnie, Woodlawn (Security Square) and Easton. We serve more than 45,000 unique patients annually, most of whom are underserved and would not have any other access to health care. Of the 45,000+ patients, 45% are insured by Medicaid, and 26% are uninsured.. As a safety net provider, Chase Brexton relies on the 340b margins from these diabetic medications to provide comprehensive outpatient services to care for our patients and sustain our mission.. Our chief medical officer, Dr. Sebastian Ruhs has submitted a separate letter to comment on the clinical benefits of these medications and potential negative effects if an upper payment limit negatively impacts the ability of patients to receive these medications.

Once again, we would like to bring to your attention that Federally Qualified Health Centers such as Chase Brexton Health Care have a dedicated mission to serve impoverished communities "regardless of ability to pay". Chase Brexton Health Care and other FQHCs utilize their 340B savings to provide the array of integrated care that includes, but not limited to, adult and pediatric primary care, behavioral health, substance use, psychiatry, ob/gyn services, dental services, pharmacy, social services, LQBTQ affirming care, food assistance, transportation, and housing. The 340B savings are essential to safety-net providers in reducing health care disparities, increasing access to comprehensive services, and ensuring patients have access to life saving medications. Indeed, FQHCs are some of the best stewards of the program and any reduction in the 340B savings reduces those entities' ability to serve the most marginalized of Marylanders. **We respectfully ask the Board to review the potentially negative impacts to 340B covered entities before implementing any actions. Thank you for the opportunity to comment.**

Patrick F. Mutch

Patrick F. Mutch
President & Chief Executive Officer

Pronouns (he/him)

Chase Brexton Health Care
Because everyone's health matters.

Chase Brexton Health Care

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

July 19, 2024

Submitted for Public Comment: Maryland Prescription Drug Affordability Board

Dear Members of the Maryland Prescription Drug Affordability Board,

As Chief Medical Officer, I write on behalf of the medical and pharmaceutical team at Chase Brexton Health Care which foresees a potentially significant negative impact on the health outcomes of Diabetes Mellitus (DM) patients should an upper payment limit on vital, preferred medications, such as Ozempic, Trulicity, Farxiga, and Jardiance, be established and restrict these medications from use. Cost increases may be seen should providers have to switch patients to non-preferred drug options. I will not address the other issue which is the significant 340b margins from these medications which are totally reinvested in caring for the vast majority of our patients who have complex healthcare needs and are underserved and often uninsured.

I can attest to both the importance and complexity of treating this chronic disease which has been diagnosed in nearly 500,000 (1 in 10) Marylanders and remains undiagnosed in an estimated 140,000 Marylanders. This number of patients and potential patients in need of effective and accessible treatment options should lead the Prescription Drug Affordability Board (PDAB) to reduce restrictions to ensure positive and cost-effective health outcomes for every community member in our state.

Patient outcomes and cost effective, accessible treatment for this complex disease is a priority. As providers and pharmacists, we must consider many factors in creating our treatment plan including adherence, identified comorbid conditions, and risks of developing comorbid conditions.

Treatment of DM is a complex matter and when prescribing medications, many factors must be considered:

> **1) Adherence**: Complex regimens, such as insulin injections multiple times a day, are less likely to be taken as prescribed than simple regimens. Trulicity and Ozempic, which are once weekly injections, have shown to greatly improve adherence, which leads to better controlled sugar levels. **Optimized blood glucose control decreases the risk of developing costly complications from DM, such as renal failure, heart attacks, and strokes.**
>
> **2) Comorbid conditions:** People with DM are more likely to have other comorbid conditions, such obesity, hypertension, kidney disease, and cardiovascular disease. Some of those conditions are strongly associated with DM and a result of poorly treated or untreated DM. Some medications treating DM can

Chase Brexton Health Care

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improve clinical outcomes in patients with existing renal or cardiovascular disease. Farxiga and Jardiance belong to the class of sodium-glucose co-transporter-2 (SGLT2) inhibitors. SGLT2 inhibitors have shown to improve clinical outcome in patients with preexisting congestive heart failure and preexisting renal disease. **SGLT2s, like Farxiga and Jardiance, can improve overall mortality and decrease hospital admissions in patients with those conditions.** Not having the option to choose from such DM regimens can lead to further exacerbation of such preexisting conditions, such as renal failure leading to dialysis and congestive heart failure with increases in hospital admissions and worsening overall mortality.

3) Risk of developing new cardiovascular disease in patients at risk: Some DM drugs decrease the risk for developing new cardiovascular disease, such as heart attacks and strokes. Ozempic and Trulicity belong to the class of glucagon-like-peptide-1 (GLP-1) agonists. In addition to improving blood glucose levels, those GLP-1s promote weight loss, which is an important factor in treatment of DM, and they decrease the risk of heart attacks and strokes in at risk patients. **Being able to choose from Ozempic and Trulicity to treat DM minimizes the risk of developing cardiovascular complications which can lead to poor clinical outcomes and increase in cost.**

To treat DM, we need to be able to choose from options that improve adherence, and which can be tailored to the individual needs of the patient, depending on their pre-existing comorbid conditions, or their risk of developing such. **Limiting access to Farxiga, Jardiance, Ozempic, and Trulicity and aswitching patients to non-preferred, less effective medications, will put multitudes of patients at risk of reduced adherence, poor control of blood sugar level, and increases in complications from comorbid conditions all of** which then further increases the risk of developing complications from DM. These factors will ultimately lead to an increase in new drugs prescribed and an increase in hospital admissions, and therefore an increase in overall cost.

Sincerely,

Sebastian Ruhs, MD, PhD
Infectious Disease Physician
Chief Medical Officer

CC: Patrick Mutch, CEO, Chase Brexton Health Care
Mahro Ershadi, Chief Pharmacy and Strategy Officer, Chase Brexton Health Care
Jeff Cywinski, Director of Pharmacy, Chase Brexton Health Care

July 22, 2024

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

RE: SIX DRUGS CHOSEN FOR COST REVIEW
(FARXIGA, JARDIANCE, OZEMPIC, TRULICITY, DUPIXENT, SKYRIZI)

Dear Members of the Board,

As a broad coalition of advocacy organizations representing patients, caregivers and health care providers, we write concerning the value of the six drugs chosen by the Prescription Drug Affordability Board for cost review and consideration of affordability. The Coalition has previously submitted comments expressing concern that methods available to the Board to lower health care spending – the setting of upper payment limits, in particular – may restrict patients' access to needed treatments. Therefore, we are hopeful that the Board will consider the value of access to these drugs when considering affordability.

The Value of Care Coalition believes that value is best determined by those who know – providers who prescribe medicines and patients who rely on the medicine to keep their medical conditions stable. Just as the term "affordability" has many different definitions and could be determined by a multitude of criteria, so does "value". Cost and value are not the same thing, but cost, or affordability, cannot be fully considered without accounting for value.

DIABETES TREATMENTS

At the May 20 meeting of the Prescription Drug Affordability Board, the Board voted to review four drugs with an indication for type 2 diabetes as a "class". It is not clear what this grouping means for how reviews are conducted, or the drugs are compared to each other or other treatments, and it is not clear if such a grouping is appropriate considering the different types of treatments within the group.

FARXIGA, JARDIANCE, OZEMPIC, TRULICITY

Two of these treatments, Farxiga and Jardiance, are SGLT-2 inhibitors. Two others, Ozempic and Trulicity, are GLP1 agonists. While each drug is used to treat type 2 diabetes, they are not all the same and physicians value each for their unique role in their toolbox of treatments.

For example, Farxiga and Jardiance both treat chronic kidney disease and heart failure independent of diabetes, but are commonly used for patients with both heart failure or chronic kidney disease and diabetes. Farxiga has also been shown to reduce cardiovascular death with certain kinds of heart failure, while Jardiance may be prescribed for people with diabetes and established cardiovascular disease or stroke. These two drugs are taken orally.

Ozempic and Trulicity are commonly prescribed for type 2 diabetes and weight loss. Ozempic has also been shown to reduce risk of cardiovascular hospitalizations and death. These two drugs are injected.

There is a well-established connection between diabetes and cardiovascular disease. People with diabetes are at a greater risk of heart failure.[1] In fact, according to the Partnership to Advance Cardiovascular Health, "people with type 2 diabetes are twice as likely to develop heart disease and if they struggle with obesity their risk is even higher."[2]

Cardiovascular disease was the cause of death for over 900,000 Americans in 2020 – more than all forms of cancer and Chronic Lower Respiratory Disease combined. Meanwhile, in 2020, heart attacks occurred approximately every 40 seconds, and someone died of stroke every 3 minutes 17 seconds in the United States. As of 2018, the prevalence of adult obesity stood at 43% of males and 41.9% of females in America with an upward trend over the previous twenty years.[3]

In the face of these statistics, physicians value treatments tailored to patients' unique needs and comorbidities. Additionally, loss of access to these medications could force doctors to veer from evidence-based guidelines.

At the same time, the value patients find in these treatments is immense. Without access to a treatment that works for them, that they're comfortable with and that keeps their condition stable, their diabetes may be less well controlled. This can lead to weight gain and higher risk for other complications such as eye disease, neuropathy, foot complications and limb loss, gum disease, hearing loss, and cardiovascular disease, chronic kidney disease, and stroke.[4] These comorbidities are each debilitating in their own way, causing patients pain, suffering and an inability to go about their day to day lives as they otherwise would.

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[1] CDC, *Your Heart and Diabetes,* https://www.cdc.gov/diabetes/diabetes-complications/diabetes-and-your-heart.html

[2] Partnership to Advance Cardiovascular Health, *The Diabetes-Cardiovascular Connection, https://www.youtube.com/watch?v=RshYNrftKwo*

[3] American Heart Association, *2023 Heart Disease and Stroke Statistics Updated Fact Sheet, https://professional.heart.org/en/science-news/-/media/453448D7D79948B39D5851D1FF2A0CFE.ashx*

[4] American Diabetes Association, *Diabetes Complications, https://diabetes.org/about-diabetes/complications*

Left untreated, the progression of chronic kidney disease can lead to cardiovascular complications, hospitalizations, dialysis and kidney transplant.

Likewise, the benefits of these treatments related to cardiovascular diseases are profound. Consider a patient who suffers a stroke. Lucky to be alive, they may face paralysis causing them to lose mobility, have speech and language problems, vision problems, trouble thinking and memory issues. They can no longer work or even hold their child or grandchild. The value of treatment proven to reduce stroke risk is extraordinary to this patient.

In addition to the value found in quality-of-life aspects provided by these treatments, a forced switch to another medication may result disease progression, symptoms re-emerge or new side effects surfacing, more doctor visits, hospitalizations, additional treatments, and lost economic output in terms of missed work. In fact, the American Heart Association estimates the indirect cost of cardiovascular disease alone to be "$155.9 billion in lost productivity/mortality" from 2018-2019.[5]

DUPIXENT

Dupixent is a biologic approved for several conditions, including eczema, asthma, nasal polyps and eosinophilic esophagitis, including approval for young children for many of those indications. Prescribers value Dupixent for its versatility as asthma and nasal polyps often coexist, as do asthma and eczema. Like other treatments being assessed, Dupixent treats multiple debilitating conditions at the same time.

From the patient perspective, consider a patient with severe asthma and nasal polyps. Symptoms of polyps can include runny nose or congestion, postnasal drip, loss of smell and taste, pain in the face and teeth, headache and snoring.[6] With proper treatment, polyps shrink. The patient no longer needs surgery to remove polyps. Their nose stops running and they can breathe again. They can smell again and taste food. And they may feel better than they have in decades.

In the short term, asthma patients can have trouble breathing, suffer from wheezing, coughing and tightness or pain in the chest. Symptoms can be exacerbated by simple changes in the weather, seasonal cycles, and many other common triggers. [7]

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[5] American Heart Association, *2023 Heart Disease and Stroke Statistics Updated Fact Sheet, https://professional.heart.org/en/science-news/-/media/453448D7D79948B39D5851D1FF2A0CFE.ashx*
[6] Mayo Clinic, *Nasal Polyps, https://www.mayoclinic.org/diseases-conditions/nasal-polyps/symptoms-causes/syc-20351888#:*
[7] Asthma and Allergy Foundation of America, *Asthma Facts, https://aafa.org/asthma/asthma-facts/*

Like many chronic conditions, uncontrolled asthma can lead to further complications. Damage to airways and lungs can occur, sleep can be disrupted, pregnancy complications can arise, patients face an increased risk of infection, gastroesophageal reflux disease and obesity.[8] On average, 10 Americans die from asthma each day and nearly all deaths are avoidable with proper treatment and care.[9]

Conversely, when not facing common asthma symptoms or reducing the impact of common triggers, patients value the ability to live their daily lives, missing fewer days of work, exercising, playing outdoors with their friends or their children.

For a patient with eczema, the impact of proper treatment can be equally valuable. According to the National Eczema Association (NEA), 10% of Americans have some form of eczema. Unbearable itching can occur, lasting 12 or more hours per day. Some patients have severe pain. About a third of patients face insomnia, shorter sleep time, daytime sleepiness and fatigue. NEA states that hospitalizations due to flares of atopic dermatitis "and related infections is associated with an 8.3-year reduction in lifespan compared to the general population."[10]

Without their condition controlled, sores emerge requiring regular antibiotics. Lifestyle impacts emerge. Patients report feeling angry or embarrassed about their appearance due to their disease, causing them to limit interactions with others. They turn down job or educational opportunities. Children and teens are bullied because of their disease. Mental health can suffer as feelings of isolation, frustration, helplessness and sadness set in. Economically speaking, NEA reports "nearly 5.9 million work days annually are lost due to eczema."[11]

SKYRIZI

Plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis are all treated with Skyrizi. The inflammatory bowel diseases can be life-threatening, while psoriatic arthritis can be debilitating, and plaque psoriasis can be associated with severe complications. Like other treatments chosen for assessment, prescribers value Skyrizi in their toolbox because of its versatility. It is not uncommon for psoriatic arthritis and inflammatory bowel disease to occur simultaneously, and Skyrizi is one of only two drugs in its class that are approved to treat the joint, skin and bowel conditions.

Clinicians also note that the medical benefits of this drug can be life-changing for patients, and switching to another drug on the PDAB's therapeutic alternative list may be inappropriate for

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[8] Asthma.com, *Uncontrolled Asthma's Effects Over Time,* https://www.asthma.com/treating-asthma/effects-of-asthma/
[9] Asthma and Allergy Foundation of America, *Asthma Facts, https://aafa.org/asthma/asthma-facts/*
[10] National Eczema Association, *Eczema Stats, https://nationaleczema.org/research/eczema-facts/*
[11] ibid

the patient's condition. Moreover, when talking about autoimmune diseases, it is important to understand that people sometimes have an initial response to a treatment followed by a change in their immune system which causes them to need a different treatment. Similarly, a patient switched to another drug followed by a return to the original drug may find that the original drug does not work anymore due to changes in the immune system. Therefore, prescribers value access to multiple treatments with a variety of mechanisms of action and the ability to maintain access to the treatment as long as it's working.

Among psoriasis patients, plaque psoriasis is the most common type of psoriasis and causes scaly, itchy, painful patches on skin.[12] If not controlled, this can lead to frequent complications such as infections, requiring additional doctor visits and treatments. Psoriatic skin disease can cause superinfections than can lead to life-threatening sepsis. Unfortunately, about one in three people with plaque psoriasis will develop psoriatic arthritis.[13]

For patients whose psoriatic arthritis is newly controlled by proper, effective treatment, the elimination of joint inflammation leads to incredible gains in quality of life. Where their disease can be deforming, debilitating and deadly due to an increased risk of early heart disease, and it had previously caused them to be unable to work or do hobbies, play with their kids or be active in their communities, effective treatment allows them to function, work, and go about their daily lives.

Meanwhile patients with inflammatory bowel disease face persistent diarrhea, abdominal pain, bleeding, weight loss and fatigue.[14] This disease puts patients at risk for gastrointestinal cancer and can lead to removal of portions of the gastrointestinal tract. If the disease is active, the patient may be bleeding and not absorbing food, which can be deadly. With proper treatment, symptoms can be managed, and disease progression can be slowed or stopped, preventing these outcomes.

Unfortunately, inflammation in the gut, skin and joints can flare relentlessly and simultaneously. Without proper treatment, this can lead to worse health outcomes and absorption of more medical resources, time and cost for the system and the patient.

CONCLUSION

Each treatment selected for review by the Maryland Prescription Drug Affordability Board provides unique value to prescribers and the patients they treat.

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[12] National Psoriasis Foundation, *Plaque Psoriasis,* https://www.psoriasis.org/plaque/
[13] National Psoriasis Foundation, *About Psoriasis,* https://www.psoriasis.org/about-psoriasis/
[14] CDC, *What is inflammatory bowel disease?,* https://www.cdc.gov/ibd/what-is-IBD.htm#

In each instance, prescribers value the ability to treat their patients more efficiently and holistically as the conditions the drugs treat often exist simultaneously (i.e. psoriatic arthritis and inflammatory bowel disease) or create greater risk for each other (i.e. diabetes and cardiovascular disease). To be able to effectively treat one condition while also lowering the risk of another with one medication is impactful to their practice of medicine. While there may be other treatments for each indication, each drug listed is a valuable tool in the toolbox for doctors as they assess the medical needs of each individual patient.

Patients value the ways these treatments change their lives for the better. What was once a deadly diagnosis is something that can now be managed. They now have the power to control their symptoms and do things many Americans may take for granted – work, play, interact with friends, family and colleagues in a meaningful, productive way, exercise, go outside, and even simply breathe normally.

While it may be difficult to properly quantify the value doctors find in these treatments or that patients receive in terms of quality of life, these benefits cannot be ignored when considering cost and affordability. The Value of Care Coalition asks that as the Board evaluates the affordability of the treatments its chosen, it considers the value these treatments provide to clinicians and patients in Maryland.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition

Exhibit 6B-

Written Comments

(Request October 28, 2024)

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

November 8, 2024

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

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

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

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first.

On behalf of our national network of patient organizations, we appreciate the opportunity to provide comments to the board on Jardiance. We continue to urge the board to carefully evaluate the impact implementing UPLs could have on patients in the state and to consider the concerns of patient organizations as they proceed with cost reviews and consideration of UPLs.

Ensure Patients Will Benefit from Cost Reviews

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

Therefore, we urge the board to focus its time on identifying and addressing patient-reported obstacles to drug affordability. Failing to resolve the underlying factors that lead to higher costs for patients can result in short-term relief and uneven benefits – aiding some but potentially leaving others with higher costs and drug accessibility challenges. Additionally, regulators should clearly define cost-saving targets, including what percentage will be for patients and what will be the state or the broader healthcare system.

Enact Patient Protections

At their core, cost reviews necessitate selecting individual drugs for review and implementing market interventions for the selected drugs. This alone puts PDABs in a position of picking winners and losers between drugs and within the broader population of Maryland patients.

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies. We appreciate the board's recognition that this could be a consequence of UPL implementation; however, we are disappointed that the board only intends to monitor for these changes after the UPL has been implemented.

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

Focus on Patient Experiences and Perspectives

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

We urge that the board utilize the cost review process to gather more in-depth input from patients in the form of roundtables or focus groups. We urge the board to utilize this organization and its members as a direct conduit to understanding and incorporating patient and caregiver perspectives, as well as those of patient organizations who have an understanding of the life cycle of disease from the lens of prevention, diagnosis, and disease management.

While our health system and the policies that impact it are complicated, one principle is simple: every change that we make and policy we implement should ultimately benefit patients. We urge the board to keep this principle as a singular focus of the policy review process.

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

Sincerely,

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

Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

Jardiance

Lynnette McCollum [redacted] > Tue, Oct 29, 2024 at 6:11 PM
To: comments.pdab@maryland.gov

I am a retired senior citizen and my doctor at Kaiser recently put me on jardiance for diabetes. The cost for the medication is over $50. This, in addition to all my other insulins and medications, is too much for my budget and I am at a point where I may have to make decisions as to which medications I can afford to continue.

--
Lynnette
Jardiance

[redacted]

Exhibit 6C-

Written Comments

(Request January 27, 2025)

EACH PIC COALITION

January 22, 2025

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

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

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

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

On behalf of our national network of patient organizations, we appreciate the opportunity to provide comments to the board on Jardiance. We continue to urge the board to carefully evaluate the impact implementing UPLs could have on patients in the state and to consider the concerns of patient organizations as they proceed with cost reviews and consideration of UPLs.

Ensure Patients Will Benefit from Cost Reviews

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

Therefore, we urge the board to focus its time on identifying and addressing patient-reported obstacles to drug affordability. Failing to resolve the underlying factors that lead to higher costs for patients can result in short-term relief and uneven benefits – aiding some but potentially leaving others with higher costs and drug accessibility challenges. Additionally, regulators should clearly define cost-saving targets, including what percentage will be for patients and what will be the state or the broader healthcare system.

Enact Patient Protections

At their core, cost reviews necessitate selecting individual drugs for review and implementing market interventions for the selected drugs. This alone puts PDABs in a position of picking winners and losers between drugs and within the broader population of Maryland patients.

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies. We appreciate the board's recognition that this could be a consequence of UPL implementation; however, we are disappointed that the board only intends to monitor for these changes after the UPL has been implemented.

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

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

Focus on Patient Experiences and Perspectives

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

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

While our health system and the policies that impact it are complicated, one principle is simple: every change that we make and policy we implement should ultimately benefit patients. We urge the board to keep this principle as a singular focus of the policy review process.

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

Sincerely,

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

PUBLICCITIZEN
1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

Jardiance

Maryland is working to support affordability through its Prescription Drug Affordability Board (PDAB), while advocates press for the expansion of this authority to help more residents. Among the drugs up for review by the PDAB is Jardiance (empagliflozin). Jardiance is sold by Boehringer Ingelheim and Eli Lilly and is used to treat diabetes and heart failure.

As Boehringer Ingelheim and Eli Lilly reaped huge profits by charging Americans over 11 times more than they charge comparable countries for Jardiance, Eli Lilly spent billions on self-enriching activities like executive compensation, stock buybacks (a practice where a company repurchases shares, thereby inflating stock prices and enriching shareholders—including executives often paid in stock), and dividends (another way publicly traded companies return cash to investors).

Boehringer Ingelheim and Eli Lilly have made billions from Jardiance.

- Jardiance has generated **over $26.8 billion in sales since its launch in 2014.**
- Revenues obtained through Jardiance sales are nearly **38 times** the median cost for research and development of a new drug estimated by experts.

Boehringer Ingelheim and Eli Lilly charge Americans the highest price in the world for Jardiance.

- Jardiance's list price is $611 for a 30-day supply — this is 11.7 times higher than the average price across comparable countries ($52), according to a recent analysis.

Boehringer Ingelheim and Eli Lilly ripping us off is even more egregious considering significant taxpayer contributions to research prior to the approval of Jardiance, including $434.2 million[3] in NIH funding for basic and applied research.[4]

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

- According to Public Citizen research, Boehringer Ingelheim's patents covering methods for screening patients for use of empagliflozin can be exploited to exclude generics until as late as 2034 — an extra five years beyond the expiry of the drug compound patent and almost 20 years beyond the drug's initial approval.

Eli Lilly[5] spends huge sums on payouts to executives and shareholders, rather than R&D.

- In 2023 alone, Eli Lilly spent nearly $6 billion enriching shareholders through stock buybacks and dividends, maintaining its exorbitant executive compensation, and advertising its products.
- Since 2017, Eli Lilly has spent an average of over $1 billion on advertising each year. This is more than the total retail sales for prescription drugs covered by Medicaid in Maryland in 2019.

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

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

[5] Eli Lilly and Boehringer Ingelheim commercialized Jardiance together, but the latter company is privately held. Thus, data on self-enriching activities is only available for Eli Lilly.

Exhibit 6D-

Written Comments

(Request June 18, 2025)

One Park Place, Suite 475 | Annapolis, MD 21204
866-542-8163 | Fax: 410-837-0269 | aarp.org/md
facebook.com/aarpmd | md@aarp.org | X: @aarpmd

July 1, 2025

To the Members of the Maryland Prescription Drug Affordability Board:

AARP Maryland, on behalf of its more than 850,000 members in the state, urges the Maryland Prescription Drug Affordability Board (PDAB) to move rapidly to adopt Upper Payment Limits (UPLs) on Jardiance and Farxiga. The cost savings that will result from the first two UPLs adopted by the board are both critically needed and clearly warranted, as the PDAB's own research has found. These two drugs are very widely used for treating diabetes, heart failure and chronic kidney disease, and their lofty and rising prices are major cost drivers for state and local government entities that would benefit from these UPLs.

Putting these UPLs into effect sooner rather than later is important for multiple reasons. First of all, the savings involved are large and will aid both the state and local government agencies at a time when they are severely challenged financially, as are their employees and dependents who also will benefit. Second, these two drugs not only are very high priced and show a history of recent significant price increases, but they also are critically needed by patients. It is with such factors in mind that the federal government chose these two Rx drugs as among the first batch for Medicare's own negotiated drug prices.

AARP Maryland also urges the PDAB to be wary of comments from entities, purportedly representing patient organizations, urging delays in the UPL process. Some of these groups draw their principal financial backing from pharmaceutical producers and other entities in the Rx drug industry. And they are acting in the interests of their sponsors rather than of patients themselves. This has become apparent in comments submitted to, or presented at, meetings of the PDAB's Stakeholder Council, of which I am a member. For instance, one recent comment urged the PDAB to work with the Maryland legislature to put in place unspecified "safeguards for patients" prior to moving forward with UPL policies. This comment fails to recognize everything the PDAB already has done to ensure that UPLs are applied in the right way.

It has been more than six years since the law establishing the PDAB was enacted. During that time, the board has been meticulously preparing for the start of UPLs, keeping all stakeholders informed in the process. It very carefully selected the initial drugs for UPLs, using the federal government's research as well as its own to decide that Farxiga and Jardiance are the right products to start with. And it has kept all stakeholders informed throughout the process of what it plans to do and why. AARP Maryland commends the PDAB for all these steps and urges it to go forward with the initial UPLs now.

Sincerely,

James Gutman
AARP Maryland Health Care Advocacy Volunteer Lead
and PDAB Stakeholder Council Member

Boehringer Ingelheim

July 09, 2025

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

Dear PDAB Board Members and Staff,

Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer) is sending this letter in response to the cost dossier published by the Maryland Prescription Drug Affordability Board (PDAB) for Jardiance (empagliflozin). Boehringer is a research driven company with approximately 53,500 employees around the world dedicated to the discovery and development of breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, we create value through innovation in areas of high unmet medical need focused on breakthrough therapies and first in-class innovations for the patients we serve. We share a common goal with Maryland PDAB to ensure affordability and access for patients to medicines. Given our limited time to respond, enclosed is high level feedback we strongly encourage Maryland PDAB to consider in order to develop meaningful reform. We remain committed to working with the Board and its staff to develop solutions that help patients better afford their medicines.

Price-setting tactics do not consider the complexity of US drug pricing and do not address individual patient out-of-pocket (OOP) costs or affordability.

Evaluating cost impact of Jardiance to the state of Maryland by looking at "total gross spending" in Section 4 of the dossier is an inaccurate and misleading metric to assess pricing and patient affordability because it does not reflect actual spend or patient OOP costs. Gross sales do not reflect the substantial rebates and discounts, which may be both mandatory (such as to Medicare and Medicaid programs) and discretionary (such as rebates to commercial health plans), and to various stakeholders involved in the supply chain. These rebates and discounts are a competitive market requirement to ensure formulary coverage and access to Jardiance and may be used by payers to subsidize benefit costs across members, but do not directly benefit the individual patient taking Jardiance. Price-setting approaches, like imposition of an "upper payment limit," could further exacerbate, not alleviate, access barriers for patients and impede Boehringer's R&D investments into treatments for unmet needs.

Furthermore, evaluating "total number of patients in the State using [Jardiance]" reflects a *system* level budget impact of drug cost, whereas patient affordability assesses *individual patient* OOP burden and access to therapy. Conflating the two can lead to conflicting conclusions and undermine the transparency and predictability necessary to complete an analysis. For example, Factor 7.7 attempts to project gross spending for Jardiance "if all patients used a full year of treatment" based on the annual WAC cost. Even if this analysis included the more accurate actual cost of Jardiance to Maryland after discounts and rebates were applied and real-world adherence patterns, the output would still be wholly irrelevant to what individual patient OOP costs are for Jardiance and overall patient affordability.

Inconsistent and missing information suggest additional time and resources are needed to conduct an accurate assessment of Jardiance.

Boehringer recognizes the challenges to appropriately evaluate a product like Jardiance with four FDA-approved indications, extensive and comprehensive clinical and real-world evidence data, and a broad Cardiovascular Renal Metabolic (CRM)–eligible patient population that is often comorbid and

complex. However, given the significant implications of any price-setting measures to patients and access, it is imperative that resources and attention to detail in the materials used in this decision-making process, including the development of a publicly available dossier, be commensurate to the task.

In Section 2.2 of the dossier outlining the "disease burden of the condition that is treated by the prescription drug product," Boehringer observes that only 3 of the 4 indications for Jardiance are mentioned: Type 2 Diabetes Mellitus (DM), Heart Failure (HF), and Chronic Kidney Disease (CKD).[1] The use of Jardiance to reduce risk of cardiovascular death in DM patients with established cardiovascular disease (eCVD) is absent despite eCVD being the most prevalent of the 4 CRM diseases in Maryland (41.3%, compared to 13.4% with HF, 28.4% with DM, and 6.4% with CKD).[1,2]

Similarly, there is inconsistent reporting of information across the 4 indications further suggesting that any analyses or conclusions made from the information in the dossier would be incomplete. The dossier includes that the "diabetes-attributable total and per-person productivity losses due to morbidity were $3.4B and $6,224, respectively" in 2021 in Maryland. However, no similar figures are reported in the HF and CKD sections, and eCVD is absent entirely.

Boehringer must also note that "dapagliflozin", rather than "empagliflozin", the correct chemical name for Jardiance, was listed on page 64 as the search term used by staff to search for relevant articles in the dossier. This, along with numerous other misspellings throughout the document, raises concerns of invalid word searches and review. Several links that are referenced in support of the dossier are also missing or invalid (please see appendix for full list). These inaccuracies may lead reviewers to incorrect or incomplete conclusions.

There are limited conclusions that can be drawn from claims and pricing analyses with redacted or incomplete source information.

As stated above, drug pricing in the US is multifaceted and involves several interrelated factors across a variety of stakeholders, including, but not limited to, manufacturers, payers, distributors, wholesalers, pharmacies, and patients. While Boehringer appreciates the attempt to consider some of these factors in the dossier, there are inherent limitations with prescription claims data as well as the sources Maryland PDAB cited for its pricing assumptions.

Claims data, even if complete, is most appropriate to evaluate specific moments in time or *trends* in drug utilization. On its own, however, claims data cannot inform what the specific cause or drivers are for any observed trends. For example, the analyses in Factor 7.1 to estimate the "impact on patient access resulting from the cost of [Jardiance] relative to insurance benefit design" attempts to compare reported patient OOP costs to the change in utilization or "number of prescriptions a patient has in a year." Regardless of the results, a *causal* relationship cannot be confirmed. Changes in an individual patient's utilization may or may not be related to OOP cost or more plainly, patient OOP cost is only one of many factors that may influence utilization.

It's also critical to note that final patient OOP costs in claims data are rarely accurate, especially in the commercial channel, because secondary insurance or manufacturer copay programs that further reduce patient responsibility are not included. For Jardiance, 47% of Commercial *claims*, not patients, in Maryland utilized the copay program as of June 2024,[3] which means the OOP spend of nearly half of all Commercial claims included in the analysis would be overestimated.

Lastly, Boehringer strongly cautions that any assumptions related to commercial or Medicare rebates and net pricing from SSR health may not be accurate and should not be uniformly assumed across all payer channels or calendar years. For example, in Factor 5.2, Maryland PDAB attempts to estimate "net sales amounts of [Jardiance]" by applying the most recently available SSR rebate estimate (2024 Q2) to 2023 Commercial and 2022 Medicare gross sales.

The dossier does not recognize the transformative value of Jardiance across 4 CRM conditions.

Jardiance is a transformative medication that addresses multiple interconnected diseases with a single once-a-day oral[1] treatment. The well-established safety profile and holistic approach to treatment offered by Jardiance has led to a paradigm shift in the management of CKD, HF, and DM, as recognized by professional guidelines and FDA Fast-Track designations. Despite this, Factor 2.1 "clinical information" and 2.2 "disease burden of the condition that is treated" does not mention this overlap of CRM conditions that Jardiance treats, nor the significant economic and clinical value of a single oral treatment across these comorbid conditions. Traditional claims data, which are cited in the dossier, often fails to capture the full spectrum of cost savings from improved patient outcomes, such as reduced hospitalizations, fewer ER visits, enhanced productivity, and lower mortality rates, thereby underrepresenting Jardiance's true value. Jardiance provides substantial cost savings across its CRM indications by lowering healthcare expenses. For patients with T2, Jardiance results in annual savings of $13,704 per patient per year compared to other antidiabetic medications, including an approximate 50% reduction in medical costs.[4] This includes a 60% reduction in emergency room (ER) costs, a 37% reduction in outpatient costs, and a 62% reduction in inpatient costs.[4] Heart failure patients, with or without type 2 diabetes, experience annual savings of $14,271 per patient per year and a 53% reduction in medical costs with Jardiance.[4] For chronic kidney disease patients, annual expenses range from $8,700 to $144,000 for those 65 and under, with medical costs comprising 93.6% and prescription drug costs 7.4% of all costs.[5,6]

Jardiance is already affordable for Maryland patients.

Boehringer remains committed to ensuring Jardiance remains accessible and affordable for all patients in Maryland. In 2024, the average commercial OOP cost for State of Maryland employees (net manufacturer assistance and copay card support) was $32.40 for both 30-day and 90-day prescriptions.[7] This amount is lower than the average commercial OOP cost of Jardiance for the State of Maryland, which was $44.13, and the national commercial average OOP cost of Jardiance which is $44.41.[7] Additionally, the copay for Jardiance, as a preferred formulary product, is $25 for patients enrolled in the Maryland Commercial and Employer Group Waiver Plans (EGWP) and $15 for Maryland State Law Enforcement Labor Alliance (SLEOLA) employees.[8] The lower copay for State of Maryland Employees and 47% commercial utilization rate of Boehringer's copay assistance program mentioned above highlight Jardiance as an accessible, affordable, and highly efficacious treatment option for a wide range of patients in Maryland.

Boehringer works collaboratively with partners to help patients afford their medications by enrolling in programs that also help them stay compliant and adherent to their therapy. Our goal behind our efforts working across the healthcare ecosystem is to improve patient outcomes and minimize the need for additional healthcare services like routine lab visits or expensive hospitalizations, or search for other affordable options for their medications.

Boehringer respectfully urges the Board to consider the above information and the implications of price setting tactics—like imposing an "upper payment limit"—due to the complexities of the prescription drug supply chain. Jardiance is a transformative therapy for patients in Maryland with serious, costly, and inter-related CRM conditions. Jardiance provides clinical and economic value for these patients via broad access, highly discounted pricing and low OOP cost that already benefits patients.

APPENDIX

The following links do not lead to a valid webpage:

a. Page 2: https://pdab.maryland.gov/index.html
b. Page 22 – reference 45: https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/summarysupplemental-applications-proposing-labeling-changes-approved-drugs-and-biologicalproducts
c. Page 23 – reference 53: https://www.fda.gov/advisory-committees/endocrinologic-and-metabolicdrugs-advisory-committee/june-28-2016-meeting-endocrinologic-and-metabolic-drugsadvisory-committee
d. Page 65 – reference 66: https://www.cms.gov/priorities/medicare-prescription-drugaffordability/overview/medicare-drug-price-negotiation-program/selected-drugs-andnegotiated-prices

REFERENCES:

1. JARDIANCE® (empagliflozin tablets), for oral use. Prescribing Information. Boehringer Ingelheim; 2023.
2. Torch Insight - Analysis of 2021 Medicare Claims limited data sets, 2017. Salt Lake City, UT. Data retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets
3. RelayHealth Pharmacy Solutions. Data run September 2024.
4. Data on File. Boehringer Ingelheim Pharmaceuticals, Inc. 2024
5. Golestaneh L, Alvarez PJ, Reaven NL, et al. All-cause costs increase exponentially with increased chronic kidney disease stage. *Am J Manag Care*. 2017;23(10 Suppl):S163-S172.
6. U.S. Bureau of Labor Statistics. CPI for All Urban Consumers (CPI-U): Medical care in U.S. city average, all urban consumers, not seasonally adjusted. January 2022-December 2022.
7. IQVIA Longitudinal Access and Adjudication Data (LAAD). Data run September 2024.
8. MedImpact Healthcare Systems, Inc. MedImpact Prescription Handbook. Maryland Department of Budget and Management. 2023. Accessed July 1, 2025. https://dbm.maryland.gov/benefits/Documents/CY25%20Medimpact%20Prescription%20Handbook.pdf

EACH PIC COALITION

July 3, 2025

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

RE: Public Comments on Jardiance Dossier

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

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

On behalf of our national network of patient organizations, we appreciate the opportunity to provide comments to the board on Jardiance. We continue to urge the board to carefully evaluate the impact implementing UPLs could have on patients in the state and to consider the concerns of patient organizations as they proceed with cost reviews and consideration of UPLs.

Comment Deadlines and Complexity of Process

While we appreciate the board's continued effort to implement a transparent and thorough cost review process, we again must emphasize that Maryland has established an incredibly complex process with multiple and overlapping deadlines for comment. Further, providing only a 15 day comment period on the dossiers for Farxiga and Jardiance is inadequate to allow for substantive analysis and response.

We again urge the board and staff to provide greater clarity around the cost-review process as a whole and provide a minimum 60-day comment period on data related to cost reviews and UPL implementation.

Centering the Process on Patient Burdens and Affordability

We continue to encourage the board to center cost reviews around the lived experiences of patients and the real-world affordability challenges they face. A review that focuses solely on systemic or payer-level costs risks overlooking the most meaningful aspect of affordability: the context behind affordability concerns, including the impact on people's ability to access and adhere to their prescribed medications.

We urge the board to make good on its commitment to consider multiple policy interventions, by utilizing the cost review process to clearly identify the root causes of affordability and access challenges for patients for each drug under review.

Therapeutic Alternatives Are Not Interchangeable

The course of treatment for each patient is as unique as the individual and their disease. Once diagnosed with a chronic condition, each patient starts an often life-long journey to identify the correct treatments and regimen to successfully manage their symptoms and improve their

health. Many will also face multiple chronic conditions or need medications to treat specific symptoms or even side effects of their preferred treatment. Patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered.

For these patients, therapeutic alternatives may not be alternatives at all. Very often drug interactions or other health conditions would prevent individual patients from being able to switch to an alternative medication that, on paper, seems like it would be an appropriate treatment. Further, patients with chronic conditions can build up a tolerance to medications over time, so they must retain access to all treatments in a class of drugs to prolong their treatment.

Therefore, we urge the board to carefully evaluate the needs of all patients. Failure to do so can result in limiting options within a therapeutic class to only one option - which might not be the right option for many patients.

Protect Patient Access to Care

At their core, cost reviews necessitate selecting individual drugs for review and implementing market interventions for the selected drugs. This alone puts PDABs in a position of picking winners and losers between drugs and within the broader population of Maryland patients.

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies.

We encourage the board to take the necessary time and care to ensure this process supports, not disrupts, continuity of care. Patients must not face unintended consequences from policy decisions that limit treatment options or impose additional burdens.

To that end, we strongly urge the board and staff to utilize the authority of the board to fully explore with all healthcare stakeholders how they will implement UPLs to identify in advance any potential adverse impact to patients.

Finally, we invite the board to utilize this organization and its EACH and PIC members as a direct conduit to understanding and incorporating patient and caregiver perspectives, as we have the best understanding of the life cycle of disease from the lens of prevention, diagnosis, and disease management.

We appreciate your commitment to this work and offer our coalition as a continued resource in elevating patient voices and informing thoughtful, patient-centered policymaking.

Sincerely,

Tiffany Westrich-Robertson
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

DOSSIER COMMENT - Jardiance

1 message

Joan Leahy [redacted] > Thu, Jun 19, 2025 at 8:18 AM
To: comments.pdab@maryland.gov

Affordability problem - with Part D, this medication costs us approximately $400/month until we reach the $2000 cap set by Medicare this year. Already taking much less expensive medication Metformin, so not an alternative choice.

Sent from Yahoo Mail for iPhone

July 2, 2025

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff;

The Maryland Health Care for All Coalition (HCFA) is pleased to offer our support for the work the Prescription Drug Affordability Board (PDAB) and its staff are doing to complete the Cost Review Study for Jardiance, including the published dossier.

Jardiance is widely used for treating diabetes, heart failure, and chronic kidney disease, and we know from the Board's work and previous public comment that its high cost has harmed Maryland patients and is a direct contributor to the immense strain that expensive prescription drugs place on our state and local government budgets. Comment submitted by Public Citizen for the January 2025 Board meeting indicated that Jardiance has generated more than $28 billion in revenue for AstraZeneca, largely from charging patients in the United States over eleven times more than in comparable countries. Predatory patenting tactics have extended the monopoly on this product, keeping costs to patients and our health care system higher for longer.

We have held forums across the state in past years, and routinely heard from patients about their struggle to afford Jardiance. One patient wrote, "I'm on Medicaid and if I ever make just enough to not be on Medicaid I won't be able to afford this medication [Jardiance] which works tremendously well for me. I forgot to take it for about 3 or 4 days a few months ago and my blood sugar went up, I started having neuropathy in my feet, I felt constantly tired, and that's what made me look to see if I had the Jardiance in my 'pill minder' and I didn't. **Within a day back on the Jardiance I was feeling better. It is a serious worry for me – not being able to afford the drug that is keeping me health and functional so I can still work.**"

We know this issue extends beyond the pharmacy counter for patients, as anti-diabetics are the single biggest expenditure for the state health plan, meaning our state and local governments are burdened by the skyrocketing costs of these medications. It is important that the Board acts quickly to establish an upper payment limit for this prescription drug, along with Farxiga, so that taxpayers can begin to save millions of dollars that are essential for other critical services.

Importantly, since Jardiance is on the CMS list of Medicare Maximum Fair Price negotiated products, the Maryland PDAB could utilize this negotiated cost as an upper payment limit for our state. An estimated 19,000 state residents on Medicare use Jardiance, and we look forward to the savings these Marylanders will see come January 1, 2026 when the negotiated price is utilized. We encourage the PDAB to build on this progress to generate real savings to the state.

2600 St. Paul Street Baltimore, MD 21218
www.healthcareforall.com
Phone (410)235-9000 Fax (410)235-9000

Our coalition thanks the PDAB for its great work so far and encourages thoughtful, swift action on this matter. Should the Board and Staff wish to speak to Maryland patients regarding their experiences with Jardiance, we would be happy to connect you with consumers willing to provide feedback.

2600 St. Paul Street Baltimore, MD 21218
www.healthcareforall.com
Phone (410)235-9000 Fax (410)235-9000

July 3, 2025

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

Re: FARXIGA AND JARDIANCE COST REVIEW DOSSIERS

Dear Members of the Board,

As a broad network of patient, caregiver, and health care provider advocacy organizations, the Value of Care Coalition (VCC) writes to share concerns regarding the recently published cost review dossiers on Farxiga and Jardiance. We appreciate the Board's commitment to reviewing one aspect of health care affordability in Maryland and value the opportunity to submit these comments.

VCC's July 2024 comments, which can be found within Exhibit 4A of each dossier, emphasize the belief that no discussion of prescription drug affordability is complete without consideration of value. We believe value is best defined by patients who receive the life-changing benefit of these treatments and by clinicians who weigh individual risks, comorbidities, and long-term outcomes of these treatments.

The current dossiers for Farxiga and Jardiance reflect great effort to compile certain data points but ignore others through their omission. The only instances highlighting the perspectives of stakeholders closest to the drugs being reviewed are relegated to exhibits containing a handful of written comments regarding each drug.

The dossiers lack any data on why clinicians prescribe these specific drugs, why patients choose these drugs, or how health outcomes would be impacted without these drugs. Data is not included regarding the value to the society that these drugs provide – whether it be direct savings from additional health care services that are no longer needed thanks to the slowed disease progression or prevention these treatments provide, or the economic benefit received through the increased productivity of patients whose conditions are now stable.

The dossiers, as they stand, reflect little effort to understand the value these treatments provide to health care providers and the patients they serve.

The Value of Care Coalition urges a focus on thorough, complete processes and re-refers the Board to its previous comments dated July 22, 2024, informed by prescribers of each treatment, for a brief summary of the value they and their patients perceive in these innovative, life-changing medications. As we wrote nearly a year ago:

"While it may be difficult to properly quantify the value doctors find in these treatments or that patients receive in terms of quality of life, these benefits cannot be ignored when considering cost and affordability. The Value of Care Coalition asks that as the Board evaluates the affordability of the treatments its chosen, it considers the value these treatments provide to clinicians and patients in Maryland."

Thank you for your willingness to consider stakeholders' perspectives of value. Each affordability review will benefit from the input of the full range of stakeholders, particularly patients and healthcare providers.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition

APPENDIX B-
July 28, 2025
Jardiance Resolutions

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

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

WHEREAS, the Board selected Jardiance for study; and

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

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

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

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

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

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

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

It is hereby

RESOLVED that:

The Board makes a preliminary determination that use of Jardiance:

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

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

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

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

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

(3) total gross spending for Jardiance for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments (public session).

Be it **FURTHER RESOLVED** that:

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

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

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

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

_____