# Ozempic (semaglutide)-
# Cost Review Study Report

Maryland Prescription Drug Affordability Board

May 11, 2026

Version 2.0

MARYLAND
Prescription Drug Affordability Board

Van T. Mitchell
**Board Chair**

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Van T. Mitchell **Board Chair**

Stephen Rockower, **Board Member**

MARYLAND
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Julia Slejko, Ph.D. **Board Member**

Georges Benjamin, M.D. **Board Member**

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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

This document reflects the cost review study report for Ozempic. 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 the 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.

Ozempic is a drug used for patients with type 2 diabetes (T2DM), 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 Ozempic. Initially, Ozempic was approved for T2DM before getting additional indications. The use of Ozempic was spread across multiple NDCs, but when added together made up almost 4.87% of the gross drug spending in some market segments. On a list price basis, the data suggested that Ozempic had prices (not including rebates) in excess of $11,000 per year. However, rebates substantially reduced the average net price of the drug. Generally, the use of Ozempic was associated with higher spending but better health outcomes. Finally, the average out-of-pocket (OOP) costs for the two most common NDCs (00169-4130-13 and 00169-4181-13) were $258.21 and $241.02 respectively for the full year of 2023 for patients with commercial insurance (Table 21). The average OOP costs for state and local government beneficiaries utilizing the same NDCs were $90.16 and $77.32, respectively (Table 21).

During the in-person Board Meeting on November 17, 2025, the Board considered whether use of Ozempic 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 Ozempic (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. An amended version of this resolution is included as an Appendix B.

# Background

Established in 2019, the Maryland Prescription Drug Affordability Board ("Board") is an independent agency charged with "protecting State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drugs." Md. Code Ann., Health-Gen. ("HG") § 21-2C-02(b). The Board confers with, and receives input from, a 29-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 Ozempic for study to determine whether use of the drug has or will create an affordability challenge.

Board Staff developed the 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.

On November 17, 2025, the Board, at an open in-person Board meeting, considered whether use of Ozempic 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 met in closed session to review and discuss certain proprietary, trade secret and confidential information concerning Ozempic. The Board voted unanimously to make a preliminary determination that Ozempic has created an affordability challenge to the State health care system and high out-of-pocket costs for patients, and identified one circumstances under which use of the prescription drug product has led to an affordability challenge: at the 90th percentile patient out-of-pocket cost to state and local government markets is disproportionate to the net cost paid by payors. The Board then adjourned the closed session.

The Board met in open session and made a preliminary determination that use of Ozempic has created an affordability challenge for the State health care system and identified one circumstance under which use of the prescription drug product led to the affordability challenge: total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments (public session).

The Board adopted Resolution 2025-03, which ratified the closed and open session preliminary determinations.

The Board Chair subsequently observed that, based on the calculations and methods used when analyzing and discussing another drug in closed session (clarifying that certain data was provided on an annual versus monthly basis), it was apparent that resolution 2025-03 should be amended to strike and rescind the finding that Ozempic created an affordability challenge based on the following circumstance: at the 90th percentile patient out-of-pocket cost in state and local government markets is disproportionate to the net cost paid by payors. The sole remaining preliminary determination of an affordability challenge is, therefore, based on the circumstance that total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments (public session). The Board voted unanimously to amend Resolution 2025-03.

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 the 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 final Dossier and exhibits are incorporated as Appendix A.[1]

The Board reviewed and considered the Dossier and exhibits as well as a PowerPoint presentation 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.

Ozempic is approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM), to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD), and to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease (CKD). The Dossier assessed the clinical guidelines for each indication.

GLP-1 RA (the therapeutic class in which Ozempic belongs) is a preferred drug class in the treatment of T2DM. GLP-1 RAs are typically considered as a first line therapy option for T2DM given the overall safety (low risk of hypoglycemia), effectiveness in lowering blood sugar, and

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

CKD and CVD benefits and protection. SGLT2 inhibitors have demonstrated similar outcomes and are an alternative first-line therapy. Metformin, a biguanide, is also considered first line therapy with effectiveness in lowering blood sugar, low hypoglycemia risk, and potential CVD benefit; but has not demonstrated benefit in progression of CKD. Ozempic, Trulicity (dulaglutide), and Victoza (liraglutide) are the preferred choices in this class for medical professionals given their proven benefits for CVD and CKD. Trulicity and Ozempic (semaglutide) require less frequent injections (weekly) than Victoza (liraglutide, daily).

T2DM is disease of great importance to public health. It is a major source of morbidity and mortality in the state and has severe public health consequences. The additional benefits for the indications with comorbid diseases is also of public health importance because data suggested high commodity rates between T2DM, CVD, and CKD.

**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

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

FDA has recently listed Ozempic as in shortage, but that is now resolved. Semaglutide products were listed as in shortage from 03/31/2022-02/21/2025. In listing this shortage, FDA noted that Wegovy products were listed as "unavailable" while Ozempic products were listed as available.

According to patent data, Ozempic has a number of patents. Ozempic had multiple patents listed as drug substance or drug product patents, the last of which is set to expire on December 5, 2031. The last patent listed at the time of creating the Dossier expires June 21, 2033.

The manufacturer has produced other products that contain the same active ingredient as Ozempic. Rybelsus is a tablet formulation of semaglutide approved to improve glycemic control in adults with T2DM. Rybelsus utilization was much lower than Ozempic. Wegovy is a separate injectable formulation of semaglutide approved for conditions other than T2DM such as to help reduce weight in those with obesity and to reduce cardiovascular risks for those with obesity.

**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. 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, each representing different concentrations and volumes of the drug. The use of Ozempic was spread across multiple NDCs, but when added together made up over 4.87% 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 Ozempic. Staff calculated the annual pricing measures based on daily injections 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 [redacted] per year (2024 Wholesale Acquisition Cost (WAC)). The proprietary data found substantial rebates that reduced prices well below the listed prices. This proprietary data suggested an average net price (including rebates) of [redacted].

**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.

To date, the FDA has not approved any therapeutic equivalent products for Ozempic. In terms of therapeutic alternatives, the Dossier contains pricing and utilization information for a variety of drugs used to treat diabetes. Some drugs are in the same therapeutic class; other drugs are in different classes. The Dossier also contains information on published studies related to the incremental costs and incremental benefits of the drug.

Therapeutic alternatives vary widely in price. Prices for drugs in the same therapeutic class were in the same price range as Ozempic, but some of the older GLP-1s have slightly lower prices.

In terms of incremental cost and benefits, the Dossier contains studies regarding the incremental effects of Ozempic. The studies differed in terms of patient populations, pricing assumptions, and comparator products. The studies 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 Ozempic 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 Ozempic. This section contains analysis of data from the Maryland Medical Care Database (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 the use of Ozempic by priority populations, and information from the manufacturer website regarding patient assistance programs. The average out-of-pocket for the two most common NDCs (00169-4130-13 and 00169-4181-13) were $258.21 and $241.02 for the full year of 2023 for patients with commercial insurance. The averages were $90.16 and $77.32 for state and local government.

**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.

**Appendix C:** Written Comments received for the November 17, 2026 Board meeting mentioning Ozempic.

# II. Summary of Deliberations

On November 17, 2025, the Board convened to consider whether use of Ozempic 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. The Board considered the data, analyses, and information assembled in the Dossier, as presented, and the public oral and written comments received as part of the cost review process.

**Closed Session**

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

The Board considered how the wholesale acquisition cost (WAC) changed over time. The Dossier includes graphs reflecting the WAC and the WAC adjusted for inflation for each NDC. (Exhibit 1-Ozempic Pricing History (1) _Unredacted). The Board reviewed the Ozempic WAC Pricing History (Nominal vs Inflation Adjusted) graphs on page 11 of Exhibit 1, focusing on price changes for the two NDC codes (00169-4130-13 and 00169-4181-13) with the highest State and Local government gross spending in 2023.

As reflected in the charts, the Board observed no significant increase in Ozempic WAC prices (NDC 00169-4130-13 and 00169-4181-13) relative to inflation.

The Board discussed the relationship between out-of-pocket costs paid by patients and net prices. The Board reviewed Factor 5.2 (Table 12) and Exhibit 3 (Therapeutic Alternative Pricing Unredacted) to identify the Ozempic 2024 WAC [redacted] per year). Using the SSR rebate rate of [redacted], the Board multiplied the WAC by the rebate rate and subtracted that amount from the WAC to calculate the net paid to the insurer in the amount of [redacted] per year, or [redacted] per month (or per 30-day supply).

The Board reviewed Factor 7.5 (Table 21), which reflects out-of-pocket (OOP) spending for state and local government at the 90th percentile ranging from $100 to $240. Using the OOP at the 90th percentile cost of $200 (NDC 00169-4130-13 and 00169-4130-01 as benchmarks based on NDCs with the highest commercial patient utilizations; Table 9a), the Board compared the OOP cost ($200) to patients under State and Local Government health plans to the net cost of [redacted], which yielded a ratio of [redacted].

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 Ozempic has created an affordability challenge to the State healthcare system and an affordability challenge in

the form of high out-of-pocket costs to patients 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 Ozempic represents 4.87% of all prescription drug spend for state and local government (Table 9b). Citing this percentage as representing a significnt portion of drug spending, the Board member proposed that this constitutes a circumstance under which use of Ozempic has created an affordability challenge.

The Board also made the following observations and comments:

- Discussion on the data trends in Table 10a;
- A Board member noted that when summarizing Factor 6.4 and 6.5, the Cost Effectiveness Analysis and Cost Effectiveness Research, it would be helpful if the summary included the source of the data (i.e. trial, claims data, etc.);
- A Board member asked whether the State of Maryland covers Ozempic for weight loss for state employees. The drug is only being studied for approved indications; There was a question about the MCDB data and who gathers this data, especially in Element 7.3. There was inquiry regarding what other information can be pulled from the APCD (MCDB) such as information concerning priority populations and disparities; and
- A Board member observed that confidence intervals may also be helpful.

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

On November 17, 2025, the Board ratified the preliminary determination made identifying a single circumstance during the closed session, and the affordability determination and circumstance identified in open session, by adopting Resolution 2025-03 by unanimous roll call vote.

Later in the meeting, the Chair observed that, based on the calculations and methods used when analyzing and discussing another drug in closed session (clarifying that certain data was provided on an annual versus monthly basis), it was apparent that resolution 2025-03 should be amended to strike and rescind the finding that Ozempic created an affordability challenge based on the following circumstance: at the 90th percentile patient out-of-pocket cost in state and local government markets is disproportionate to the net cost paid by payors.

The Resolution 2025-03, as amended, reads, in pertinent part:

> **RESOLVED** that:
>
> The Board makes a preliminary determination that use of Ozempic:
>
> 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:
>
> total gross spending for Ozempic for state and local governments exceeds 4.87% 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.

Amended Resolution 2025-03 (Appendix B).

# APPENDIX A-
# November 4, 2025
# Ozempic Dossier

# DOSSIER CONTENTS

# Ozempic (semaglutide)-Dossier

Maryland Prescription Drug Affordability Board

November 4, 2025

Version 2.0

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Eberechukwu Onukwugha, MS, Ph.D.
**Board Member**

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**Board Member**

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Andrew York, Pharm.D., J.D.
**Executive Director**
16900 Science Drive, Suite 112-114
Bowie, MD 20715

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# Cost Review Study Dossier - Ozempic (semaglutide)

## 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 Ozempic (proprietary name) and semaglutide (non-proprietary name).[1] The NDC-11 codes were identified by staff through searching the RxNorm database.[2]

**Table 1. NDC List**

| National Drug Code | Proprietary Name | Non-Proprietary Name | Dosage-Strength |
|---|---|---|---|
| 00169-4132-90 | Ozempic | Semaglutide | 0.5 MG/1ML |
| 00169-4181-03 | Ozempic | Semaglutide | 0.5 MG/3ML |
| 00169-4181-90 | Ozempic | Semaglutide | 0.5 MG/3ML |
| 00169-4772-90 | Ozempic | Semaglutide | 2.86 MG/ML |
| 50090-5138-00 | Ozempic | Semaglutide | 0.5 MG/1.5ML |
| 50090-5139-00 | Ozempic | Semaglutide | 1 MG/1.5 ML |
| 70518-2143-00 | Ozempic | Semaglutide | 2 MG/1.5 ML |
| 00169-4181-97 | Ozempic | Semaglutide | 0.68 MG/ML |
| 00169-4132-97 | Ozempic | Semaglutide | 1.34 MG/ML |
| 00169-4132-11 | Ozempic | Semaglutide | 2 MG/1.5ML |
| 00169-4132-12 | Ozempic | Semaglutide | 2 MG/1.5ML |
| 00169-4136-02 | Ozempic | Semaglutide | 2 MG/1.5ML |
| 00169-4136-11 | Ozempic | Semaglutide | 2 MG/1.5ML |
| 00169-4181-13 | Ozempic | Semaglutide | 2 MG/3ML |
| 00169-4772-97 | Ozempic | Semaglutide | 2.68 MG/ML |
| 00169-4130-01 | Ozempic | Semaglutide | 4 MG/3ML |
| 00169-4130-13 | Ozempic | Semaglutide | 4 MG/3ML |
| 50090-5949-00 | Ozempic | Semaglutide | 4 MG/3ML |
| 00169-4772-11 | Ozempic | Semaglutide | 8 MG/3ML |
| 00169-4772-12 | Ozempic | Semaglutide | 8 MG/3ML |
| 50090-6051-00 | Ozempic | Semaglutide | 8 MG/3ML |

[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, Ozempic is referred to as semaglutide.

[2] https://www.nlm.nih.gov/research/umls/rxnorm/index.html. This list contains NDCs for products that are discontinued, and products that are not sold commercially—such as sample product NDCs, NDCs owned by repackagers and relabelers, and NDCs that contain only the active ingredient. In the interest of completeness, these NDCs are included in the dossier.

## 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: U.S. Food & Drug Administration (FDA) labels and clinical guidelines

**Summary of Clinical Information**

**Table 2. Ozempic® (semaglutide): 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 with type 2 diabetes mellitus. | **Initial dose**<br>Inject 0.25mg subcutaneously once weekly for 4 weeks<br>Increase to 0.5mg subcutaneously once weekly<br><br>**If additional glycemic control is needed, may titrate stepwise every 4 weeks to the following once weekly subcutaneous dosages:**<br>1mg<br>2mg (max dose) |
| To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. | **Initial dose**<br>Inject 0.25mg subcutaneously once weekly for 4 weeks<br>Increase to 0.5mg subcutaneously once weekly<br><br>**If additional glycemic control is needed, may titrate stepwise every 4 weeks to the following once weekly subcutaneous dosages:**<br>1mg<br>2mg (max dose) |
| To reduce the risk of sustained eGFR decline, end-stage kidney disease (ESKD) and cardiovascular (CV) death in adults with type 2 diabetes mellitus and chronic kidney disease. | **Initial dose**<br>Inject 0.25mg subcutaneously once weekly for 4 weeks<br>Increase to 0.5mg subcutaneously once weekly for 4 weeks<br>Increase to 1mg once weekly |

[3] Ozempic. Plainsboro (NJ): Novo Nordisk Inc; 2025 Feb. Package Insert. NDC 0169-4181-13.

**Standard Medical Practice Recommendations**

**Ozempic® (semaglutide) Place in Therapy for Diabetes Mellitus Type 2**

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

Ozempic and other medications in the GLP-1 RA class are recommended by the American Diabetes Association (ADA) and the American Association of Clinical Endocrinology (AACE) as one of the seven medication classes 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 Ozempic, is equal to other therapeutic options indicated for Type 2 DM (such as insulin, metformin, sodium-glucose cotransporter-2 inhibitors (SGLT2i), sulfonylurea, etc).[7] The AACE similarly considers patient specific factors and explicitly prefers GLP-1 RA (or SGLT2i) for patients with overweight or obesity or at risk of low blood sugar.[8] These guideline recommendations are in line with other major society guidelines, including the American College of 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

[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* 1 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] *Id*. at 5.
[8] *Id*. at 6.
[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.

obesity, high blood pressure, protein in urine, smoking, high cholesterol), the ADA and AACE recommend the use of GLP-1 RA with proven benefit [Ozempic, Trulicity (dulaglutide), and Victoza (liraglutide)] or SGLT2 inhibitors with proven benefit [Jardiance (empagliflozin) and Invokana (canagliflozin)] as first line therapy.[11,12] This recommendation is independent of the patient's use of other medications or glycemic control.

In adult patients with Type 2 DM and *chronic kidney disease (CKD)*, the ADA recommends as first line therapy the use of GLP-1 RA with proven benefit [Ozempic – proven benefit; Trulicity (dulaglutide) and Victoza (liraglutide) secondarily recommended due to renal benefits in cardiovascular outcome trials though not separately indicated] or SGLT2 inhibitors with proven benefit [Farxiga (dapagliflozin), Jardiance (empagliflozin), Invokana [canagliflozin]) for control of blood sugars and slowing progression of CKD. This recommendation is independent of the patient's use of other medications or glycemic control. GLP-1 RA is preferred for glycemic management in patients with advanced CKD, eGFR <30ml/min/$m^2$, due to lower risk of hypoglycemia, and for cardiovascular event reduction. SGLT2 inhibitors are not preferred for eGFR <30/min/$m^2$ as they do not effectively lower glucose at this stage of renal dysfunction.[13] The AACE recommends as first line therapy the use of SGLT2 inhibitors for adult patients with Type 2 DM and CKD.[14] The KDIGO guidelines also recommend GLP-1 RA as second-line therapy after SGLT2i in patients with Type 2 DM and CKD.[15] Discordance in guideline recommendations for this subpopulation may be explained by the cadence in which the guidelines are updated to incorporate new literature and evidence. The ADA guidelines update yearly in January, while AACE guidelines where most recently updated in 2023 and KDIGO guidelines are from 2022 (note: updated KDIGO guidelines are expected in 2025).

**Clinical use in DM Key Takeaway:** GLP-1 RA is a preferred drug class in the treatment of Type 2 DM. GLP-1 RAs are typically considered as a first line therapy option for Type 2 DM given the overall safety (low risk of hypoglycemia), effectiveness in lowering blood sugar, and CKD and CVD benefits and protection. SGLT2 inhibitors have demonstrated similar outcomes and are an alternative first-line therapy. Metformin, a biguanide, is also considered first line therapy with effectiveness in lowering blood sugar, low hypoglycemia risk, and potential CVD benefit; but has not demonstrated benefit in progression of CKD. Ozempic, Trulicity (dulaglutide) and Victoza (liraglutide) are the preferred choices in this class for medical professionals given their proven benefits for CVD and CKD. Trulicity and Ozempic (semaglutide) require less frequent injections (weekly) than Victoza (liraglutide, daily).

[11] *Id*. at 5.
[12] *Id*. at 6.
[13] *Id*. at 5.
[14] *Id*. at 6.
[15] *Id*. at 10.

## 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

**Summary of Clinical Impact: Type 2 Diabetes Mellitus (DM)**

***Prevalence***

- In the United States (US), 38.4 million (11.6%) people have diagnosed or undiagnosed diabetes mellitus (DM).[16,17] Type 2 DM accounts for 90-95% of all diagnosed cases of diabetes.[18]
- In Maryland, the total age-adjusted percentage of adults aged 18 years or older with diagnosed diabetes was 10.5% in 2022.[19]

***Incidence***

- In 2021, 1.2 million adults were diagnosed with diabetes (rate of 5.9 per 1000 people).[20,21] Worth noting, 98 million adults, more than 1 in 3 people, have prediabetes (38% of adult US population).[22,23] In individuals 65 years or older, 48.8% have prediabetes.[24]
- In Maryland, the age-adjusted rate of adults aged 18 years or older with newly diagnosed diabetes was 7.8 per 1000 in 2022.[25]

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[16] 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
[17] 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.
[18] *Id*. at 16.
[19] 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#.
[20] *Id.* at 16.
[21] *Id*. at 17.
[22] *Id*. at 16.
[23] *Id*. at 17.
[24] *Id*. at 17.
[25] *Id*. at 19.

***Comorbid Disease***

- Based on data from 2017-2020 in US persons 18 years or older with diagnosed diabetes, 39.2% have chronic kidney disease (CKD, stages 1-4) and 15.7% had moderate to severe kidney disease (stages 3 and 4).[26]
- In Maryland, as of 2023 data, 42.9% of surveyed adults 18 years of age or older with diagnosed kidney disease also have concomitant diagnosed diabetes.[27]
- 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.[28]
- Type 2 Diabetes Mellitus contributes to the development and worsening of CKD and CVD. A 2018 study of >500,000 US adults with Type 2 Diabetes Mellitus found that <10% had no associated cardiovascular or kidney disorder. These disease states in turn can initiate and perpetuate each other, leading to increased morbidity and mortality.[29]

***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.[30] 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.[31]

***Cost of Illness/Financial Impact***

[26] *Id*. at 17 [Accessed 2025 April 23].
[27] 2023 Maryland Behavioral Risk Factor Surveillance System, accessed at https://ibis.health.maryland.gov on [5 May 2025].
[28] 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.
[29] Usman MS, Khan MS, Butler J. The Interplay Between Diabetes, Cardiovascular Disease, and Kidney Disease. In: Chronic Kidney Disease and Type 2 Diabetes. Arlington (VA): American Diabetes Association; 2021 Jun. Available from: https://www.ncbi.nlm.nih.gov/books/NBK571718/doi: 10.2337/db20211-13.
[30] 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.
[31] 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.

- 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.[32]
- 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.[34]

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

[32] *Id*. at 17.
[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.
[34] *Id*.
[35] *Id*. at 17.
[36] *Id*.
[37] *Id*.

**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[38]**

| 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.

***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).[39]
- Including diabetes as a contributing cause of death, the rate increases to 120.3 per 100,000 people (399,401 death certificates).[40]
- 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.[41]

[38] *Id*.
[39] *Id*.
[40] *Id*.
[41] *Id*. at 19.

## 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

Ozempic was approved under standard review by the FDA on December 5th, 2017 for glycemic control in adults with type 2 diabetes mellitus.[42] An advisory committee was held on October 18th, 2017, to discuss the risks and benefits of semaglutide for subcutaneous injection.[43] The committee voted 16–0 (with one abstain) that the benefits outweighed the risks.[44] There have been ten subsequent supplemental applications, two of which were for new indications.[45] Accompanying the original approval, the FDA required a post-market commitment to:

> "Conduct a medullary thyroid carcinoma registry-based case series of at least 15 years duration to systematically monitor the annual incidence of medullary thyroid carcinoma in the United States and to identify any increase related to the introduction of Ozempic (semaglutide) into the marketplace. This study will also establish a registry of incident cases of medullary thyroid carcinoma and characterize their medical histories related to diabetes and use of Ozempic (semaglutide)."[46]

Following a SUSTAIN 6 cardiovascular outcomes trial, "A Long-term, Randomized, Double-blind, Placebo-controlled, Multinational, Multi-center Trial to Evaluate Cardiovascular and Other Long-term Outcomes With Semaglutide in Subjects With Type 2 Diabetes," Novo Nordisk submitted an sNDA on March 20th, 2019.[47] On January 16th, 2020, Ozempic was approved to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.[48]

On March 28th, 2024, Novo Nordisk submitted a second sNDA for a new indication, and on January 28th, 2025, Ozempic was approved to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.[49]

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[42] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf
[43] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000SumR.pdf at 32-33
[44] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000SumR.pdf at 33
[45] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process
[46] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf at 4
[47] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf
[48] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf
[49] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/209637Orig1s025ltr.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

Ozempic (semaglutide) is not currently in shortage.[50]

Semaglutide products were listed as in shortage from 03/31/2022-02/21/2025, but these shortages have since been resolved.[51] The FDA lists the products in the table below for the most recent shortage related to the entry "semaglutide."

**Table 4. Resolved Semaglutide Injection Shortages as of 07/23/2025**

| National Drug Code | Proprietary Name | Non-Proprietary Name | Dosage-Strength |
|---|---|---|---|
| 00169-4181-13 | Ozempic | Semaglutide | 0.68 MG/1 ML |
| 00169-4130-13 | Ozempic | Semaglutide | 1.34 MG/1 ML |
| 00169-4772-12 | Ozempic | Semaglutide | 2.68 MG/1 ML |
| 00169-4525-14 | Wegovy | Semaglutide | 0.25 MG/0.5 ML |
| 00169-4505-14 | Wegovy | Semaglutide | 0.5 MG/0.5 ML |
| 00169-4501-14 | Wegovy | Semaglutide | 1 MG/0.5 ML |
| 00169-4517-14 | Wegovy | Semaglutide | 1.7 MG/0.75 ML |
| 00169-4524-14 | Wegovy | Semaglutide | 2.4 MG/0.75 ML |

Board staff monitored the shortage while it was ongoing. Based on an inquiry submitted to the FDA, Board staff learned that the FDA routinely places all products with the same active ingredient and dosage form on the shortage list. In the case of the semaglutide shortage, the FDA placed both products with the brand name Ozempic and products with the brand name Wegovy on the shortage list. At the time the shortage was active, the FDA published documents noting whether particular NDCs were available while the shortage was still active. Board staff had previously saved copies of the documents in April 2024, reflected in the table below.

[50] FDA Drug Shortage Databases. https://dps.fda.gov/drugshortages
[51] https://dps.fda.gov/drugshortages/resolved/semaglutide-injection (Page visited on 07/23/2025).

**Table 5. Sample Previous Availability Report from FDA, April 1, 2024**

| Presentation | Availability Information | Date of Update |
|---|---|---|
| Wegovy, Injection, .25 mg/.5 mL (NDC 0169-4525-14) | Limited Availability | 4/1/2024 |
| Wegovy, Injection, .5 mg/.5 mL (NDC 0169-4505-14) | Limited Availability | 4/1/2024 |
| Wegovy, Injection, 1 mg/.5 mL (NDC 0169-4501-14) | Limited Availability | 4/1/2024 |
| Wegovy, Injection, 1.7 mg/.75 mL (NDC 0169-4517-14) | Limited Availability | 4/1/2024 |
| Wegovy, Injection, 2.4 mg/.75 mL (NDC 0169-4524-14) | Available | 4/1/2024 |
| Ozempic, Injection, 1.34 mg/1 mL (NDC 0169-4130-13) | Available | 4/1/2024 |
| Ozempic, Injection, 2.68 mg/1 mL (NDC 0169-4772-12) | Available | 4/1/2024 |
| Ozempic, Injection, .68 mg/1 mL (NDC 0169-4181-13) | Available | 4/1/2024 |

In addition, Board Staff has attempted to find updates after this date using the internet archive.[52] This search revealed that additional presentations were listed as available over time. In particular, by November 11, 2024, all presentations were listed as available, but the FDA continued to list the drug as actively in shortage.

[52] https://web.archive.org/web/20250000000000*/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**

Twenty listed patents apply to four products of Ozempic. Nineteen of those patents are listed for all four products and one is listed for only three products. One patent expires on August 13, 2025, and two patents will expire on October 20, 2025. The primary patents (listed as both a drug substance and a drug product patent) expire on March 20, 2026, and December 5, 2031. There are five additional drug patents that expire on January 20, 2026. Four drug product patents expire July 17, 2026. The last patent expires on June 21, 2033, and was listed in the Orange Book on July 25, 2019. *See* Patent Listing Table below.

**Table 6. Patent Listing Table**

| Patent Number | DS Patent[1] | DP Patent[2] | Patent Use Code | Submission Date | Original Patent Expiration | Listed for Product 1: 2 MG/1.5 ML | Listed for Product 2: 4 MG/3 ML | Listed for Product 3: 8 MG/3 ML | Listed for Product 4: 2 MG/3 ML |
|---|---|---|---|---|---|---|---|---|---|
| 10220155 | No | Yes | | 4/4/2019 | 7/17/2026 | Yes | Yes | Yes | Yes |
| 10335462 | | | U-2580 | 7/25/2019 | 6/21/2033 | Yes | Yes | Yes | Yes |
| 10357616 | No | Yes | | 8/8/2019 | 1/20/2026 | Yes | Yes | Yes | Yes |
| 10376652 | No | Yes | | 9/13/2019 | 1/20/2026 | Yes | Yes | Yes | Yes |
| 11097063 | No | Yes | | 9/21/2021 | 7/17/2026 | Yes | Yes | Yes | Yes |
| 11311679 | No | Yes | | 5/20/2022 | 1/20/2026 | Yes | Yes | Yes | Yes |
| 11446443 | No | Yes | | 10/7/2022 | 10/20/2025 | Yes | Yes | Yes | Yes |
| 8114833 | | Yes | | 12/20/2017 | 8/13/2025 | Yes | Yes | Yes | Yes |
| 8129343 | Yes | Yes | U-2202 | 12/20/2017 | 12/5/2031 | Yes | Yes | Yes | Yes |
| 8536122 | Yes | Yes | U-2202 | 12/20/2017 | 3/20/2026 | Yes | Yes | Yes | Yes |
| 8684969 | No | Yes | | 12/20/2017 | 10/20/2025 | Yes | Yes | Yes | Yes |
| 8920383 | No | Yes | | 12/20/2017 | 7/17/2026 | Yes | Yes | Yes | Yes |
| 9108002 | No | Yes | | 12/20/2017 | 1/20/2026 | Yes | Yes | Yes | Yes |
| 9132239 | No | Yes | | 12/20/2017 | 2/1/2032 | Yes | Yes | Yes | Yes |
| 9457154 | No | Yes | | 12/20/2017 | 9/27/2027 | Yes | Yes | Yes | Yes |
| 9616180 | No | Yes | | 8/17/2018 | 1/20/2026 | Yes | Yes | Yes | Yes |
| 9687611 | No | Yes | | 12/20/2017 | 2/27/2027 | Yes | Yes | Yes | Yes |
| 9775953 | No | Yes | | 12/20/2017 | 7/17/2026 | Yes | Yes | Yes | Yes |
| 9861757 | No | Yes | | 8/17/2018 | 1/20/2026 | Yes | Yes | Yes | Yes |
| RE46363 | No | Yes | | 12/20/2017 | 8/3/2026 | Yes | Yes | No | Yes |

1 DS Patent refers to the Drug Substance Patent
2 DP Patent refers to a Drug Product Patent

Ozempic has one active marketing exclusivity from the FDA for its indication, expiring on January 28, 2028.[53][54]

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[53] https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=209637&Appl_type=N

[54] "Marketing exclusivity precludes FDA from approving any other application for an identical or biosimilar product for the same use, even if the applicant has generated its own data." https://www.congress.gov/crs-product/IF11217#:~:text=There%20are%20two%20general%20categories,necessary%20safety%20and%20effectiveness%20data

**Other Products with the Same Active Ingredient**

The manufacturer markets multiple products that contain the same active ingredient as Ozempic (semaglutide). Rybelsus (semaglutide) is a product with the same active ingredient as the active ingredient in Ozempic (semaglutide). Rybelsus was approved on September 20, 2019. [55] The Rybelsus label states that it "is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." [56] Unlike Ozempic, which is an injectable product, Rybelsus comes in oral tablets.

Wegovy (semaglutide) is a product with the same active ingredient as the active ingredient in Ozempic (semaglutide). Wegovy was approved on June 4, 2021. [57] The Wegovy label states that it "is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced calorie diet and increased physical activity:

- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.
- to reduce excess body weight and maintain weight reduction long term in:
    - Adults and pediatric patients aged 12 years and older with obesity
    - Adults with overweight in the presence of at least one weight-related comorbid condition." [58]

The tables below display APCD data on patient counts and total gross spending in each segment. For each drug, there are two tables; one contains data from the Commercial Segment and a subset of the Commercial Segment that includes information for State/Local Government Employees, and the other contains data from the Medicare and Medicaid segments.

[55] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213051
[56] https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/213051Orig1s020,213051Orig1s021lbl.pdf
[57] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process
[58] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215256s021lbl.pdf

## Rybelsus

### Table 7a. Rybelsus 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 |
| 00169-4314-13 | Rybelsus | 14 MG | 112 | $429,661.00 | *** | *** |
| 00169-4314-30 | Rybelsus | 14 MG | 3,333 | $22,820,299.00 | 329 | $1,939,672.00 |
| 00169-4303-13 | Rybelsus | 3 MG | 124 | $329,609.00 | *** | *** |
| 00169-4303-30 | Rybelsus | 3 MG | 4,114 | $12,926,062.00 | 319 | $769,781.00 |
| 00169-4307-13 | Rybelsus | 7 MG | 151 | $539,832.00 | *** | *** |
| 00169-4307-30 | Rybelsus | 7 MG | 6,040 | $33,293,233.00 | 536 | $2,596,628.00 |

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

### Table 7b. Rybelsus 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 |
| 00169-4314-13 | Rybelsus | 14 MG | 20 | $28,554.26 | 66 | $267,998.80 |
| 00169-4314-30 | Rybelsus | 14 MG | 211 | $906,059.06 | 596 | $3,271,014.59 |
| 00169-4303-13 | Rybelsus | 3 MG | 74 | $114,121.51 | 141 | $295,603.78 |
| 00169-4303-30 | Rybelsus | 3 MG | 545 | $1,056,395.29 | 1,090 | $2,852,524.88 |
| 00169-4307-13 | Rybelsus | 7 MG | 80 | $177,602.39 | 162 | $445,993.14 |
| 00169-4307-30 | Rybelsus | 7 MG | 609 | $1,947,931.80 | 1,513 | $6,614,193.06 |

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Blank spaces indicate that no data was provided.

## Wegovy

### Table 8a. Wegovy 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 |
| 00169-4525-14 | Wegovy | 0.25 MG/0.5 ML | 3,994 | $8,554,630.00 | 502 | $1,342,790.00 |
| 50090-5824-00 | Wegovy | 0.25 MG/0.5 ML | *** | *** | *** | *** |
| 00169-4505-14 | Wegovy | 0.5 MG/0.5 ML | 2,728 | $5,989,087.00 | 337 | $865,768.00 |
| 00169-4501-14 | Wegovy | 1 MG/0.5 ML | 2,272 | $5,515,363.00 | 289 | $889,383.00 |
| 00169-4517-14 | Wegovy | 1.7 MG/0.75 ML | 2,418 | $8,114,926.00 | 295 | $1,367,542.00 |
| 00169-4524-14 | Wegovy | 2.4 MG/0.75 ML | 2,053 | $14,799,471.00 | 256 | $2,013,051.00 |

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Blank spaces indicate that no data was provided.

### Table 8b. Wegovy 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 |
| 00169-4525-14 | Wegovy | 0.25 MG/0.5 ML | | | | |
| 50090-5824-00 | Wegovy | 0.25 MG/0.5 ML | | | | |
| 00169-4505-14 | Wegovy | 0.5 MG/0.5 ML | | | | |
| 00169-4501-14 | Wegovy | 1 MG/0.5 ML | | | | |
| 00169-4517-14 | Wegovy | 1.7 MG/0.75 ML | | | | |
| 00169-4524-14 | Wegovy | 2.4 MG/0.75 ML | | | | |

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## 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 9a. Ozempic 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 |
|---|---|---|---|---|---|
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $38,443,989.00 | 16,236 | 0.3836% |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | $146,981,672.88 | 36,524 | 1.4667% |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $168,156,204.87 | 30,259 | 1.6780% |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $464,808.00 | 147 | 0.0046% |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | $92,438,730.19 | 14,428 | 0.9224% |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | $312,144.00 | 99 | 0.0031% |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | $120,231.00 | 40 | 0.0012% |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | *** | *** | *** |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | $222,950.00 | 72 | 0.0022% |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | *** |

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Blank spaces indicate that no data was provided.

**Table 9b. Ozempic 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 |
|---|---|---|---|---|---|
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $2,653,728.00 | 1,275 | 0.3870% |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | $10,774,847.00 | 3,129 | 1.5712% |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $12,857,706.00 | 2,796 | 1.8750% |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $26,267.00 | 11 | 0.0038% |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | $7,085,183.00 | 1,345 | 1.0332% |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | *** | *** | *** |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | *** | *** | *** |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | *** | *** | *** |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | | | |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | *** |

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Blank spaces indicate that no data was provided.

**Table 9c. Ozempic 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 |
|---|---|---|---|---|---|
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $22,923,445.90 | 5,998 | 1.2525% |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | | | |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $18,189,313.12 | 3,630 | 0.9938% |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $47,805.01 | 18 | 0.0026% |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | $2,081,087.21 | 808 | 0.1137% |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | $104,064.17 | 52 | 0.0057% |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | $168,007.28 | 75 | 0.0092% |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | | | |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | $22,746.06 | 12 | 0.0012% |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | *** |

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Blank spaces indicate that no data was provided.

**Table 9d. Ozempic 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 |
|---|---|---|---|---|---|
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $33,681,086.83 | 7,731 | 0.9312% |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | | | |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $31,382,232.67 | 5,119 | 0.8676% |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $72,883.71 | 18 | 0.0020% |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | $3,195,736.95 | 989 | 0.0884% |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | $84,825.27 | 29 | 0.0023% |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | $166,732.73 | 54 | 0.0046% |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | | | |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | *** | *** | *** |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | | | |

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

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 10a. Ozempic 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 |
| 00169-4132-12 | Ozempic | 2 MG/1.5ML | $-57,048,057.00 | 59.74% | -8,557 | -46,090 | -147,334 |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | | | | | |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $73,517,789.87 | 77.68% | 12,857 | 39,918 | 138,425 |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $348,106.00 | 298.29% | 113 | 277 | 951 |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | $81,154,171.19 | 719.16% | 10,719 | 46,409 | 209,310 |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | $106,999.00 | 52.16% | 10 | 6 | -114 |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | $-346,301.00 | 74.23% | -106 | -283 | -1,563 |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | *** | *** | *** | *** | *** |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | $181,281.00 | 435.05% | 56 | 124 | 307 |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** | *** | *** |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | *** | *** | *** |

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Blank spaces indicate that no data was provided.

**Table 10b. Ozempic 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 |
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $-4,281,807.00 | 61.74% | -546 | -2,865 | -11,425 |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | | | | | |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $5,069,250.00 | 65.09% | 1,313 | 3,629 | 12,962 |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | | | | | |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | $6,004,750.00 | 555.77% | 1,017 | 3,685 | 18,366 |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** | *** | *** |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | *** | *** | *** | *** | *** |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | *** | *** | *** | *** | *** |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | *** | *** | *** | *** | *** |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | | | | | |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | *** | *** | *** |

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Blank spaces indicate that no data was provided.

**Table 10c. Ozempic 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 |
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $7,959,792.80 | 53.19% | 2,273 | 4,427 | 8,695 |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | | | | | |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $12,184,692.26 | 202.92% | 1,817 | 4,743 | 41,134 |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $33,571.78 | 235.87% | 8 | 13 | 114 |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | | | | | |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | $71,236.55 | 217.00% | 41 | 59 | 82 |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | $-4,633,488.63 | 96.50% | -1,273 | -2,151 | -16,909 |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | | | | | |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | | | | | |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** | *** | *** |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | *** | *** | *** |

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**Table 10d. Ozempic 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 |
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $13,119,719.87 | 63.81% | 3,052 | 8,680 | 19,351 |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | | | | | |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $20,399,966.67 | 185.75% | 2,575 | 11,933 | 64,842 |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $67,491.53 | 1251.66% | 15 | 46 | 213 |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | | | | | |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | $60,913.44 | 254.74% | 20 | 46 | 95 |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | $-7,082,168.53 | 97.70% | -1,761 | -4,493 | -24,869 |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | | | | | |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | *** | *** | *** | *** | *** |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** | *** | *** |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | | | | | |

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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.[59] The SAAC is provided by Myers and Stauffer, a contractor of the State of Maryland.[60] The ASP is publicly available from the Centers for Medicare and Medicaid Services.[61] The FSS is publicly available from the U.S. Department of Veterans Affairs.[62] 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.

The following tables reflect (a) the effective date, (b) the current* unit price, and (c) the estimated annual price (based on the FDA's recommended dosing regimens and current* unit prices) for each NDC-11 associated with the prescription drug product under review.

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

NOTE: WAC, AWP, and NADAC price history plots by NDC-11 are presented in Exhibit 1 of this file.

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

**Table 11a. Ozempic WAC and AWP Pricing**

| National Drug Code | WAC Unit Price | Est. WAC per Yr | AWP Unit Price | Est. AWP per Yr |
|---|---|---|---|---|
| 00169-4130-01 (4 MG/3 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4130-13 (4 MG/3 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4132-11 (2 MG/1.5 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4132-12 (2 MG/1.5 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4136-02 (2 MG/1.5 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4136-11 (2 MG/1.5 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4181-03 (0.5 MG/3 ML) | | | | |
| 00169-4181-13 (2 MG/3 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4772-11 (8 MG/3 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4772-12 (8 MG/3 ML) | [redacted] | [redacted] | [redacted] | [redacted] |
| 50090-5949-00 (4 MG/3 ML) | | | [redacted] | [redacted] |
| 50090-6051-00 (8 MG/3 ML) | | | [redacted] | [redacted] |

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Blank spaces indicate that no data was provided.

**Table 11b. Ozempic NADAC, SAAC, and FSS Pricing**

| National Drug Code | NADAC Unit Price | Est. NADAC per Yr | SAAC Rate | Est. SAAC per Yr | FSS Unit Price | Est. FSS per Yr |
|---|---|---|---|---|---|---|
| 00169-4130-01 (4 MG/3 ML) | $311.78 | $12,192.79 | $310.93 | $12,159.74 | | |
| 00169-4130-13 (4 MG/3 ML) | $311.78 | $12,192.79 | $310.93 | $12,159.74 | $307.22 | $12,014.50 |
| 00169-4132-11 (2 MG/1.5 ML) | $620.52 | $12,133.43 | $624.94 | $12,219.76 | | |
| 00169-4132-12 (2 MG/1.5 ML) | $620.52 | $12,133.43 | $624.94 | $12,219.76 | $565.75 | $11,062.50 |
| 00169-4136-02 (2 MG/1.5 ML) | | | | | | |
| 00169-4136-11 (2 MG/1.5 ML) | | | | | | |
| 00169-4181-03 (0.5 MG/3 ML) | $311.81 | $12,194.06 | | | | |
| 00169-4181-13 (2 MG/3 ML) | $311.81 | $12,194.06 | | | $307.22 | $12,014.50 |
| 00169-4772-11 (8 MG/3 ML) | $311.74 | $12,191.09 | $310.32 | $12,135.63 | | |
| 00169-4772-12 (8 MG/3 ML) | $311.74 | $12,191.09 | $310.32 | $12,135.63 | $307.22 | $12,014.50 |
| 50090-5949-00 (4 MG/3 ML) | | | | | | |
| 50090-6051-00 (8 MG/3 ML) | | | | | | |

*** 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.

Exhibit 1 (attached) reflects pricing history for Ozempic.

## 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

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

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

**Table 12. Ozempic Net Price and Net Spending Estimates**

| Drug Information | | | Annual Price or Sales After SSR Application (Price*SSR) | | | | |
|---|---|---|---|---|---|---|---|
| National Drug Code | Strength | SSR Rebate | Est. WAC per Yr | Commercial (2023) Estimated Net Spend | State Local Govt Emp (2023) Estimated Net Spend | Medicaid (2022) Estimated Net Spend | Medicare (2022) Estimated Net Spend |
| 00169-4130-13 | 4 MG/3 ML | [redacted] | [redacted] | | | | |
| 00169-4181-13 | 2 MG/3 ML | [redacted] | [redacted] | | | | |
| 00169-4772-12 | 8 MG/3 ML | [redacted] | [redacted] | [redacted] | | [redacted] | [redacted] |
| 00169-4132-12 | 2 MG/1.5 ML | [redacted] | [redacted] | [redacted] | | | |
| 00169-4130-01 | 4 MG/3 ML | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4132-11 | 2 MG/1.5 ML | [redacted] | [redacted] | [redacted] | *** | [redacted] | [redacted] |
| 00169-4772-11 | 8 MG/3 ML | [redacted] | [redacted] | [redacted] | *** | [redacted] | *** |
| 00169-4136-02 | 2 MG/1.5 ML | [redacted] | [redacted] | [redacted] | *** | [redacted] | [redacted] |
| 50090-6051-00 | 8 MG/3 ML | [redacted] | | *** | *** | | |
| 50090-5949-00 | 4 MG/3 ML | [redacted] | | *** | *** | *** | |
| 00169-4136-11 | 2 MG/1.5 ML | [redacted] | [redacted] | *** | | *** | *** |

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

| Drug Information | | | Annual Price or Sales After SSR Application (Price*SSR) | | | | |
|---|---|---|---|---|---|---|---|
| National Drug Code | Strength | SSR Rebate | Est. WAC per Yr | Commercial (2023) Estimated Net Spend | State Local Govt Emp (2023) Estimated Net Spend | Medicaid (2022) Estimated Net Spend | Medicare (2022) Estimated Net Spend |
| 00169-4130-13 | 4 MG/3 ML | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4181-13 | 2 MG/3 ML | [redacted] | [redacted] | [redacted] | [redacted] | | |
| 00169-4772-12 | 8 MG/3 ML | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4132-12 | 2 MG/1.5 ML | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4130-01 | 4 MG/3 ML | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 00169-4132-11 | 2 MG/1.5 ML | [redacted] | [redacted] | [redacted] | *** | [redacted] | [redacted] |
| 00169-4772-11 | 8 MG/3 ML | [redacted] | [redacted] | [redacted] | *** | [redacted] | *** |
| 00169-4136-02 | 2 MG/1.5 ML | [redacted] | [redacted] | [redacted] | *** | [redacted] | [redacted] |
| 50090-6051-00 | 8 MG/3 ML | [redacted] | | *** | *** | | |
| 50090-5949-00 | 4 MG/3 ML | [redacted] | | *** | *** | *** | |
| 00169-4136-11 | 2 MG/1.5 ML | [redacted] | [redacted] | *** | | *** | *** |

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

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

Blank spaces indicate that no data was provided.

## 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

Ozempic was selected as a drug subject to the Medicare Price Negotiation Program.[63] The negotiated price will go into effect on January 1, 2027, and has not yet been announced.

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.

[63] https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower

## 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] [redacted]

Staff developed the attached supplemental excel document (Exhibit 3_REDACTED "OZEMPIC 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 (Ozempic 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 Ozempic (semaglutide). Staff used Embase (Elsevier interface) to identify potential analyses. Staff combined the following string in Embase with the relevant drug terms: ('cost effectiveness analysis'/exp OR 'cost effectiveness':ti,ab,kw OR 'cost efficiency':ti,ab,kw OR 'incremental cost effectiveness ratio'/exp OR 'incremental cost'/exp OR 'incremental cost*':ti,ab,kw OR 'incremental cost utility ratio'/exp) AND ('semaglutide'/exp OR 'glucagon like peptide 1 [7-37] [8 (2 amino 2 methylpropanoic acid) 26 [6 n [18 [n (17 carboxyheptadecanoyl) gamma glutamyl] 10 oxo 3, 6, 12, 15 tetraoxa 9, 18 diazaoctadecanoyl] lysine] 34 arginine]':ti,ab,kw OR 'nn 6535':ti,ab,kw OR 'nn 9535':ti,ab,kw OR 'nn 9536':ti,ab,kw OR 'nn 9924':ti,ab,kw OR 'nn 9931':ti,ab,kw OR 'nn 9932':ti,ab,kw OR 'nn6535':ti,ab,kw OR 'nn9535':ti,ab,kw OR 'nn9536':ti,ab,kw OR 'nn9924':ti,ab,kw OR 'nn9931':ti,ab,kw OR 'nn9932':ti,ab,kw OR 'nnc 0113 0217':ti,ab,kw OR 'nnc01130217':ti,ab,kw OR 'og 217 sc':ti,ab,kw OR 'og 217sc':ti,ab,kw OR 'og217sc':ti,ab,kw OR 'ozempic':ti,ab,kw OR 'rybelsus':ti,ab,kw OR 'semaglutide':ti,ab,kw OR 'wegovy':ti,ab,kw) AND ('chronic kidney failure'/exp OR 'chronic kidney disease':ti,ab,kw OR 'chronic kidney disorder':ti,ab,kw OR 'chronic kidney failure':ti,ab,kw OR 'chronic kidney insufficiency':ti,ab,kw OR 'chronic nephropathy':ti,ab,kw OR 'chronic renal disease':ti,ab,kw OR 'chronic renal failure':ti,ab,kw OR 'chronic renal insufficiency':ti,ab,kw OR 'kidney chronic failure':ti,ab,kw OR 'obesity'/exp OR 'adipose tissue hyperplasia':ti,ab,kw OR 'adipositas':ti,ab,kw OR 'adiposity':ti,ab,kw OR 'corpulency':ti,ab,kw OR 'fat overload syndrome':ti,ab,kw OR 'obesitas':ti,ab,kw OR 'obesity':ti,ab,kw OR 'overweight':ti,ab,kw OR 'excess body weight':ti,ab,kw OR 'non insulin dependent diabetes mellitus'/exp OR 'niddm':ti,ab,kw OR 't2dm':ti,ab,kw OR 'tiidm':ti,ab,kw OR

'adult onset diabetes':ti,ab,kw OR 'diabetes mellitus type 2':ti,ab,kw OR 'diabetes mellitus type ii':ti,ab,kw OR 'diabetes type 2':ti,ab,kw OR 'diabetes type ii':ti,ab,kw OR 'dm 2':ti,ab,kw OR 'insulin independent diabetes':ti,ab,kw OR 'insulin independent diabetes mellitus':ti,ab,kw OR 'ketosis resistant diabetes mellitus':ti,ab,kw OR 'maturity onset diabetes':ti,ab,kw OR 'non insulin dependent (type 2) diabetes mellitus':ti,ab,kw OR 'non insulin dependent diabetes':ti,ab,kw OR 'noninsulin dependent (type 2) diabetes mellitus':ti,ab,kw OR 'noninsulin dependent diabetes':ti,ab,kw OR 'type 2 (insulin independent) diabetes':ti,ab,kw OR 'type 2 diabetes':ti,ab,kw OR 'type ii diabetes':ti,ab,kw) AND ('article'/it OR 'article in press'/it OR 'preprint'/it OR 'review'/it). In total, this search had 171 results.[64]

The results of these studies are summarized in Exhibit 5A.

[64] Search conducted on 24 February, 2024

## 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 sources. First, staff used Embase (Elsevier interface) to combine the following string with the relevant drug and approved indications terms: ('treatment outcome'/exp OR 'patient outcome*':ti,ab,kw OR 'therapeutic outcome*':ti,ab,kw OR 'therapy outcome*':ti,ab,kw OR 'treatment outcome*':ti,ab,kw OR 'quality of life'/exp OR 'hrql':ti,ab,kw OR 'health related quality of life':ti,ab,kw OR 'life quality':ti,ab,kw OR 'quality of life':ti,ab,kw) AND ('semaglutide'/exp OR 'glucagon like peptide 1 [7-37] [8 (2 amino 2 methylpropanoic acid) 26 [6 n [18 [n (17 carboxyheptadecanoyl) gamma glutamyl] 10 oxo 3, 6, 12, 15 tetraoxa 9, 18 diazaoctadecanoyl] lysine] 34 arginine]':ti,ab,kw OR 'nn 6535':ti,ab,kw OR 'nn 9535':ti,ab,kw OR 'nn 9536':ti,ab,kw OR 'nn 9924':ti,ab,kw OR 'nn 9931':ti,ab,kw OR 'nn 9932':ti,ab,kw OR 'nn6535':ti,ab,kw OR 'nn9535':ti,ab,kw OR 'nn9536':ti,ab,kw OR 'nn9924':ti,ab,kw OR 'nn9931':ti,ab,kw OR 'nn9932':ti,ab,kw OR 'nnc 0113 0217':ti,ab,kw OR 'nnc01130217':ti,ab,kw OR 'og 217 sc':ti,ab,kw OR 'og 217sc':ti,ab,kw OR 'og217sc':ti,ab,kw OR 'ozempic':ti,ab,kw OR 'rybelsus':ti,ab,kw OR 'semaglutide':ti,ab,kw OR 'wegovy':ti,ab,kw) AND ('chronic kidney failure'/exp OR 'chronic kidney disease':ti,ab,kw OR 'chronic kidney disorder':ti,ab,kw OR 'chronic kidney failure':ti,ab,kw OR 'chronic kidney insufficiency':ti,ab,kw OR 'chronic

nephropathy':ti,ab,kw OR 'chronic renal disease':ti,ab,kw OR 'chronic renal failure':ti,ab,kw OR 'chronic renal insufficiency':ti,ab,kw OR 'kidney chronic failure':ti,ab,kw OR 'obesity'/exp OR 'adipose tissue hyperplasia':ti,ab,kw OR 'adipositas':ti,ab,kw OR 'adiposity':ti,ab,kw OR 'corpulency':ti,ab,kw OR 'fat overload syndrome':ti,ab,kw OR 'obesitas':ti,ab,kw OR 'obesity':ti,ab,kw OR 'overweight':ti,ab,kw OR 'excess body weight':ti,ab,kw OR 'non insulin dependent diabetes mellitus'/exp OR 'niddm':ti,ab,kw OR 't2dm':ti,ab,kw OR 'tiidm':ti,ab,kw OR 'adult onset diabetes':ti,ab,kw OR 'diabetes mellitus type 2':ti,ab,kw OR 'diabetes mellitus type ii':ti,ab,kw OR 'diabetes type 2':ti,ab,kw OR 'diabetes type ii':ti,ab,kw OR 'dm 2':ti,ab,kw OR 'insulin independent diabetes':ti,ab,kw OR 'insulin independent diabetes mellitus':ti,ab,kw OR 'ketosis resistant diabetes mellitus':ti,ab,kw OR 'maturity onset diabetes':ti,ab,kw OR 'non insulin dependent (type 2) diabetes mellitus':ti,ab,kw OR 'non insulin dependent diabetes':ti,ab,kw OR 'noninsulin dependent (type 2) diabetes mellitus':ti,ab,kw OR 'noninsulin dependent diabetes':ti,ab,kw OR 'type 2 (insulin independent) diabetes':ti,ab,kw OR 'type 2 diabetes':ti,ab,kw OR 'type ii diabetes':ti,ab,kw) AND ('comparative effectiveness'/de OR 'comparative study'/de OR comparative:ti,ab,kw OR comparison:ti,ab,kw) AND ('article'/it OR 'article in press'/it OR 'preprint'/it OR 'review'/it). In total, this search had 181 results.[65] In addition, staff retrieved the cited references from the Comparative Effectiveness section of the drug's monograph in DRUGDEX (via Micromedex).[66] In total, staff retrieved 13 unique results.[67]

See Exhibits 5A and 5B for a summary of the literature.

[65] Search conducted on 24 February, 2025
[66] The monograph was last modified 20 February, 2025
[67] Retrieved 24 February 2025

## 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

Ozempic 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 Ozempic, there are no therapeutically equivalent drug products approved by the FDA under other applications.[68]

[68] FDA Orange Book Database. https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm

## Section 7: Cost-Sharing and Insurance Benefit Design

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

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

MCDB Analysis

The following analysis aims to estimate the impact on patient access resulting from the cost of prescription drug products under study relative to insurance benefit design. In particular, we are interested in seeing (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 under study.

**Methods**

1. Extract claims for the prescription drug product of interest from commercial eligibility file
    a. Initial Inclusion Criteria:
        i. Patients filling claims for the prescription drug product of interest 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. Claims for patients whose 30-day normalized ratio (i.e., [total 30-day equivalents received]/[expected 30-day equivalents]) >1 are excluded
        vi. Claims for patients whose first instance of using the prescription drug product was in December were excluded.
2. Assign copay and coinsurance flags to each eligible claim and determine 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
   a. Yi= **β 0+** β 1x1 **+** β 2x2 + β 3x3 + β 4x4 + β 5x5 where
      i. Yi = Normalized 30 Day Equivalent
      ii. β 0= Intercept
      iii. β 1 = Patient's Average Copay per Claim
      iv. β 2= Patient's Average Coinsurance per Claim
      v. β 3= Continuous User Indicator
      vi. β 4= Interaction Term – Continuous User*Avg Copay
      vii. β 5= Interaction Term – Continuous User*Avg Coinsurance

**Results**

*Data Characteristics*

| **Table 13.** 2023 Commercial Pharmacy Claims Characteristics for Ozempic Analysis | | |
|---|---|---|
| | **Patient Count** | **Claim Count** |
| ***Total Population*** | | |
| Counts | 61,072 | 288,758 |
| ***Eligible Patients (≥ 11 months of pharmacy coverage)*** | | |
| Counts | 54725 | 267310 |
| ***Final Summary File for Eligible Claims*** | | |
| Counts | 35794 | 148570 |

### Ozempic

**Table 14. Ozempic Out of Pocket Cost Frequency Analysis**

| COIN_FLAG | COPAY_FLAG | Frequency | Percent | Cumulative Frequency | Cumulative Percent |
|---|---|---|---|---|---|
| 0 | 0 | 45981 | 30.95 | 45981 | 30.95 |
| 0 | 1 | 89209 | 60.05 | 135190 | 90.99 |
| 1 | 0 | 12268 | 8.26 | 147458 | 99.25 |
| 1 | 1 | 1112 | 0.75 | 148570 | 100.00 |

Among eligible commercial claims for Ozempic, copay is used most often (60%) as part of the insurance benefit design. Use of coinsurance as part of the benefit design, either by itself or in conjunction with coinsurance payments, is observed in approximately 9% of claims.

### Regression Analysis

**Table 15.** Summary statistics for regression variables

| | N | NMiss | Min | Max | Mean | Std |
|---|---|---|---|---|---|---|
| **Normalized 30 Day Equivalent** | 35794 | 0 | 0.08 | 1.00 | 0.63 | 0.29 |
| **Continuous User Indicator** | 35794 | 0 | 0.00 | 1.00 | 0.40 | 0.49 |
| **Average Coinsurance** | 35794 | 0 | 0.00 | 5174.00 | 14.45 | 93.84 |
| **Average Copay** | 35794 | 0 | 0.00 | 3000.00 | 28.72 | 49.06 |
| **Continuous User*Avg. Coinsurance** | 35794 | 0 | 0.00 | 3184.33 | 5.01 | 46.68 |
| **Continuous User*Avg. Copay** | 35794 | 0 | 0.00 | 3000.00 | 11.60 | 33.31 |

**Table 16.** Analysis of Variance

| Source | DF | Sum of Squares | Mean Square | F Value | Pr > F |
|---|---|---|---|---|---|
| **Model** | 5 | 10.80337 | 2.16067 | 25.48 | <.0001 |
| **Error** | 35788 | 3034.38112 | 0.08479 | | |
| **Corrected Total** | 35793 | 3045.18449 | | | |

| **Table 17.** Model Statistics | | | |
|---|---|---|---|
| **Root MSE** | 0.29118 | **R-Square** | 0.0035 |
| **Dependent Mean** | 0.62740 | **Adj R-Sq** | 0.0034 |
| **Coeff Var** | 46.41117 | | |

**Table 18. Parameter Estimates**

| Variable | Label | DF | Parameter Estimate | Standard Error | t Value | Pr > \|t\| |
|---|---|---|---|---|---|---|
| **Intercept** | Intercept | 1 | 0.61693 | 0.00232 | 266.04 | <.0001 |
| **AVG_COPAY** | Average Copay | 1 | 0.00028726 | 0.00003986 | 7.21 | <.0001 |
| **AVG_COIN** | Average Coinsurance | 1 | -0.00012126 | 0.00001891 | -6.41 | <.0001 |
| **CONT_USER** | Continuous User Indicator | 1 | 0.01242 | 0.00370 | 3.35 | 0.0008 |
| **INTX_COIN** | Continuous User*Avg. Coinsurance | 1 | 0.00005782 | 0.00003828 | 1.51 | 0.1309 |
| **INTX_COPAY** | Continuous User*Avg. Copay | 1 | -0.00011079 | 0.00006483 | -1.71 | 0.0874 |

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 semaglutide." Staff identified two articles after excluding articles focused solely on obesity as the indication.

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.[69] 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 72% of patients with low copayment levels had more than 80% of prescription days covered. In comparison, 66% of those with medium and 60% of those with high copayments had 80% covered. Controlling for demographic, clinical, and socioeconomic factors, the authors found that the odds ratio for those with medium copayments was 0.62 and those with high copayments was 0.47 compared to the low copayment group.

The second study examined the association between patient out-of-pocket (OOP) costs and nonadherence to glucagon-like peptide 1 receptor agonists (GLP-1 RAs) in a commercial database.[70] After classifying patients into four OOP cost quartiles, researchers found that among adults who initiated GLP-1RA therapy, higher 30-day OOP costs were associated with decreased adherence: the odds ratio of nonadherence for patients in the highest quartile (OOP cost $80-$3,375) compared with the lowest quartile (OOP cost $0-$21) was 1.25.

[69] 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

[70] Donglan Zhang, Nihan Gencerliler, Amrita Mukhopadhyay, Saul Blecker, Morgan E. Grams, Davene R. Wright, Vivian Hsing-Chun Wang, Anand Rajan, Eisha Butt, Jung-Im Shin, Yunwen Xu, Karan R. Chhabra, Jasmin Divers; Association of Patient Cost Sharing With Adherence to GLP-1RA and Adverse Health Outcomes. *Diabetes Care* 21 July 2025; 48 (8): 1329–1336. https://doi.org/10.2337/dc24-2746

## 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 Ozempic. The first program is the Ozempic Savings Card.[71] The terms of use and eligibility for the program are expressed as follows:

> **Eligibility and Restrictions:**
>
> In order to redeem this offer, patient must have a valid prescription for the brand being filled. A valid Prescriber ID# is required on the prescription. Patient is not eligible if he/she is enrolled in any federal or state health care program with prescription drug coverage, such as Medicaid, Medicare, Medigap, VA, DOD, TRICARE, or any similar federal or state health care program (each a government program), or where prohibited by law. Patients are also ineligible for this offer if they are Medicare-eligible and enrolled in an employer-sponsored group waiver health plan (EGWP) or government-subsidized prescription drug benefit program for retirees. Note: The Federal Employees Health Benefits (FEHB) Program, Affordable Care (Health Exchange) Plans, and insurance provided through state employee plans are NOT federal or state government health care programs for purposes of this savings offer. Patient must be enrolled in a commercial insurance plan. The brand and the prescription being filled must be covered by the patient's commercial insurance plan. Offer excludes full cash-paying patients. This offer may not be redeemed for cash. This offer is not valid when the entire cost of your prescription drug is eligible to be reimbursed by a commercial insurance plan or other commercial health or pharmacy benefit programs. Medication filled prior to enrollment in this program will not be eligible for copay assistance and cannot be reimbursed. By using this offer, you are certifying that you meet the eligibility criteria and will comply with the terms and conditions described herein and will not seek reimbursement for any benefit received through this offer. Novo Nordisk's Eligibility and Restrictions, and Offer Details, may change from time to time, and for the most recent version, please visit this webpage. Reconfirmation of patient information may be requested periodically to ensure accuracy of data and compliance with terms. Patients with questions about the savings offer may call 1-877-304-6855.

[71] https://www.ozempic.com/savings-and-resources/save-on-ozempic.html

This offer is valid only in the United States and its territories, unless prohibited by law, and may be redeemed at participating retail pharmacies. Availability of the savings offer in Massachusetts will be dependent upon state law in effect at the time patient presents the savings offer when paying for the covered medications.

This offer is not transferable and is limited to one offer per person. Not valid if reproduced.

Cash Discount Cards and other noninsurance plans are not valid as primary insurance under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. This savings offer is provided solely for the benefit of the patient. This savings offer may be combined with a manufacturer-sponsored automatic eVoucher offer (at participating pharmacies) but cannot be combined with any other coupon, certificate, voucher, or similar offer. This includes, without limitation, any program offered through a third-party payer or pharmacy benefits manager, or an agent of either, that adjusts cost-sharing obligations. No other purchase is necessary.

Patient is responsible for complying with any insurance carrier copayment disclosure requirements, including disclosing any savings received from this program. Novo Nordisk intends that all savings from this offer accrue to the patient and are intended to be credited toward patient out-of-pocket obligations and maximums, including applicable copayments, coinsurance, and deductibles. Some insurance plans have established programs that require you to enroll in a manufacturer copay assistance program, including:

- Programs in which payments made by you that are subsidized by manufacturer savings offer programs do not count toward your deductibles or other patient out-of-pocket cost-sharing amounts (eg, accumulator adjustment programs); and/or
- Programs that adjust patient out-of-pocket cost-sharing amounts based on the availability of a manufacturer savings offer (eg, maximizer programs)

Except where prohibited by law, if your insurer has implemented these types of programs, you will not be eligible for and agree not to use this savings program, and Novo Nordisk reserves the right to reduce or discontinue financial assistance under this savings program, including, but not limited to, reducing your per-claim maximum savings benefit and/or your annual maximum savings benefit. If you learn that your insurance company or health plan has implemented either an accumulator adjustment program or a copay maximizer program, you agree to inform Novo Nordisk. Since you may be unaware whether you are subject to an accumulator adjustment or copay maximizer program when you enroll in the Novo Nordisk saving program, Novo Nordisk

> will monitor program utilization data and reserves the right to reduce, discontinue, or otherwise modify this savings offer at any time, and with or without notice.
> It is illegal to (or offer to) sell, purchase, or trade this offer.
>
> This program is not health insurance. This program is managed by ConnectiveRx on behalf of Novo Nordisk. The parties reserve the right to rescind, revoke, or amend this offer without notice at any time.
>
> **Offer Details:**
>
> This offer is good for eligible patients purchasing up to a 90-day supply.
> **(a) OZEMPIC® (semaglutide) injection 0.5 mg, 1 mg, or 2 mg:** As of January 2, 2025, pay as little as ("PALA") $25, subject to a maximum savings of $100 per 1-month prescription, $200 per 2-month prescription, and $300 per 3-month prescription. The savings offer activation is valid for up to 48 months from date of enrollment. Month is defined as 28 days. In order to obtain the "PALA $25 per 3-month prescription" offer, the patient must have a prescription, written and dispensed for a 3-month supply, and the patient's commercial insurance plan must provide coverage for a 3-month fill.[72]

The second program is the Novo Nordisk Patient Assistance Program (PAP).[73] According to the website:

> Patients who are approved for the PAP may qualify to receive free medicine from Novo Nordisk. There is no registration charge or monthly fee for participating.
>
> **To be eligible for this program, you must:**
>
> - Be a US citizen or legal resident
> - Have a total household income that is at or below 400% of the federal poverty level (FPL). Visit the NeedyMeds website, which lists the current FPL guidelines
> - Have Medicare or no insurance (Note: If you have private or commercial insurance, you are not eligible for the PAP)

[72] Accessed August 6, 2025 : https://www.novocare.com/eligibility/diabetes-savings-card.html?_gl=1*18y6zo0*_gcl_aw*R0NMLjE3NTQ1MDA0ODAuQ2p3S0NBanctc3ZFQmhCNkVpd0FFelNkcnNCd2tYczhWZ3NqZXhCVWJoR2N5bmJjbWlWTDk1OW9hR0ZubHYxbVdCMWtkTmJQUjh1Q2ZCb0NqUkFRQXZEX0J3RQ..*_gcl_dc*R0NMLjE3NTQ1MDA0ODAuQ2p3S0NBanctc3ZFQmhCNkVpd0FFelNkcnNCd2tYczhWZ3NqZXhCVWJoR2N5bmJjbWlWTDk1OW9hR0ZubHYxbVdCMWtkTmJQUjh1Q2ZCb0NqUkFRQXZEX0J3RQ..*_gcl_au*NzY2MzIwNDY5LjE3NTQ1MDA0MTk.*_ga*MTA2OTEyOTQ2LjE3NTQ1MDA0MjA.*_ga_F40L5513K4*czE3NTQ1MDA0MTkkbzEkZzEkdDE3NTQ1MDA1ODIkajM4JGwwJGgw

[73] https://www.novocare.com/diabetes/help-with-costs/pap.html

- Not be enrolled in or qualify for any other federal, state, or government program such as Medicaid, Low Income Subsidy, or Veterans Affairs (VA) Benefits
    - If you are eligible for Medicaid, you must sign the Patient Declaration section of the latest version of the PAP application stating that you are not enrolled in, plan to enroll in, or are eligible for Medicaid or Medicare Extra Help/LIS (proof of denial must be submitted if requested)[74]

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

[74] Accessed August 6, 2025 https://www.novocare.com/diabetes/help-with-costs/pap.html

## 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 19a. Ozempic 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 |
|---|---|---|---|---|---|---|
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $66.39 | $50.12 | $19.41 | $14.71 |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | $82.12 | $78.55 | $33.90 | $46.44 |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $65.74 | $95.17 | $39.65 | $57.64 |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $11.35 | $37.27 | $13.38 | $25.69 |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | $78.06 | $100.52 | $43.21 | $63.74 |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | $34.35 | $27.23 | $11.81 | $33.28 |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | $0.00 | $27.95 | $0.10 | $0.00 |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | *** | *** | *** | *** |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | $54.97 | $27.42 | $16.11 | $5.85 |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** | *** |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | *** | *** |

*** 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 19b. Ozempic 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 |
|---|---|---|---|---|---|---|
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | $4.69 | $37.00 | $6.06 | $3.85 |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | $3.71 | $60.40 | $11.81 | $1.41 |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | $4.02 | $70.94 | $12.09 | $3.11 |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | $0.00 | $83.18 | $0.00 | $0.00 |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | $4.18 | $77.37 | $13.73 | $2.21 |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | *** | *** | *** | *** |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | *** | *** | *** | *** |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | *** | *** | *** | *** |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | *** | *** | *** | *** |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | | | | |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | *** | *** |

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Blank spaces indicate that no data was provided.

## Factor 7.4: The average cost share

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

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

**Table 20. Ozempic 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 |
|---|---|---|---|---|---|
| 00169-4132-12 | Ozempic | 2 MG/1.5 ML | 0.0004% | 0.0019% | 0.0007% |
| 00169-4181-13 | Ozempic | 2 MG/3 ML | 0.0002% | 0.0007% | |
| 00169-4130-13 | Ozempic | 4 MG/3 ML | 0.0002% | 0.0007% | 0.0009% |
| 00169-4130-01 | Ozempic | 4 MG/3 ML | 0.0189% | 0.3167% | 0.1240% |
| 00169-4772-12 | Ozempic | 8 MG/3 ML | 0.0003% | 0.0014% | 0.0037% |
| 00169-4132-11 | Ozempic | 2 MG/1.5 ML | 0.0342% | *** | 0.0775% |
| 00169-4136-02 | Ozempic | 2 MG/1.5 ML | 0.0233% | *** | 0.0532% |
| 50090-6051-00 | Ozempic | 8 MG/3 ML | *** | *** | |
| 00169-4772-11 | Ozempic | 8 MG/3 ML | 0.0468% | *** | *** |
| 00169-4136-11 | Ozempic | 2 MG/1.5 ML | *** | | *** |
| 50090-5949-00 | Ozempic | 4 MG/3 ML | *** | *** | |

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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 21. Ozempic 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 |
| 00169-4132-12 | 2 MG/1.5 ML | $150.63 | $50.00 | $300.00 | $51.60 | $30.00 | $100.00 | $319.46 | $67.54 | $1,143.35 |
| 00169-4181-13 | 2 MG/3 ML | $241.02 | $80.00 | $525.00 | $77.32 | $50.00 | $175.00 | | | |
| 00169-4130-13 | 4 MG/3 ML | $258.21 | $90.00 | $550.00 | $90.16 | $50.00 | $200.00 | $406.69 | $94.00 | $1,477.80 |
| 00169-4130-01 | 4 MG/3 ML | $87.69 | $25.00 | $246.00 | $83.18 | $30.00 | $200.00 | $117.05 | $29.55 | $352.54 |
| 00169-4772-12 | 8 MG/3 ML | $285.53 | $100.00 | $590.00 | $97.48 | $50.00 | $240.00 | $142.54 | $19.70 | $490.00 |
| 00169-4132-11 | 2 MG/1.5 ML | $106.68 | $11.00 | $275.00 | *** | *** | *** | $48.18 | $8.00 | $150.00 |
| 00169-4136-02 | 2 MG/1.5 ML | $28.05 | $0.00 | $95.00 | *** | *** | *** | $148.20 | $47.00 | $250.00 |
| 50090-6051-00 | 8 MG/3 ML | *** | *** | *** | *** | *** | *** | | | |
| 00169-4772-11 | 8 MG/3 ML | $104.35 | $7.00 | $125.00 | *** | *** | *** | *** | *** | *** |
| 00169-4136-11 | 2 MG/1.5 ML | *** | *** | *** | | | | *** | *** | *** |
| 50090-5949-00 | 4 MG/3 ML | *** | *** | *** | *** | *** | *** | | | |

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

The Maryland Manual On-line provides estimates of the Maryland median household income and per capita personal income based on data from the U.S. Census Bureau.[75] 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.

[75] 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.[76]

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 initiation.

In one study, researchers examined GLP-1 RA utilization among commercially insured patients with Type 2 diabetes mellitus (T2D) with or without atherosclerotic cardiovascular disease (ASCVD).[77] For GLP-1 RA use among all patients, multivariable analysis revealed the following information: Female sex was associated with higher GLP-1 RA use, with an odds ratio of 1.22. When compared with White individuals, Asian, Black, and Hispanic patients had lower GLP-1 RA use, with odds ratios of 0.59, 0.81, and 0.91, respectively. The researchers also found that higher annual median household incomes ≥$50,000 were associated with higher GLP-1 RA use compared to lower median household incomes <$50,000, with an odds ratio of 1.13.

For patients with both T2D and ASCVD, multivariable analyses provided similar results: Female sex was associated with higher GLP-1 RA use, with an odds ratio of 1.18. When compared with White individuals, Asian, Black, and Hispanic patients had lower GLP1-RA use, with odds ratios

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

[77] Eberly LA, Yang L, Essien UR, et al. Racial, Ethnic, and Socioeconomic Inequities in Glucagon-Like Peptide-1 Receptor Agonist Use Among Patients With Diabetes in the US. *JAMA Health Forum.* 2021;2(12):e214182. doi:10.1001/jamahealthforum.2021.4182

of 0.69, 0.82, and 0.94, respectively. For this subgroup, higher median household incomes were also associated with more GLP-1 RA use when compared with lower income <$50,000 (>$100,000 odds ratio: 1.06; $50,000-$99,000 odds ratio: 1.15).

A second study examined, among other things, sociodemographic and clinical factors associated with the initiation of GLP-1 RA therapy compared to sulfonylurea therapy in a Medicare fee-for-service patient population with CKD and T2D.[78] The researchers found that female sex was associated with higher GLP-1 RA therapy initiation, with an odds ratio of 1.20. Black, Asian, and Hispanic patients were associated with lower odds of GLP-1 RA therapy initiation compared to White patients, with odds ratios of 0.73, 0.74, and 0.81, respectively. When compared to patients with a household median income of $60,000-$99,000, patients with a median income of ≥$100,000 were more likely to initiate GLP-1 RA therapy (odds ratio: 1.21), whereas those with median income <$60,000 were less likely (odds ratio for income ≤$34,999: 0.87; odds ratio for income between $35,000-$59,999: 0.88).

[78] Julie Z. Zhao, Eric D. Weinhandl, Angeline M. Carlson, Wendy L. St. Peter. Disparities in SGLT2 Inhibitor or Glucagon-Like Peptide 1 Receptor Agonist Initiation Among Medicare-Insured Adults With CKD in the United States. *Kidney Medicine*. Volume 5, Issue 1, 2023, 100564, ISSN 2590-0595. https://doi.org/10.1016/j.xkme.2022.100564.

## 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. In addition, these numbers assume that patients have completed their initial doses, and all prescriptions are based on steady state doses consistent with the maximum or only dose each NDC is designed to administer.

**Table 22. Ozempic Cost Consistent with FDA Label**

| National Drug Code | Dosage Strength | Projected Yearly Spending Commercial | Projected Yearly Spending State and Local Government | Projected Yearly Spending Medicare | Projected Yearly Spending Medicaid |
|---|---|---|---|---|---|
| 00169-4132-12 | 2 MG/1.5 ML | ^^^ | ^^^ | ^^^ | ^^^ |
| 00169-4181-13 | 2 MG/3 ML | ^^^ | ^^^ | | |
| 00169-4130-13 | 4 MG/3 ML | ^^^ | ^^^ | ^^^ | ^^^ |
| 00169-4130-01 | 4 MG/3 ML | ^^^ | ^^^ | ^^^ | ^^^ |
| 00169-4772-12 | 8 MG/3 ML | ^^^ | ^^^ | ^^^ | ^^^ |
| 00169-4132-11 | 2 MG/1.5 ML | ^^^ | *** | ^^^ | ^^^ |
| 00169-4136-02 | 2 MG/1.5 ML | ^^^ | *** | ^^^ | ^^^ |
| 50090-6051-00 | 8 MG/3 ML | *** | *** | | |
| 00169-4772-11 | 8 MG/3 ML | ^^^ | *** | *** | ^^^ |
| 00169-4136-11 | 2 MG/1.5 ML | *** | | *** | *** |
| 50090-5949-00 | 4MG/3 ML | *** | *** | | *** |

*** 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.

# 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 Ozempic 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 Ozempic received in response to this request are attached as Exhibit 6B and are also available on the Board's website.[79]

[79] Ozempic Public Comment Pages 5-6
https://pdab.maryland.gov/Documents/comments/11.8.2024%20Cost%20Review%20Comment%20Packet_updated.pdf

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

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

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

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

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

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

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

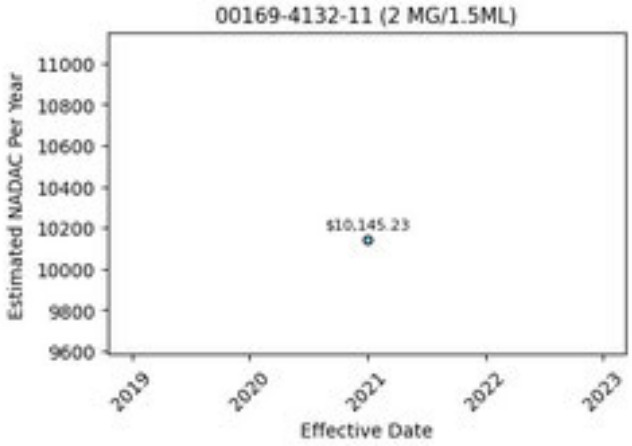


**In accordance with Health-General Article §§ 21-2c-10 and 21-2c-03, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. The documents contained in Exhibit 2 are, therefore,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

# Exhibit 1- Ozempic Pricing History

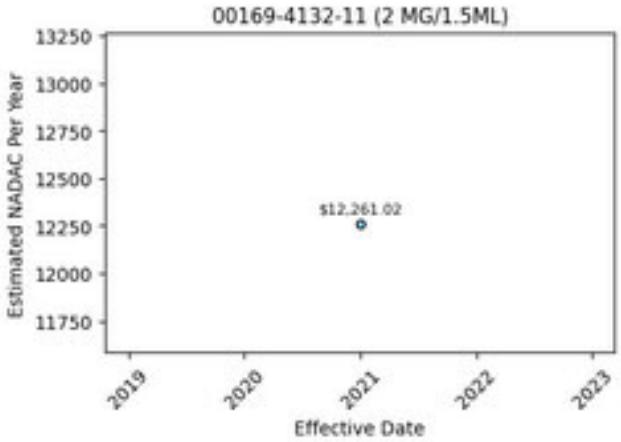
# Ozempic Historical NADAC (Nominal) And Ozempic Historical NADAC (Inflation-Adjusted to Aug 2024)

**Ozempic NADAC Pricing History (Nominal) by NDC-11 (01/01/20 to 12/30/20)**



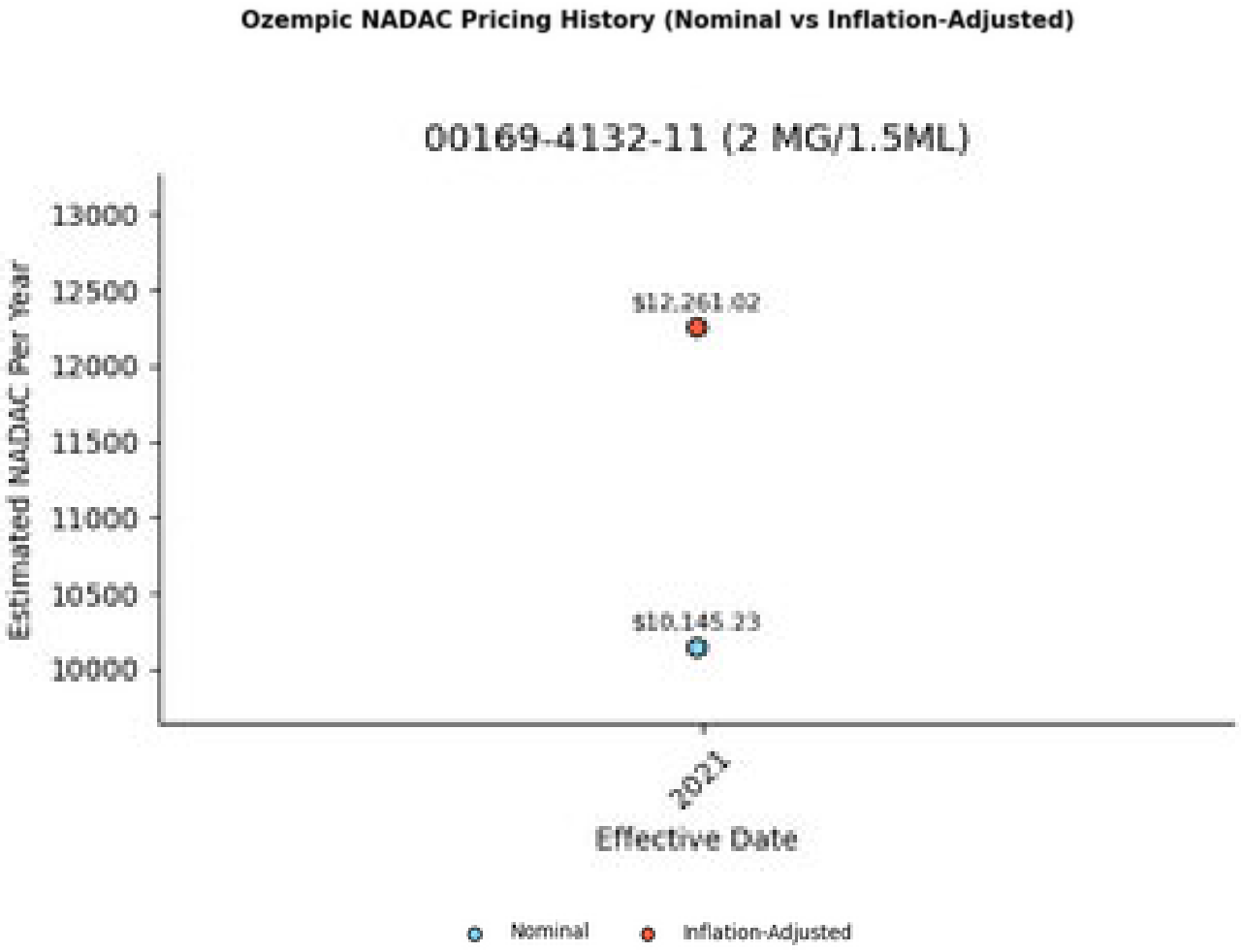

NADAC Pricing History is displayed as annual estimates based on recommended dosing regimens.

**Ozempic NADAC Pricing History (Inflation-Adjusted to Aug 2024) by NDC-11 (01/01/20 to 12/30/20)**




NADAC Pricing History is displayed as annual estimates based on recommended dosing regimens.

# Ozempic NADAC (Nominal vs Inflation-Adjusted)


Ozempic NADAC Pricing History (Nominal vs Inflation-Adjusted)
00169-4132-11 (2 MG/1.5ML)
Estimated NADAC Per Year
13000
12500
12000
11500
11000
10500
10000
$12,261.02
$10,145.23
2021
Effective Date
Nominal
Inflation-Adjusted

# Ozempic Historical WAC (Nominal)

**Ozempic WAC Pricing History (Nominal) by NDC-11 (12/05/17 to 01/01/24)**

WAC Pricing History is displayed as annual estimates based on recommended dosing regimens.

# Ozempic Historical WAC (Inflation-Adjusted to Aug 2024)

**Ozempic WAC Pricing History (Inflation-Adjusted to Aug 2024) by NDC-11 (12/05/17 to 01/01/24)**

WAC Pricing History is displayed as annual estimates based on recommended dosing regimens.

# Ozempic WAC (Nominal vs Inflation-Adjusted)

**Ozempic WAC Pricing History (Nominal vs Inflation-Adjusted)**

# Ozempic Historical AWP (Nominal)

**Ozempic AWP Pricing History (Nominal) by NDC-11 (12/05/17 to 01/01/24)**

AWP Pricing History is displayed as annual estimates based on recommended dosing regimens.

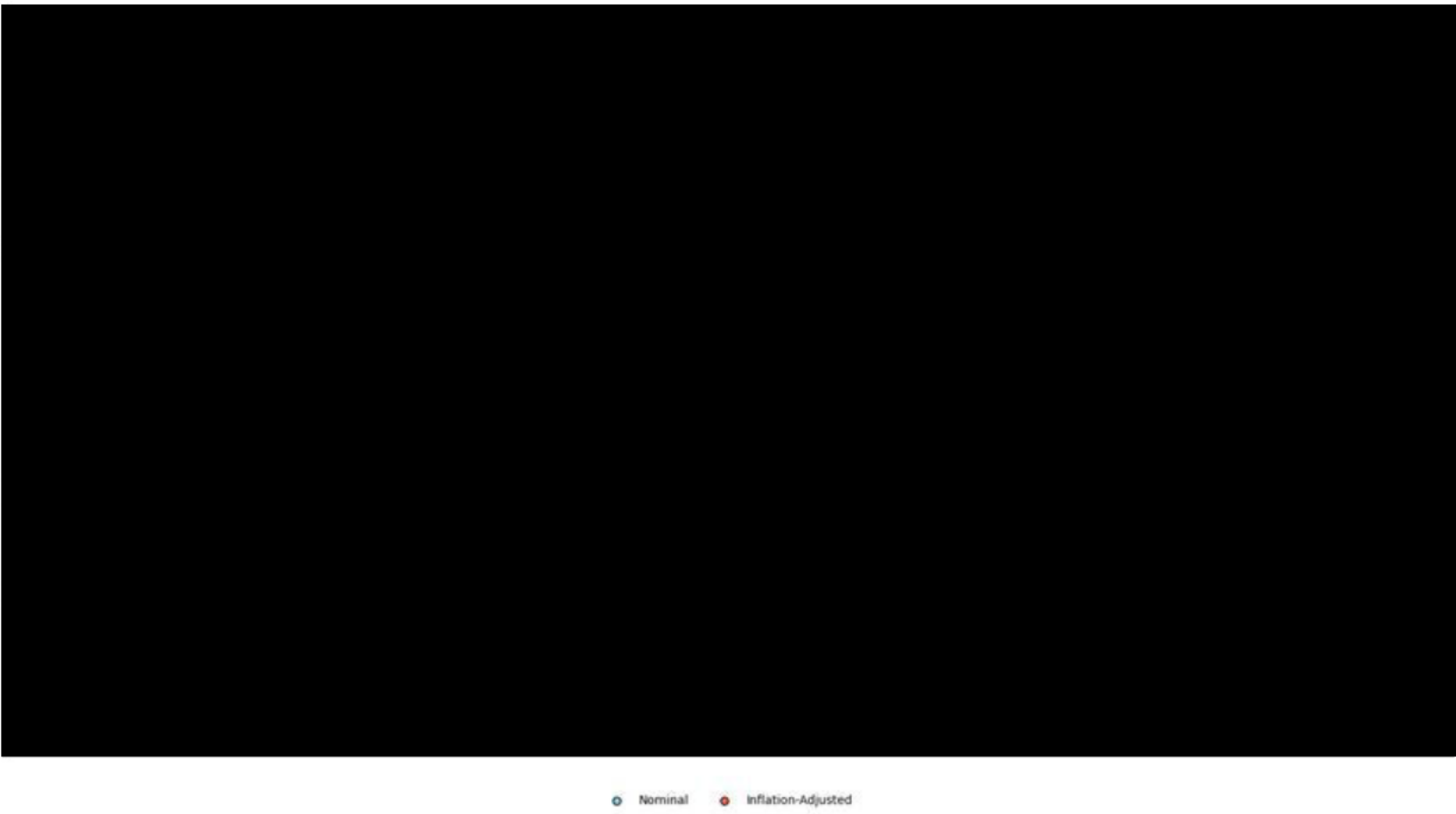
# Ozempic Historical AWP (Inflation-Adjusted to Aug 2024)

**Ozempic AWP Pricing History (Inflation-Adjusted to Aug 2024) by NDC-11 (12/05/17 to 01/01/24)**

AWP Pricing History is displayed as annual estimates based on recommended dosing regimens.

# Ozempic AWP (Nominal vs Inflation-Adjusted)

**Ozempic AWP Pricing History (Nominal vs Inflation-Adjusted)**



# DOSSIER EXHIBIT 2

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

# DOSSIER EXHIBITS 3-5 Attached Separately

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

# Exhibit 6A-

Written Comments

(60-day COMAR 14.01.04.05C(2))

Maryland

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

# Board Selected Drugs: Jardiance, Ozempic, Trulicity and Farxiga

1 message

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

Dear Members of PDAB,

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

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

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

Patrick F. Mutch

**Patrick F. Mutch**
*President & Chief Executive Officer*

*Pronouns (he/him)*

Chase Brexton Health Care
*Because everyone’s health matters.*

Chase Brexton Health Care

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

July 19, 2024

Submitted for Public Comment: Maryland Prescription Drug Affordability Board

Dear Members of the Maryland Prescription Drug Affordability Board,

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

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

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

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

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

Chase Brexton Health Care

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

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

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

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

Sincerely,

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

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

**July 22, 2024**

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

**VIA EMAIL TO:** comments.pdab@maryland.gov

**RE:** Board Selected Drugs – Ozempic®

Dear Members of the Maryland Prescription Drug Affordability Board:

Novo Nordisk appreciates the opportunity to submit written comments to the Maryland Prescription Drug Affordability Board (Board) regarding the Board's cost review of Ozempic®. Novo Nordisk is a global healthcare company committed to improving the lives of those living with serious chronic conditions, including diabetes, hemophilia, growth disorders, and obesity. The Novo Nordisk Foundation, our majority shareholder, is among the top five largest charitable foundations in the world. Accordingly, our company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and the sustainability of society.

As we have expressed in our previous comments to the Board, we share the Board's interest in making prescription medications affordable to patients. **We believe, however, that any efforts by the Board to pursue an upper payment limit (UPL) are misguided and will ultimately harm Marylanders' ability to access prescribed medications and disrupt their clinical care.** For these reasons, we are providing the following information to not only reaffirm the cost-effectiveness of Ozempic®, but to also urge the Board to reconsider its decision to subject Ozempic® to a cost review.

**Diabetes is a devastating disease**.

Type 2 diabetes is a chronic disease that places an enormous strain on patients suffering from it; families across America; the entire U.S. healthcare system, including the Maryland healthcare system; and the economy as a whole. To fully understand the impact that GLP-1 medications like Ozempic® can have, it is important to understand the toll that metabolic chronic disease has on society. The CDC estimates that 36 million Americans are living with type 2 diabetes today, and an additional 98 million Americans are prediabetic and at risk for developing the disease.[1]

[1] *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States*, CDC (accessed May 22, 2024), https://www.cdc.gov/diabetes/php/data-research/index.html; *Statistics About Diabetes*, Am. Diabetes Ass'n (accessed May 22, 2024), https://diabetes.org/about-diabetes/statistics/about-diabetes.

In Maryland 537,000 adults (11.1% of the adult population) are living with diagnosed diabetes. [2] These numbers are only projected to increase, and by 2045 it is expected that 783 million adults will be living with type 2 diabetes,[3] with one third of that population experiencing cardiovascular disease, and two fifths facing chronic kidney diseases.[4] [5] Patients living with type 2 diabetes often face a significant disease burden that impacts their quality of life and overall health. This chronic condition is a progressive and insidious disease that worsens over time and requires continuous management. [6] Many patients living with diabetes suffer from debilitating symptoms that include exhaustion, depression, and damage to their eyes, nerves, kidneys, and limbs. [7] Without proper and stable treatment, these symptoms can quickly advance to even more serious complications.

**Diabetes is a costly chronic condition.**

The state of Maryland allocates significant resources to managing diabetes, including substantial healthcare expenditures for treatment, hospitalization, and management of complications associated with the disease. These costs are driven by the high prevalence of the disease. However, Ozempic® and other GLP-1 therapies pioneered by Novo Nordisk have the potential to transform patients' lives and to drive hundreds of billions of dollars in long-term savings for the state. [8] [9] By effectively managing blood sugar levels, Ozempic® helps reduce the risk of type 2 diabetes complications such as cardiovascular disease, kidney damage, and neuropathy. Studies showed that patients with HbA1c below the ADA target for glycemic control (HbA1c<7%) incur substantially lower diabetes-related annual costs compared to patients with insufficient glycemic control.[10] In addition to reducing direct medical costs, lower HbA1c is also associated with statistically significant lower diabetes-related outpatient costs, acute care costs, and drug costs. Fewer complications mean fewer hospital visits, medical procedures, and long-term care needs. Any drug therapy able to reduce the prevalence of these expensive and deadly diseases will provide enormous personal, economic, and societal value to individuals, families, and communities across the country, including those in Maryland.

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[2] The American Diabetes Association. The Disease Burden of Diabetes in Maryland. adv_2024_state_fact_maryland.pdf (diabetes.org)
[3] International Diabetes Federation. IDF Diabetes Atlas. 10th edn. 2021. https://www.diabetesatlas.org/ (accessed December 2023); IDF 2021 report;
[4] *Murphy D et al. Ann Intern Med 2016; 165(7):473-481*
[5] *Saran R et al. Am J Kidney Dis 2019; S0272-6386(19)31008-X*
[6] Vivian A. Fonseca, Defining and Characterizing the Progression of Type 2 Diabetes, Diabetes Care (Nov. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811457/.
[7] *E.g.*, Divya Gopisetty et al.*, How Does Diabetes Affect Daily Life? A Beyond-A1C Perspective on Unmet Needs*, Clinical Diabetes (April 1, 2018), https://diabetesjournals.org/clinical/article/36/2/133/32827/How-Does-Diabetes-Affect-Daily-Life-A-Beyond-A1C; Christopher J. Bulpitt et al., *Association of Symptoms of Type 2 Diabetic Patients With Severity of Disease, Obesity, and Blood Pressure*, Diabetes Care (Jan. 1, 1998), https://diabetesjournals.org/care/article/21/1/111/19852/Association-of-Symptoms-of-Type-2-Diabetic; Matt Reynolds, *What the Scientists Who Pioneered Weight-Loss Drugs Want You to Know*, Wired (June 12, 2023), https://www.wired.com/story/obesity-drugs-researcher-interview-ozempic-wegovy/.
[8] Financial Times Editorial Board, *The promise of anti-obesity drugs*, Financial Times (Sept. 6, 2023), https://www.ft.com/content/a6e0ccbd-66b4-4e5d-9a9a-002b95b0d19f.
[9] Gina Kolata, We Know Where New Weight Loss Drugs Come From, But Not Why They Work, N.Y. Times (Aug. 17, 2023), https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.
[10] Boye KS, Lage MJ, Thieu VT. The Association Between HbA1c and 1-Year Diabetes-Related Medical Costs: A Retrospective Claims Database Analysis. Diabetes Ther. 2022;13(2):367-377. doi:10.1007/s13300-022-01212-4

**Novo Nordisk is committed to curing diabetes.**

We are the largest private investor in diabetes research and development in the world**.** We are not only further investing in innovation to enhance diabetes treatment but are also striving to cure it. GLP-1-based therapies represent a significant advance in the treatment of type 2 diabetes, and Ozempic® reduces the risk of all-cause mortality, major adverse cardiovascular events, and stroke among people with type 2 diabetes. The development of semaglutide, the active ingredient in Ozempic®, spanned over a decade. This long and rigorous process reflects the complexity and precision required to bring a new therapeutic molecule from concept to market. The work of the scientists, researchers, and personnel not only made Novo Nordisk the industry leader in treating diabetes, but it also radically altered the medical management of this complicated and devastating chronic disease and opened the door to new possibilities and avenues of inquiry for other serious chronic diseases—including heart, kidney, liver, and Alzheimer's diseases.

Ozempic® was approved by the Food and Drug Administration ("FDA") in 2017 for the treatment of type 2 diabetes. It increases the body's production of insulin, a hormone that lowers blood sugar levels, and reduces production of glucagon, which increases blood sugar levels. As the New York Times recently reported, Ozempic® is "changing diabetes treatment," as many patients "have been able to lower their insulin doses after starting Ozempic [®], and some have been able to go off insulin entirely." [11] Ozempic® is a once weekly GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events (MACE) (Cardiovascular death, non-fatal myocardial infarction (MI) or non-fatal stroke) in adults with type 2 diabetes and established cardiovascular disease.[12] Research and clinical trials demonstrate the superiority of GLP-1 receptor agonist to other antihyperglycemic drugs in improving glycemic efficacy, reducing weight and blood pressure, and having a cardioprotective effect, all without the risk of hypoglycemia.[13] These drugs have transformed the guidelines for the management of patients with diabetes.[14] All told, Ozempic has revolutionized the management of diabetes and related comorbidities – providing unsurpassed value to the healthcare system.

**Novo Nordisk works to make our medicines accessible.**

Novo Nordisk devotes significant resources, like rebates to insurers and pharmacy benefit managers (PBMs) for formulary placement, to make its medicines accessible and we will continue to collaborate with policymakers to expand access for patients. However, gaps will remain as long as the U.S. healthcare system allows intermediaries, such as PBMs, to stand between innovators and patients. The complexities of the system unfortunately reduce access and affordability for many Americans. At Novo Nordisk, we are driven by our commitment to

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[11] Dani Blum, How Ozempic Is Changing Diabetes Treatment, N.Y. Times (May 13, 2024), https://www.nytimes.com/2024/05/13/well/live/insulin-ozempic-diabetes.html; see also Paresh Dandona, Ajay Chaudhuri, and Husam Ghanim, Semaglutide in Early Type 1 Diabetes, N. Engl. J. Med. (2023) https://www.nejm.org/doi/full/10.1056/NEJMc2302677.
[12] Ozempic® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. https://www.novo-pi.com/ozempic.pdf
[13] Latif W, Lambrinos KJ, Rodriguez R. Compare and Contrast the Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) [Updated 2023 Mar 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572151/
[14] American Diabetes Association. Standards of care in diabetes—2024. Diabetes Care. 2024;47(suppl 1):S1- S321.

improving the lives of those living with serious chronic conditions—a commitment we demonstrate through our efforts to promote access and affordability.

Notably, the price of Ozempic® has substantially declined every year since launch. Since Ozempic® was first introduced in 2018, the net price—the amount that is actually paid to Novo Nordisk for the medicine—has declined by roughly 40 percent in the U.S. The decrease in net price has been driven largely by the market dynamics that are common in highly competitive product classes, where health plans negotiate substantial price concessions from manufacturers in exchange for preferred formulary access. As more GLP-1 receptors enter the market, increased competition will continue to place downward pressure on net prices. Today, 80 percent of U.S. patients—and 82.5% percent of Maryland patients, specifically—with insurance coverage for Ozempic® are paying $25 or less for each prescription, and 90 percent —are paying $50 or less. Additionally, 99.6% of Medicaid patients pay less than $5 on average for Ozempic®.[15] Short-sighted price-setting policies advanced by state governments are likely to disrupt these competitive dynamics by discouraging additional manufacturers, including generic manufacturers, from entering the market.

For patients who continue to struggle to afford their medication, either due to inadequate plan benefit design or a lack of coverage altogether, Novo Nordisk provides additional financial support through our affordability programs. We also provide copay assistance for Ozempic® that reduces a commercially insured patient's out-of-pocket cost to as little as $25. As evidenced by our efforts, Novo Nordisk remains committed to ensuring access to our medications by reducing the out-of-pocket cost burden, helping to transform the complex pricing system, and fostering better pricing predictability.

**The methodology used by the Board to select Ozempic® for a cost review is misguided.**

The information underpinning the Board's decision to proceed with a cost review on Ozempic® is based on limited data that does not reflect the actual price that health care systems, plans, and PBMs pay. As noted previously, 80 percent of U.S. patients—and 82.5% percent of Maryland patients, specifically—with insurance coverage for Ozempic® are paying $25 or less for each prescription, and 90 percent— are paying $50 or less. While the process of conducting a cost review includes gathering additional information regarding a drug and its price, the Board's process so far has been opaque and uneven. For instance, it remains unclear how the Board assessed all drugs eligible for a cost review and ultimately selected the six drugs subject to review. Additionally, there is no clear process for manufacturers to dispute or correct inaccurate information received by the Board before it proceeds to vote on whether use of a drug "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients"; without transparency around the data the Board is using to assess Ozempic®, Novo Nordisk is unable to verify the accuracy of the information. Given current market dynamics, the risk of inaccuracy could have dire consequences for patient access. The PDAB's process of conducting cost reviews and potentially seeking to implement a UPL must be

[15] Novo Nordisk internal data on file.

fair, reasoned, and transparent. It must allow for meaningful engagement with manufacturers and other stakeholders.

**A UPL would put Ozempic's® current access and affordability for the majority of Marylanders at risk.**

Healthcare in America is complex - varying insurance plans with different formularies and coverage policies create inconsistencies in access and affordability for patients. To ensure that our patients can access our medications, we offer substantial price concessions to ensure patients can reasonably afford their medication. Novo Nordisk has worked to ensure Ozempic® is covered by 99% of commercial insurance plans in the United States.

An UPL could undermine this affordability picture, and potentially *raise* out-of-pocket costs for patients, as plans may prefer other medications not subject to an UPL that can continue to offer larger rebates to insurers and PBMs. As we have stated in our previous comments, research has consistently shown that plans tend to prefer highly rebated products over lower priced alternatives, given the impact of rebates on keeping plan liability and premium pressure low. A recent Government Accountability Office report highlighted that "Part D plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which generally had lower rebates."[16] Setting a UPL for drugs sold in the state of Maryland, could result in decreased access to those drugs as the dynamics in the current system favor drugs that have higher rebates. The impact of a UPL would undermine the PDABs goal of lowering costs and promoting affordable access for state and local governments and Medicaid.

A UPL that is too low could lead payors to disadvantage UPL-subjected drugs in favor of competitors with higher list prices/higher rebates. While the Board is looking at a select few medications used to treat diabetes, it is not looking at the drug class in totality. As the Board seeks to apply UPLs to select drugs, it is effectively putting its thumb on the scale and picking winners and losers within a crowded and highly competitive drug class. Recent history demonstrates that this not a purely theoretical concern. In 2020, the drugmaker Viatris launched the biosimilar Semglee® at a substantially lower wholesale acquisition cost (WAC) than its reference product, Lantus®. After realizing very modest formulary uptake, Viatris launched a higher priced version of Semglee®, with the flexibility to offer manufacturer rebates to plans and PBMs. The relaunch of Semglee® at a higher WAC resulted in greater formulary access and increased market volume.[17] Novo Nordisk observed similar trends with our own unbranded

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[16] Government Accountability Office. CMS Should Monitor Effects of Rebates on Drug Coverage and Spending: Statement of John E.
Dicken, Director, Health Care Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives [Internet]. 2023 Sep 19 [cited 2024 Jun 30]. Available from: https://www.gao.gov/assets/gao-23-107056.pdf

[17] Fein AJ. How Health Plans Profit—and Patients Lose—From Highly Rebated Brand-Name Drugs [Internet]. Philadelphia, PA: Drug
Channels Institute; 2019 Feb 20 [cited 2024 Jun 30]. Available from : https://www.drugchannels.net/2019/02/how-health-plansprofitand-patients.html

biologic for NovoLog®, which launched at a 50 percent reduction from the branded list price to address policymaker interest in lower list prices and to provide an additional option to lower out of pocket costs for some patients. Plan uptake of the unbranded version was tepid. In 2023, formulary access of the insulin aspart unbranded biologic stood at 4 percent, while it was 58 percent for branded NovoLog®.[18]

The prescription drug supply chain continues to be driven by misaligned incentives – where PBMs' horizontal and vertical integration has created and compounded financial conflicts of interest and incentives for their business practices that threaten to "lessen competition, disadvantage rivals, and inflate drug costs—all to the detriment of patients." [19] As a result of this consolidation, the largest PBMs in the U.S. exert significant control over the treatment options available to patients.[20] Through formulary designs, PBMs apply influence by directing patients to medications that can generate the highest rebates from manufacturers.[21] Loss of coverage can also be extremely disruptive for patients and clinicians. Patients that need a new prescription will require additional prescriber visits that could disrupt continuity of care and increase the likelihood of care delays, increasing the risk of hospitalizations and increased overall healthcare costs.

Given these complexities outlined above, we urge the Board to reconsider making any decision related to the proposed review of Ozempic®. Further, we urge the Board to refrain from seeking to impose a UPL, as it would ultimately undermine the Board's goals of promoting access and affordability.

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Maintaining access to Ozempic® is crucial for patients living with type 2 diabetes. With its proven effectiveness in lowering blood sugar levels and reducing the risk of cardiovascular events, Ozempic® represents a valuable treatment option for managing diabetes and improving overall health outcomes. Ensuring access to Ozempic® enables patients to realize its therapeutic benefits, which ultimately leads to better disease management, enhanced quality of life, and the potential for lower healthcare costs associated with diabetes-related complications.

Novo Nordisk is committed to working with patients and payers to ensure that those who benefit from our medications have access to them. Because Ozempic® is both highly effective and broadly affordable, we respectfully request that the Board decline to conduct a cost review for Ozempic®, and caution that the unintended consequences of pursing a UPL could upend care for thousands of Marylanders living with diabetes.

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[18] Novo Nordisk internal data on file.
[19] The Federal Trade Commission. Interim Staff Report. July 2024. "Pharmacy Benefit Mangers: Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacy." Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (ftc.gov)
[20] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022. https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html
[21] *Id. at 15*

Thank you for the opportunity to provide comments and for your consideration of the issues raised in this letter. Should you have any questions or concerns, please contact Ryan Urgo, Head of Policy, at RVUR@novonordisk.com for additional information.


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 (Ozempic)**

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 Ozempic. 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.

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

**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

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

EACH PIC COALITION

# Exhibit 6C-

Written Comments

(Request September 4, 2025)

September 4, 2025

***VIA ELECTRONIC MAIL***

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
mailto:comments.pdab@maryland.gov

**Re: Dossier Comment – OZEMPIC® (semaglutide) and TRULICITY® (dulaglutide)**

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care. AbbVie is using advanced technologies and data science to gain unprecedented insights that help us to target medicines more precisely, identify opportunities for combinations and provide patients and their physicians with actionable diagnostic tools, treat disease and to respond to unmet patient needs. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives. AbbVie manufactures and markets SKYRIZI®, one of the products selected by the Board for a "cost review" (or "affordability review").

On behalf of AbbVie Inc., we appreciate the opportunity to submit comments regarding the Board's cost review dossiers for Ozempic® (semaglutide) and Trulicity® (dulaglutide). We write to affirm that all the critiques and concerns detailed in our prior comment letter on the Farxiga® dossier,[1] dated July 3, 2025, are equally and fully applicable to the Ozempic and Trulicity dossiers.

As detailed below, the Ozempic and Trulicity dossiers were prepared by the Board through substantially similar processes and methodologies as the Farxiga dossier. As such, they manifest the same procedural and substantive deficiencies we identified previously. Our principal concerns include:

1. **Process Transparency and Stakeholder Engagement**

[1] https://pdab.maryland.gov/Documents/comments/2025/Farxiga%20Dossier%20Comments%207.3.2025.pdf

- The Board continues to provide inadequate time for meaningful stakeholder review and public comment. As with the dossiers created for Farxiga and Jardiance, the Ozempic and Trulicity dossiers are lengthy, highly technical documents for which stakeholders had very limited time to review and respond to revisions. This truncated timeline impedes meaningful feedback and undermines confidence in the Board's process.
- Like Farxiga and Jardiance, the Board provides no detailed redlining or documentation of changes between dossier versions, impeding transparency and effective analysis by affected parties.

2. **Data Quality and Source Reliability**
   - All four dossiers for the Phase 1 diabetes drugs exhibit similar deficiencies in vetting data sources, with potential inclusion of incomplete, inconsistent, or incorrectly attributed data (e.g., NDC lists, utilization, and pricing fields with unexplained redactions or ambiguities). This raises concerns regarding the reliability and accuracy of the Board's analyses and conclusions.
   - Documentation on methodologies for weighing and validating data is insufficiently specific, both in general data tables and in calculations of spending, utilization, and budget impact.
3. **Inconsistent or Incomplete Consideration of Statutory Factors**
   - Consistent across the dossiers is a lack of clarity as to how the Board is applying required statutory factors—particularly patient out-of-pocket spending, the impact of patient assistance programs, and cost impacts to state/local entities. For all dossiers, it is unclear how the Board differentiates or prioritizes data relevant to public payers versus the broader commercial market, which risks exceeding statutory authority.
   - The methodology for inclusion and assessment of Health Economics and Outcomes Research (HEOR) and literature is under-described for all dossiers. There is no clear explanation of search strategies, inclusion/exclusion criteria, or weighting of study quality—replicating the transparency gap raised in our comments on the Farxiga dossier.
4. **Stakeholder and Patient Input**
   - Each dossier, including Ozempic and Trulicity, provides only summary statements or spreadsheets regarding public and patient group feedback. There is minimal evidence that stakeholder concerns have been meaningfully incorporated or addressed.
5. **Budget Impact and Real-World Context**

- As with Farxiga and Jardiance, the Board concedes that non-uniform budget data and missing contextual information impede robust assessment of impact on public budgets and patient access. Yet, the dossiers proceed with incomplete analysis rather than taking appropriate steps to obtain reliable data or revise the analytic approach.

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The OZEMPIC® and TRULICITY® dossiers continue to amplify the significant concerns we have with the Board's process for developing these data compilations, which clearly lack rigor, consistency and thoroughness and thus fall short of representing a drug's full value to patients. The Board is well aware of these concerns through comments and other stakeholder engagement throughout the cost review process but continues to ignore this feedback. Indeed, the Board even acknowledges the flaws in its dossier in public meetings yet fails to take any action in its work product to address them, or to take the additional time needed to address even the concerns raised by the Board's own members.

For all of these reasons, we maintain that the foundational flaws, procedural shortcomings, and substantive analytic gaps outlined in our Farxiga dossier comments remain equally present in the Board's cost review dossiers for both Ozempic and Trulicity. We respectfully urge the Board to revisit its review process, enhance transparency and stakeholder engagement, establish robust data vetting standards, and provide clear, meaningful opportunity for public input prior to making any affordability determinations.

As the PDAB has selected SKYRIZI for the Phase 2 drugs affordability review, AbbVie remains concerned about the dossier preparation process for SKYRIZI. We respectfully request the opportunity to review all SKYRIZI-related materials, including staff-prepared dossiers, prior to any public release. Ensuring both accuracy and the protection of confidential information are our top priorities, and we are committed to collaborating with the Board on these important matters.

Thank you for the opportunity to provide this feedback. Please feel free to contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Kim Fitpatrick
Vice President, State Government Affairs
Government Affairs
On behalf of AbbVie Inc.

[redacted] [redacted]

Maryland

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

# DOSSIER COMMENT – Ozempic

**Kerstin Haskell - WBHT** [redacted] > Wed, Aug 27, 2025 at 3:42 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

Dear Members of the Maryland Prescription Drug Affordability Board,

I am writing to share my personal experience with Ozempic and the affordability challenges it presents for patients like me.

My doctor prescribed Ozempic as part of my treatment plan, but the out-of-pocket cost was $1,300 per month. This was simply exorbitant and not sustainable. Because of the price, I was forced to seek the medication through a compounding pharmacy in order to obtain a more affordable version. Even then, the process was burdensome, long, and frustrating.

The cost of Ozempic highlights how patients are bearing an unreasonable financial burden. Drug companies are profiting significantly from the high demand for this medication and its proven effectiveness, while many patients struggle to access it. For those without comprehensive insurance coverage, or for whom this medication is not fully covered, the costs become a barrier to care and can compromise health outcomes.

In my experience, the affordability challenges are real and severe. The high cost of Ozempic does not just strain individuals—it has a broader impact on the healthcare system as patients are forced to delay or alter treatment.

I appreciate the Board's work to examine these issues and strongly encourage action to reduce costs so that patients can access life-changing medications like Ozempic without financial hardship.

Sincerely,

Kerstin Traum Haskell

Anne Arundel County Resident

September 4, 2025

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

TO: Members of the Maryland Prescription Drug Affordability Board

Having reviewed the dossiers for Ozempic and Trulicity, I am providing this information for the Board's review out of significant concern regarding the potential implementation of Upper Payment Limits (UPLs) for these two medications. I applaud the Board in convening these hearings to receive input, information, and opinions from stakeholders to address affordability challenges. Yet I am particularly troubled by what the dossier analysis reveals about the Board's approach to these essential therapies. Your impressive analyses only focus on the drugs' list prices without also assessing the total economic and health patient costs nor the drug pricing and supply ecosystem. Based on our comments in July, many of the concerns we raised about the Board's methodology and approach to evaluating these medications remain unaddressed in the current dossier analysis.

I am a board-certified pediatrician and pediatric rheumatologist and spent my career caring for young people with chronic or disabling conditions. Many of my patients, such as those with juvenile idiopathic arthritis and lupus, rely on specialized, innovative and, unfortunately, expensive therapies. My primary focus is always ensuring the well-being of my patients, but as a result of your legislative charges, I fear that the Board's analyses and decisions cannot reflect this same mandate. The prime directives for the Board, as stated by your enabling legislation, are that "… the [cost] review shall determine whether use of the prescription drug product … led or will lead to affordability challenges for the State health care system or high out–of–pocket costs for patients."For example, the lack of prioritization of the potential real-world consequences of a UPL is problematic. The creation of the Maximum Fair Price (MFP) within the Inflation Reduction Act has resulted in a 32% increase in out-of-pocket costs to patients.[1] Since a UPL creates a similar situation to the MFP, there is no reason not to expect a similar consequence within Maryland. Similarly, the National Community Pharmacists Association has reported that many of its member pharmacies will not be carrying medications with a MFP because they cannot afford to do so.[2] This too is likely to occur in Maryland. We also know that insurers and pharmacy benefit managers will likely adjust their formularies if the UPL reduces their profits by shifting such a medication to a higher tier or excluding it from the formulary; how will be the Board respond to such actions and how quickly will you be able to respond?

Clinicians view the Board's search for "therapeutic alternatives" as inherently misguided and potentially dangerous to patients for whom substitution is not clinically appropriate due to their unique medical

[1] https://pioneerinstitute.org/the-inflation-reduction-act-ira-overview/

[2] https://www.ncpa.co/pdf/2025/ncpa-comments-cms-part-d.pdf

situations, genetics and/or treatment needs. The complexities of personalized patient care cannot be considered as these so-called “alternatives” may not be able to address the patient’s individual circumstances. Further, unilaterally designating certain medications as “therapeutic alternatives” fundamentally disrupts the clinician’s ability to exercise their medical expertise in concert with their patient.

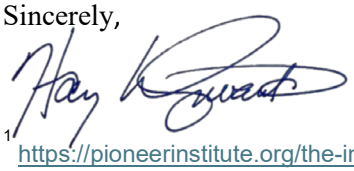
While the dossiers provided for this meeting are extensive and more transparent than many other PDAB’s analyses, they still fail to present clinically relevant alternatives. These drugs are compared to other diabetic “treatments,” but the analyses do not adequately consider interventions that directly address the full range of approved FDA indications and conditions impacted by these medications. Instead, the comparisons are primarily focused on other diabetes medications with different mechanisms of action and incomplete overlap in therapeutic indications. An easily foreseeable result of your actions could be patients now requiring 2 or 3 drugs to potentially control the multiple medical issues that were previously successfully controlled by one. Will you be tracking and reporting these potential financial increases in the State’s health care system? How will the secondary morbidities treated by theses drugs be measured and reported?

The Board's narrow focus on state budgetary savings fundamentally misrepresents and underestimates the true financial impact of establishing UPLs access to these medications. While the dossier analysis demonstrates potential savings on pharmaceutical line items, it fails to examine the broader fiscal implications for Maryland's overall healthcare expenditures. By concentrating solely on immediate drug costs rather than comprehensive health outcomes, the Board risks creating an illusion of savings while simply shifting expenses from one budget category to another, without considering the significantly higher costs down the road. The Board's approach appears designed to benefit state budget planners and insurance entities in the short term while transferring both financial burdens and health risks to patients who can least afford such shifts. This cost-shifting strategy may yield modest pharmaceutical savings today, but it virtually guarantees exponentially higher healthcare expenditures in future budget cycles when undertreated patients require more intensive and expensive medical interventions.

Everyone shares your goal to lower prescription drug costs, but the current myopic process that only focuses on the drug list prices and not the total cost to patients risks limiting access to essential medications while creating longer term negative health outcomes. Since the Board is unable to address the roles of all participants within the drug pricing and supply ecosystem, I fear your many efforts will be for naught. All clinicians and patients are eager to collaborate with the Board to ensure affordability decisions reflect real-world patient needs with a more thoughtful, patient-centered approach. As it stands, however, the Board’s actions could inadvertently restrict access to effective cost-saving medications for those Maryland residents who need them the most. We encourage the Board to address the multiple deficiencies and restrictions placed upon itby asking the legislature to consider expanding your ability to develop methods of lowering actual drug costs, not just the list prices of drugs purchased by the State and Marylanders.

Thank you for your attention to this critical issue.

Sincerely,



[1] https://pioneerinstitute.org/the-inflation-reduction-act-ira-overview/

[2] https://www.ncpa.co/pdf/2025/ncpa-comments-cms-part-d.pdf

Harry L. Gewanter, MD, FAAP, MACR
Board Member, Let My Doctors Decide Action Network

[1] https://pioneerinstitute.org/the-inflation-reduction-act-ira-overview/

[2] https://www.ncpa.co/pdf/2025/ncpa-comments-cms-part-d.pdf

MARYLAND HEALTH BENEFIT EXCHANGE

750 E. Pratt St., 6th floor
Baltimore, MD 21202
marylandhbe.com

September 4, 2025

**Re: MHBE - DOSSIER COMMENT – OZEMPIC (semaglutide)**

The Maryland Health Benefit Exchange (MHBE) respectfully submits this comment letter for – Dossiers for prescription drug product Ozempic (semaglutide).

MHBE recognizes the importance of state-wide efforts to address high costs of prescription drug products and health care costs generally. We know that prescription drugs, in particular brand name drugs, are a significant driver of premium costs in the individual market and state costs via the state reinsurance program. A report from the Maryland Health Care Commission determined that **prescription drugs accounted for almost a third (30%) of total per capita spending** for privately insured markets in Maryland in 2020.[1] In an MHBE analysis of 2022 Maryland individual market claims, **brand name drugs accounted for** 21% ($343M) of all claims costs by all enrollees and **27% ($279M) of all claims costs by enrollees in the state reinsurance program (SRP)**.

In the MHBE analysis, Ozempic accounted for a significant portion of total drug claims costs in 2022 in the individual market - **2,077 enrollees received at least one prescription of various formulations of Ozempic**[2], accounting for 2.5% ($8.62M) of brand name prescription drug claims costs in the individual market. Further, Ozempic accounted for a significant portion of individual market drug claims costs by enrollees in the SRP as well. Just **756 enrollees who received at least one prescription of various formulations of Ozempic** accounted for **1.3% ($3.62M)** of brand name prescription drug claims costs by SRP enrollees.

Lower prices for higher-cost prescription drugs could reduce commercial insurers' per capita spending, putting downward pressure on average monthly premiums, along with out-of-pocket drug costs for consumers. Recent polling by the Kaiser Family Foundation found that more than a quarter of adults taking prescription drugs report difficulty affording their medication, including 40% of those with annual household incomes below $40,000.[3]

Lowering certain prescription drug costs would also potentially decrease costs associated with the reinsurance program, which works to mitigate the impact of high-cost enrollees on premium rate increases in the individual market. Specifically, lower prescription drug costs could reduce the number of individuals whose annual costs exceed the threshold at which reinsurance payments made by the State to an individual's insurer kicks in ($21,000 for plan year 2025),[4] and, for those individuals who reach the threshold, reduce the claims costs that the reinsurance program reimburses.

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[1] Maryland Health Care Commission: Spending and Use Among Maryland's Privately Insured Report, 2020 (2022).
[2] OZEMPIC 2 MG/1.5 ML, 4 MG/3 ML, and 8 MG/3 ML.
[3] Kaiser Family Foundation: Public Opinion on Prescription Drugs and Their Prices (August 2023).
[4] Maryland Health Benefit Exchange: 2025 Reinsurance Parameters (July 2024).

MARYLAND HEALTH BENEFIT EXCHANGE

750 E. Pratt St., 6th floor
Baltimore, MD 21202
marylandhbe.com

For further discussions or questions, please contact Johanna Fabian-Marks, Director of Policy and Plan Management at johanna.fabian-marks@maryland.gov.

Sincerely,

Michele Eberle

Michele Eberle
Executive Director

[redacted] [redacted]

Maryland

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

## Dossier Comments Ozempic

1 message

**Vinny DeMarco** <demarco@mdinitiative.org> Thu, Sep 4, 2025 at 1:23 PM

[redacted]

September 4, 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 Ozempic, including the dossier published ahead of the scheduled September 29 PDAB meeting.

Ozempic is widely used for treating diabetes, heart failure, and chronic kidney disease. Its high cost is a burden on 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 Ozempic has generated billions in revenue for manufacturers, largely from charging patients in the United States ten times more than in comparable countries.

We have held forums across the state in past years, and routinely heard from patients about their struggle to afford Ozempic.

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 so that taxpayers can begin to save millions of dollars that are essential for other critical services.

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 Ozempic, we would be happy to connect you with consumers willing to provide feedback.

Vincent DeMarco
Maryland Citizens' Health Initiative
[redacted]

[redacted]

**September 4, 2025**

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

**VIA ELECTRONIC MAIL TO** COMMENTS.PDAB@MARYLAND.GOV

RE: DOSSIER COMMENT- Ozempic®

Dear Members of the Maryland Prescription Drug Affordability Board:

Novo Nordisk, Inc. (NNI) respectfully submits this letter in response to the Maryland Prescription Drug Affordability Board's (PDAB) cost review study dossier for Ozempic®. As a global healthcare company with a 100-year history of innovation, we are committed to preventing, treating, and ultimately curing diabetes, and to improving the lives of those living with serious chronic conditions, including hemophilia, growth disorders, and obesity.

Ozempic®, developed and manufactured by Novo Nordisk, is currently subject to a cost review by the Board. We support the PDAB's efforts to improve patient access and affordability—objectives we wholeheartedly share— but we maintain that the Board's current approach will not translate into meaningful results for patients.

The ongoing changes to the review timeline have made it challenging to provide the comprehensive feedback that such a significant process warrants. Nevertheless, we feel it is important to highlight key issues regarding the development and quality of the dossier, as these concerns raise substantive questions about its validity. If the Board's goal is to achieve an accurate assessment of a drug subject to review, a more rigorous and consistent process will be essential. We offer these comments as constructive feedback and hope they will be carefully considered in the ongoing effort to serve Maryland patients.

**The Dossier Contains Several Errors That Undermine Its Accuracy**

While PDAB staff have had several months to prepare the cost review study dossier for Ozempic®, there are notable errors in the document regarding the accuracy and completeness of basic information and data. **Our initial concern is the incorrect inclusion of Trulicity® information in the Ozempic® cost review dossier.** This is evidence of content being copied and pasted from the dossier for Trulicity®. For example, on Page 43 under Factor 6.4: "Staff re-

viewed published cost-effectiveness literature in the United States to identify the potential incremental costs associated with the use of *Trulicity (dulaglutide)*," and again on Page 53 under Factor 7.1, literature review: "Staff conducted a literature review using Google Scholar and PubMed for articles using the search term 'Co-payment Adherence *dulaglutide*.'" Such errors may be unintentional, but they highlight broader issues regarding the dossier's reliability, raising concerns about its suitability as a foundation for making affordability determinations. As we explain below, Ozempic is the only drug that treats multiple conditions not addressed together by any other single molecule.

It is critical to underscore the significant issues with the selection of NDC-11s included in the PDAB's cost review for Ozempic®. Strikingly, only **three** of the NDCs presented are actually saleable, whereas the majority identified by the PDAB are discontinued, pertain to other manufacturers, or represent only product inserts. This selective inclusion is not a benign oversight—it fundamentally undermines the validity of the cost data upon which the Board intends to base its affordability determinations. The reliance on non-saleable NDCs raises the risk that the resulting analysis does not accurately capture the costs relevant to Maryland patients. A saleable NDC is not just an abstract identifier; it uniquely designates the "unit of sale"—the specific individual package of a drug that is purchased, stocked, dispensed, and ultimately reaches the patient. By contrast, other NDCs may refer to bulk components, sample packaging, or configurations not reflective of actual market transactions. Therefore, the credibility and utility of the Board's analysis depend on its focus on saleable NDCs, which represent the true point of patient access and expense.

| National Drug Code | Proprietary Name | Non-Proprietary Name | Dosage-Strength | |
|---|---|---|---|---|
| 00169-4132-90 | Ozempic | Semaglutide | 0.5 MG/1ML | Discontinued |
| 00169-4181-03 | Ozempic | Semaglutide | 0.5 MG/3ML | Inner Package |
| 00169-4181-90 | Ozempic | Semaglutide | 0.5 MG/3ML | Sample |
| 00169-4772-90 | Ozempic | Semaglutide | 2.86 MG/ML | Sample |
| 50090-5138-00 | Ozempic | Semaglutide | 0.5 MG/1.5ML | Other M'er |
| 50090-5139-00 | Ozempic | Semaglutide | 1 MG/1.5 ML | Other M'er |
| 70518-2143-00 | Ozempic | Semaglutide | 2 MG/1.5 ML | Other M'er |
| 00169-4181-97 | Ozempic | Semaglutide | 0.68 MG/ML | Sample |
| 00169-4132-97 | Ozempic | Semaglutide | 1.34 MG/ML | Discontinued |
| 00169-4132-11 | Ozempic | Semaglutide | 2 MG/1.5ML | Discontinued |
| 00169-4132-12 | Ozempic | Semaglutide | 2 MG/1.5ML | Discontinued |
| 00169-4136-02 | Ozempic | Semaglutide | 2 MG/1.5ML | Discontinued |
| 00169-4136-11 | Ozempic | Semaglutide | 2 MG/1.5ML | Discontinued |
| 00169-4181-13 | Ozempic | Semaglutide | 2 MG/3ML | Saleable |
| 00169-4772-97 | Ozempic | Semaglutide | 2.68 MG/ML | Sample |
| 00169-4130-01 | Ozempic | Semaglutide | 4 MG/3ML | Inner Package |
| 00169-4130-13 | Ozempic | Semaglutide | 4 MG/3ML | Saleable |
| 50090-5949-00 | Ozempic | Semaglutide | 4 MG/3ML | Other M'er |
| 00169-4772-11 | Ozempic | Semaglutide | 8 MG/3ML | Inner Package |
| 00169-4772-12 | Ozempic | Semaglutide | 8 MG/3ML | Saleable |
| 50090-6051-00 | Ozempic | Semaglutide | 8 MG/3ML | Other M'er |

The effectiveness of the PDAB's decision-making is inherently dependent on the quality of its data. It is notable that during its drug selection and cost review process, the PDAB has consistently failed to clearly define how it will assess the accuracy, reliability, and validity of the data sources it references. Furthermore, there has been insufficient detail regarding how the PDAB will restrict its use of data and information from these sources to only those factors specified in statutes and implementing regulations.

**The Dossier Does Not Recognize the Transformative Value of Ozempic®**

Ozempic® has no therapeutic alternatives, as it offers the only comprehensive patient benefit compared to other drugs within its class and beyond. **Semaglutide treats multiple conditions not addressed together by any other single molecule and is therefore not comparable to any potential alternative treatment(s).** Notably, GLP-1 medications are differentiated by their cardiovascular benefits, which are now a cornerstone in evaluating medicines for type 2 diabetes (T2D). Since 2008, cardiovascular outcomes trials (CVOTs) have been required by regulatory

agencies to ensure T2D drugs do not increase cardiovascular risk. Semaglutide has undergone extensive evaluation through three CVOTs in T2D populations (SUSTAIN-6, PIONEER-6, and SOUL) and one in the overweight/obese population (SELECT), all demonstrating its clear superiority in reducing major adverse cardiovascular events compared to the standard of care.

Furthermore, Ozempic® is the only GLP-1 receptor agonist proven to slow the progression of kidney disease in patients with T2D and chronic kidney disease (CKD).[1] [2] Clinical studies showed a 24% reduction in the risk of kidney failure, kidney disease progression as evidenced by sustained eGFR decline, or kidney or cardiovascular death, compared to placebo. When focusing specifically on kidney events, semaglutide achieved a 21% greater reduction over placebo.

Real-world studies reinforce these outcomes. In one study of T2D and CKD patients with an average age of 65, those treated with weekly semaglutide for 12 months saw albuminuria decrease by over 50% among those with macroalbuminuria—a key marker for CKD.[3] Another study found that weekly semaglutide led to a 4.5-point improvement in estimated glomerular filtration rate (eGFR) and a 1.2% decrease in hemoglobin A1c blood tests after a year of treatment.[4]

Crucially, many of the medications considered by the PDAB as therapeutic alternatives have already failed for patients prior to those patients' being prescribed Ozempic®, making direct comparisons medically inaccurate. For example, older patients with T2D often do not achieve sufficient blood sugar control with metformin, leading to the use of Ozempic®, which brings additional benefits like reduced cardiovascular risk and weight loss. The ability of Ozempic® to prevent costly cardiovascular hospitalizations—including heart attacks and strokes, which can

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[1] Perkovic V, Tuttle KR, Rossing P, Mahaffey KW, Mann JFE, Bakris G, Baeres FMM, Idorn T, Bosch-Traberg H, Lausvig NL, Pratley R. Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes. N Engl J Med [Internet]. 2024 Jul 11 [cited 2025 Feb 11];391(2):109–21. Available from: https://pubmed.ncbi.nlm.nih.gov/38785209; Davies M, Færch L, Jeppesen OK, Pakseresht A, Pedersen SD, Perreault L, Rosenstock J, Shimomura I, Viljoen A, Wadden TA, Lingvay I. Semaglutide 2·4 mg once a week in adults with overweight or obesity, and type 2 diabetes (STEP 2): a randomised, double-blind, double-dummy, placebo-controlled, phase 3 trial. Lancet [Internet]. 2021 Mar 13;397(10278):971–84. Available from: https://pubmed.ncbi.nlm.nih.gov/33667417/

[2] Chu L, Bradley RM, Auerbach P, Abitbol A. Real-world impact of adding a glucagon-like peptide-1 receptor agonist compared with basal insulin on metabolic targets in adults living with type 2 diabetes and chronic kidney disease already treated with a sodium-glucose co-transporter-2 inhibitor: The Impact GLP-1 CKD study. Diabetes Obes Metab [Internet]. 2024 Oct 1; 26(10). Available from: https://pubmed.ncbi.nlm.nih.gov/39113258/

[3] Aviles Bueno B, Soler MJ, Perez-Belmonte L, Jimenez Millan A, Rivas Ruiz F, Garcia De Lucas MD. Semaglutide in type 2 diabetes with chronic kidney disease at high risk progression-real-world clinical practice. Clin Kidney J [Internet]. 2022 Aug 1 [cited 2025 Feb 12];15(8):1593–600. Available from: https://pubmed.ncbi.nlm.nih.gov/35892023/

[4] Data on file. Novo Nordisk.

cost $55,000–$75,000 per event and about $108 billion nationally[5]—is unmatched by drugs such as metformin.

**The Dossier Does Not Support Informed Discussions Regarding Affordability Challenges**

While the dossier is structured to satisfy statutory requirements, it fails to fully capture the broader market forces actively working to reduce the price of semaglutide. For instance, on August 18th, NNI introduced a new self-pay program for Ozempic®, allowing patients with a prescription to access the medication for $499 per month. This initiative specifically supports T2D patients who lack commercial insurance and who would otherwise pay prices at or above the WAC. Beyond this, NNI offers both a patient assistance program and copay assistance for patients for patients living with TD2. This includes offerings that reduce the price at the pharmacy counter to as little as $25 for a one-month supply of Ozempic® for patients with commercial insurance facing large co-pays. Additionally, the company's Patient Assistance Program (PAP) provides free Ozempic® to patients in need who are uninsured or receive insurance through Medicare and whose household income falls below 400% of the federal poverty line (approximately $120,000 for a family of four).[6] Such measures underscore the essential link between access and affordability, and any meaningful discussion about patient costs must include an examination of insurance benefit design and payer-related barriers.

Where the dossier references patient affordability concerns, these challenges are largely attributed to insurance benefit design—such as copays, coinsurance, and deductibles—rather than the list price of Ozempic® itself. For many patients, out-of-pocket expenses remain modest, with supportive programs available to qualifying individuals. As noted previously, Ozempic® is currently covered by 99 percent of commercial insurance plans in the United States. Since its launch in 2018, the net price—the actual amount Novo Nordisk receives for its medicines—has decreased by approximately 40%. Today, 80 % of U.S. patients with insurance coverage for Ozempic® pay $25 or less per prescription, and 90 percent pay $50 or less. In Maryland specifically, 82.5% of insured patients pay $25 or less. Among Medicaid patients, 99.6% pay less than $5 for Ozempic®.

Diabetes and its comorbidities place a significant financial burden on the US Healthcare System. In 2022 the total direct medical costs associated with those living with diabetes was $307 billion[3]. Of that $307 billion only 8%, or $24.7 billion, was associated with the costs of non-insulin

[5] National Costs for Cardiovascular-Related Hospitalizations and Inpatient Procedures in the United States, 2016 to 2021 Haidar, Amier et al. American Journal of Cardiology, Volume 234, 63 - 70

[6] See NovoCare, Patient Assistance Program, Novo Nordisk, https://www.novocare.com/diabetes/help-with-costs/pap.html.

antidiabetic medications such as Ozempic®. On the other hand, medical expenses such as inpatient hospital care, ER visits, and outpatient office visits accounted $169.5 billion, or 55.2% of the direct medical costs.

It is apparent that any drug therapies able to reduce the prevalence of these expensive and deadly diseases will provide enormous personal, economic, and societal value to individuals, families, and communities across the country. According to a recent analysis by Goldman Sachs increased utilization of GLP-1 medications could add as much as an additional 1% to U.S. gross domestic product over the next four years due to a reduction in health problems like heart attacks, strokes, and diabetes.[7] One study estimates that for each Medicare patient able to receive anti-obesity treatment, the Medicare system would see $6,800 to $7,200 of cost savings over 10 years from reduced usage of ambulatory care and prescription drugs—again, that's per patient.[8] Therefore, apart from the essential human impact, drugs that could meaningfully address the diabetes epidemic also have the potential to be fiscally transformative. That means discussions about the cost of treatment must necessarily start with the value, tangible and intangible, as well as the savings, that GLP-1 medications provide.

* * * *

In closing, it is essential that any evaluation of Ozempic® reflect its transformative impact on patient outcomes, its unmatched therapeutic advantages, and the considerable efforts NNI has undertaken to enhance affordability and access. Discussions about value and cost must consider the broader context—including real-world benefits, evolving insurance coverage, and proactive support programs.

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[7] Matthew Fox, The more Americans who take Ozempic, the faster the US economy could grow, Goldman Sachs says, Business Insider (April 26, 2024), https://www.businessinsider.com/us-economy-faster-growth-ozempic-glp-1-weight-loss-drugs-2024-2.

[8] Fang Chen et al., Ten-year Medicare budget impact of increased coverage for anti-obesity intervention, J. Med. Econ. (Aug. 19, 2019), https://pubmed.ncbi.nlm.nih.gov/31378108/.

September 4, 2025

Maryland Prescription Drug Affordability Board

16900 Science Drive, Suite 112-114

Bowie, MD 20715

Re: SEMAGLUTIDE COST REVIEW DOSSIERS

Dear Members of the Board,

The Partnership to Advance Cardiovascular Health (PACH) is a nonprofit coalition of patients, providers, and advocacy organizations with the shared mission of promoting public policies and practices that drive innovation and enhance outcomes for individuals living with heart disease. Representing 20 member organizations, PACH serves as a collaborative platform to advance reforms at the federal, state, and health plan levels that expand access to care for patients with cardiovascular and related conditions.

Recognizing that high prescription drug costs remain a significant barrier to treatment, we support the Maryland Prescription Drug Affordability Board's (PDAB) commitment to ensuring medications are accessible and affordable *for Maryland residents*. Consistent with our mission to champion both access and innovation in cardiovascular medicine, we write today to provide important context regarding a medication currently under review by the Maryland PDAB.

**The Cardiovascular Disease Burden:**

Cardiovascular disease remains the leading cause of death in Maryland and the United States.[1] America's progress in decreasing the death rate due to heart disease and stroke has stalled. In fact, the death rate for cardiovascular disease, including heart disease and strokes, has fallen just 4% since 2011 after dropping more than 70% over the prior six decades. What is particularly alarming is that certain age and demographic groups are seeing increases in the rate of cardiovascular-related death. These trends are worse for minority communities, rural communities and those with lower socioeconomic status.[2] Ensuring that patients have access to cardiovascular primary and secondary preventative treatment, as well as promoting innovation and new modalities for treatment, are of the utmost importance to PACH and our partners.

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[1] National Center for Health Statistics. (2025, August 20). *Maryland | Stats of the States*. Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/state-stats/states/md.html#cdc_data_surveillance_section_3-leading-causes-of-death

[2] National Center for Chronic Disease Prevention and Health Promotion. (2024, October 24). *Heart disease facts.* Centers for Disease Control and Prevention. https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html#:~:text=In%202023%2C%20919%2C032%20people%20died%20from%20cardiovascular%20disease.,services%2C%20medicines%2C%20and%20lost%20productivity%20due%20to%20death

**Innovation in Cardiovascular Disease Management**

GLP-1s are some of the most impactful innovations in healthcare today and, while they are known for treating type II diabetes, they also have significant cardiovascular benefits. Semaglutide is FDA approved to be used by patients with type 2 diabetes mellitus and established cardiovascular disease to prevent major adverse cardiovascular events, including cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. The specific GLP-1 the board is reviewing is one of only three drugs in their class that are recommended in the American Diabetes Association and American Association of Clinical Endocrinology guidelines to be used as first-line therapy for these cardiovascular events, making it particularly crucial for the cardiovascular patient community.[3]

The link between type II diabetes and cardiovascular disease is significant: type II diabetes increases the odds of having high blood pressure, abnormal cholesterol, and high triglycerides, which all greatly contribute to the risk of developing cardiovascular disease.[4] Individuals diagnosed with diabetes are twice as likely to have a heart attack or stroke.[5]

**Why Prevention Matters**

Data shows that effectively managing cardiovascular disease not only saves lives but saves money to the healthcare system over time. Harvard economics professor David Cutler published data in Health Affairs that examined why spending growth declined over a decade starting in 2005 in Medicare. He found that nearly "half of the spending slowdown was attributable to slower growth in spending for cardiovascular diseases." He concluded that "roughly half the reduction in major cardiovascular events was attributable to medications controlling cardiovascular risk factors." In conclusion, he states that "medically driven prevention can save money over time."[6]

Dr. Cutler's research suggests that if the PDAB's goal is to save the state money, ensuring greater access to therapies like GLP-1s is of the utmost importance.

**Comprehensive Approach to Affordability and Access**

Affordability reviews and price capping have already been attempted at the federal level with the passage of the Inflation Reduction Act. In fact, semaglutide has already been selected by the Centers for Medicare and Medicaid Services to be included in the 2025 "Maximum Fair Price"

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[3] Maryland Prescription Drug Affordability Board, Mitchell, Van T., *Ozempic (Semaglutide) - Dossier*, 2025, p. 8.
[4] "Cardiovascular Disease and Diabetes." *www.Heart.Org*, 8 Jan. 2025, www.heart.org/en/health-topics/diabetes/diabetes-complications-and-risks/cardiovascular-disease--diabetes
[5] "Diabetes Can Affect Your Heart." *www.Diabetes.Org*, www.diabetes.org/health-wellness/diabetes-and-yourheart/diabetes-affect-your-heart
[6] Cutler, David. *Explaining the Slowdown in Medical Spending Growth among the Elderly, 1999–2012 | Health Affairs Journal*, www.healthaffairs.org/doi/10.1377/hlthaff.2018.05372.

drug negotiations. The unintended consequences of this law are already impacting Medicare formularies, and more importantly, beneficiaries.

In fact, 7 of the 10 medications first selected for MFP negotiation were cardiometabolic treatments. Data provided by IQVIA and published by the Pioneer Institute shows that *patient out-of-pocket costs* for all seven of these treatments have gone up despite being price capped.[7] In the absence of larger pharmacy benefit reform, market pressures from Medicare redesign and price-negotiation are actually having the opposite effect that federal lawmakers intended.

We believe that this same scenario will translate to the state level. This would mean that Maryland's affordability assessment and upper payment limit designation will limit both access and make medications more unaffordable *for patients.*

**Actions to Protect Patients and Increase Affordability and Access**

A more holistic approach to address affordability should include reviewing health insurer and pharmacy benefit manager practices like step-therapy and prior authorization protocols, prohibiting spread pricing, requiring pass-through savings directly to patients, and prohibiting co-pay accumulator or "maximizer" programs so that any dollars spent toward a patient's deductible count toward their out-of-pocket limit. Until the medication supply chain is more transparent, we believe efforts to designate medications as unaffordable and promulgating UPLs at the state level will not achieve the board's goal of lowering costs *for patients.* Furthermore, it is crucial to remember that the most effective way to reduce healthcare costs is to prevent serious diseases before they become more dangerous and more expensive.

Thank you for your attention to this matter. We welcome any discussion on this issue and hope that the board will consider our recommendations when making further decisions regarding semaglutide.

Sincerely,

Sarah Hoffman

Senior Director

Partnership to Advance Cardiovascular Health

[7] "Patient Out of Pocket Costs." *Pioneer New England Legal Foundation*, pioneerlegal.org.


September 4, 2025

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

Re: OZEMPIC COST REVIEW DOSSIER

Dear Members of the Board,

On behalf of the Value of Care Coalition (VCC), a broad network of patient, caregiver, and health care provider advocacy organizations, thank you for the opportunity to comment on the recently published cost review dossier for Ozempic. We appreciate the Board's commitment to reviewing aspects of health care affordability in Maryland and value the opportunity to submit these comments.

The dossier offers a solid foundation on clinical indications, disease burden, pricing benchmarks, and utilization. However, two essential dimensions are underdeveloped: (1) the value this therapy provides to patients and clinicians, and (2) the role of insurance benefit design in real-world access and affordability.

First, on value. As outlined in VCC's July 2024 comments (included as Exhibit 6A) discussions of affordability are incomplete without a rigorous assessment of value as defined by the lived experience of patients who benefit from treatment and by clinicians who balance individual risks, comorbidities, and long-term outcomes. In the current dossier, perspectives from those closest to care delivery appear only in exhibits containing a handful of written comments. There is little to no analysis of why clinicians prescribe GLP-1 therapies, why patients choose them, or how outcomes would change without access to them. This gap risks skewing the affordability conversation toward price alone, rather than overall clinical and societal impact.

Second, on benefit design. The dossier's regression analysis appropriately notes that adherence declines as copays or coinsurance rise. Yet it stops short of fully examining how today's health plan benefit structures expose patients to higher costs or restrict access. Specifically, the dossier does not address:

- **Deductibles and Plan Structure**: Large up-front cost spikes that delay treatment initiation.
- **Formulary Tiering**: Placement of GLP-1 receptor agonists on higher tiers that impose substantial cost sharing.

- **Utilization Management:** Prior authorization, step therapy and other tactics – especially consequential for the GLP-1 class – that can delay or deny clinically appropriate care.

Without analyzing the impact of these utilization management levers, affordability discussions risk focusing too narrowly on top-line prices while missing the supply-chain and formulary dynamics that ultimately determine whether a patient can start and stay on guideline-consistent therapy.

Clinicians share these concerns. In a recent survey of specialists – including endocrinologists – in states with active PDABs (presented to the Board on July 28, 2025 via public oral comments), 93% reported insufficient knowledge-sharing between boards and providers. A majority (56%) of endocrinologists indicated they would not switch stable patients to another drug in the same class, while two-thirds expressed concern that PDAB actions could constrain treatment availability and clinical choice.

We were heartened to hear one PDAB Board Member, Dr. Eberechukwu Onukwugha, comment during the July 28 meeting underscoring that benefit design is central to patient access and should be incorporated into future dossiers.[1] We strongly agree.

**Recommendations**

To strengthen the Ozempic dossier – and future reviews – we respectfully urge the Board to:

1. **Integrate a structured value assessment.** Incorporate patient-reported outcomes, clinician decision-rationales, and scenario analyses of untreated or undertreated disease (e.g., complications avoided, quality-of-life gains, productivity effects).
2. **Add a benefit design impact analysis.** Evaluate how deductibles, coinsurance, tier placement, prior authorization, and step therapy influence initiation, adherence, and outcomes—using Maryland-specific plan designs where possible.
3. **Formally engage frontline stakeholders.** Establish a process for routine input from treating specialists, primary care clinicians, and patients (e.g., advisory panels, roundtables, or structured surveys) to inform both evidence selection and interpretation.
4. **Model real-world access scenarios.** Pair price analyses with access scenarios that reflect typical Maryland formularies and utilization management, quantifying expected changes in adherence and health outcomes.
5. **Report equity implications.** Assess how benefit design and access barriers differentially affect populations experiencing health disparities and propose mitigation strategies.

[1] Maryland Prescription Drug Affordability Board, *July 20 2025 Meeting,* July 2025, https://www.youtube.com/live/wtSm-_A3_kU?si=fG3ZcwoBYif-L_73&t=10393

In sum, affordability determinations require a full view of value and of benefit design — the two elements that most directly shape whether patients receive and maintain effective therapy. Refining the dossier along these lines will better support affordability, equity, and continuity of care for Maryland patients.

Thank you for your consideration.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition

# APPENDIX B-
# November 17, 2025
# Amended
# Resolution 2025-03

**AMENDED RESOLUTION 2025-03**
**OF THE**
**PRESCRIPTION DRUG AFFORDABILITY BOARD**
**PRELIMINARY DETERMINATION COST REVIEW STUDY OF OZEMPIC**
**November 17, 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 Ozempic 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 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

It is hereby

**RESOLVED** that:

The Board makes a preliminary determination that use of Ozempic:

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:

total gross spending for Ozempic for state and local governments exceeds 4.87% 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 November 17, 2025 by unanimous vote of a quorum of the Board.*

_____

# APPENDIX C-

## Written Comments (November 17, 2025 Board Meeting)

EACH PIC COALITION

November 12, 2025

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

**RE: Public Comments on Drug Reviews and UPL Framework**

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.

We appreciate the opportunity to comment on the board's upcoming review of the proposed upper payment limit (UPL) frameworks for Jardiance and Farxiga and the cost reviews of Ozempic and Trulicity.

**Transparency on Supplemental Rebate Structures**

As the board begins its discussion of the proposed UPL frameworks for Jardiance and Farxiga, we encourage greater transparency regarding the supplemental rebate component referenced in prior discussions. Although stakeholders were advised that details would be included in the UPL Action Plan, that document does not currently describe how these rebates would operate or what their intended purpose may be. We respectfully ask the board to clarify how such rebates would be designed, administered, and evaluated. Providing this information in advance will allow patients and other stakeholders to offer informed feedback on the potential impact of these mechanisms.

**UPLs Do Not Guarantee Savings for Patients**

We also underscore the limitations of a UPL in addressing patient affordability. UPLs may change what insurers or the state pay for a medication, but they do not cap or guarantee reductions in patient out-of-pocket costs. As our coalition has cautioned before, these policies can introduce new incentives for insurers and pharmacy benefit managers (PBMs) that may ultimately restrict access to needed treatments through greater utilization management, formulary reshuffling, or adverse tiering. These shifts risk delaying or disrupting care, and as our Patient Experience Survey shows, insurance barriers, not price alone, are often the real drivers of patient hardship and perceived "unaffordability."

While intended to reduce costs, implementing a UPL without complementary patient protections could worsen the very challenges patients already face. We therefore urge the board to establish clear safeguards before advancing any UPL frameworks and to continue exploring its policy alternatives—including reforms that directly address PBM and insurance practices that most influence patient costs.

**Resubmission of Comments on Ozempic and Trulicity**

As the board reviews materials on Ozempic and Trulicity, we are resubmitting comments previously sent in September and appreciate the opportunity for those comments to be considered in your review process.

**Conclusion**

We thank the board for its continued attention to these complex issues and urge a cautious, transparent, and patient-centered approach that safeguards access to care. Our coalition remains available as a resource and partner to ensure that patients' lived experiences meaningfully inform Maryland's affordability work.

Thank you for your consideration and for your commitment to ensuring patients' needs remain at the center of this process.

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

EACH PIC COALITION

September 4, 2025

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

**RE: Public Comments on Ozempic 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 Ozempic. 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.

**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.

The compiled dossiers include limited data on patient out-of-pocket costs and how assistance programs impact patient costs. Most importantly, the data only tells a small part of the story. Findings from our recent Patient Experience Survey underscore why patient input is critical to effective affordability reviews. According to patients, affordability is often shaped less by the drug's price and more by insurance barriers, cumulative health costs, and individual life circumstances. Whether patients paid $0–$10 per month or $250 a month, they still reported unaffordability due to insurance denials, utilization management, collective healthcare costs, or other access challenges that largely were unrelated to the retail or net cost of the drug.

We encourage the board to utilize the results of our study as a foundation when determining patient costs in their ongoing reviews, particularly as continued attempts to gain patient insights have proved challenging. Only by starting with patient input can the board appropriately address patient needs. For these reasons, we invite the MD PDAB to collaborate with EACH/PIC and our efforts to relaunch the Patient Experience Survey, utilizing data we collect to ensure patient testimony is included.

**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.

We also continue to 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.

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 Westrich-Robertson
tiffany@aiarthritis.org

EACH PIC COALITION

Ensuring Access through Collaborative Health (EACH) Coalition Lead

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

November 11, 2025

TO: Maryland Prescription Drug Affordability Board

FROM: Vincent DeMarco, President, Maryland Health Care For All Coalition

RE: Comments for November 17, 2025 PDAB Board Meeting

On behalf of the over 450 faith, community, labor, business and health care organizations in the Maryland Health Care For All Coalition, I am writing to commend the Maryland Prescription Drug Affordability Board (PDAB) for all the great work you have done as you prepare to make high cost drugs more affordable for state and local governments in Maryland. We have reviewed and applaud your staff for the great work done in preparation for the November 17 meeting on Jardiance, Farxiga, Ozempic and Trulicity. As you know all of these drugs are very high cost and therefore drain the budgets of state and local governments. That is why we strongly urge you to move as quickly as you can to use your upper payment limit authority to cap how much state and local governments must pay for these critically needed medications. As we are sure the prices of these drugs will continue to go up as they have done in the past at a rapid rate, the amount which the upper payment limits will save state and local governments will also increase over time, we think substantially.

We also urge you to move as quickly as you can to set the upper payment limits for Jardiance and Farxiga for state and local governments because, as you know, when you do so, that will start the one year time to begin to run after which you can set upper payment limits to help all Marylanders pursuant to the new legislation which Governor Wes Moore signed into law this past Session of the Maryland General Assembly. Drugs don't work if people can't afford them, and as much as 40 percent of Marylanders have trouble affording their necessary drugs. That is why it is urgent that you set the upper payment limits for Jardiance and Farxiga for state and local governments as soon as possible so that you can soon start helping all Marylanders afford their high cost drugs.

As you know, on October 3, the Colorado Prescription Drug Affordability Board set an upper payment limit on what all Coloradans will pay for the auto immune deficiency drug Enbrel. Advocates have calculated that this will save Coloradans over $32 million per year. We very much look forward to you making similar progress for Marylanders.

Once again, thank you so much for the great work you have done to get to this point and we are here to help in any way we can as you continue this life-saving work.

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

# APPENDIX D-

## Comments Received on Draft Cost Review Study Report (Requested 4/22/2026)

AARP Maryland

One Park Place | Suite 475 | Annapolis, MD 21401-3475
1-866-542-8163 | Fax: 410-837-0269
aarp.org/md | md@aarp.org | twitter: @aarpmd
facebook.com/aarpmd

**Maryland Prescription Drug Affordability Board**
**Comments on Draft Cost-Review and UPL Documents for Ozempic**
**April 2026**

AARP Maryland, which has about 850,000 members, congratulates the state's Prescription Drug Affordability Board (PDAB) on the three draft documents it released on April 22, 2026, regarding cost review and upper payment limits (UPLs) for Ozempic. They are thoroughly researched, balanced, clear, and justified in their conclusions and proposed actions.

Based on that and the very large and rapidly growing state and local government expenditures for Ozempic, AARP Maryland urges the prompt adoption of the draft Cost Review Study Report and draft UPL regulations for Ozempic. By doing that, the PDAB will position state and local governments to withstand the rapidly rising costs for this drug, which already accounts for 4.87 percent of their gross prescription drug spend in one instance. Moreover, the usage of this drug is likely to continue rising strongly since it is increasingly being prescribed "off label" by physicians for weight loss in addition to the FDA-approved uses for type 2 diabetes, cardiovascular disease (CVD) and chronic kidney disease (CKD).

The PDAB correctly made a unanimous prior preliminary determination that Ozempic has created an affordability challenge for the state health care system. The cost to the state and local government in Maryland, the PDAB found, is "disproportionate to the net cost paid by payors." And these costs also hit individual state and local government beneficiaries hard, with the impact likely to expand in the future, since the drug is considered the preferred GLP-1 option not only for type 2 diabetes but also for CVD and CKD.

The case for taking prompt action is strengthened further by FDA findings that Ozempic is no longer in a shortage situation. Moreover, the last of the drug's patents don't expire until December 2031 and June 2033, the PDAB noted. Therefore, no generic drugs that might exert downward pressure on Ozempic's price are on the near-term horizon.

Given this situation, the PDAB's draft UPL regulation on Ozempic is needed and appropriate. Under this draft, the UPL starting January 1, 2027, would be $274 for a 30-day supply. This cost is the same as the negotiated Medicare Fair Price, lending added credence to the suitability of the figure Maryland would use as its base when the UPL starts. And there would be annual inflation adjustments starting January 1, 2028, with the new rate then tied to the federal Consumer Price Index for 18 months before the UPL took effect.

For all these reasons, AARP Maryland praises the PDAB for the Draft Cost Review Study Report, the Calculations and Analyses Underpinning Potential UPL Values, and the draft UPL

regulations for Ozempic. AARP urges the prompt adoption of all these documents so that state and local governments in Maryland — and especially their beneficiaries — can begin receiving much-needed relief from the costs of this important drug.

Maryland

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

# The Effects of GLP Drug Pricing

**Schmitt, Benjamin [MD]** [redacted] > Fri, May 1, 2026 at 4:11 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

Members of PDAB…

Use of Ozempic, Wegovy, and similar medications for weight loss at HCPSS more than tripled over the past year for the Howard County Public School System. Because manufacturers charge employers about $1,000 per month—over three times what insured individuals typically pay ($250–$350)—projected health benefit costs were set to rise well over $10 million in a single fiscal year. HCPSS attempted to negotiate lower pricing, but vendors were unwilling to reduce costs. As a result, the decision was made to discontinue coverage for weight-loss use while continuing coverage for approved medical conditions such as diabetes.

We recognize that many employees turned to GLP-1 medications after other weight-loss efforts had not been successful, and that these treatments have been an important part of their health journeys. Maintaining a healthy body mass index plays a significant role in preventing chronic disease and supporting overall well-being. We share the concern that these medications remain financially out of reach for many and hope that more affordable options become available in the future.

The official statement that was released from HCPSS can be found below. Please feel free to reach out to me with any further questions or concerns.

Benjamin Schmitt
HCEA President
Howard County Education Association

“Art enables us to find ourselves and lose ourselves at the same time.”
-Thomas Merton

Effective March 31, 2026, the Howard County Public School System (HCPSS) will stop covering GLP-1 medications (such as Ozempic/Wegovy) specifically for weight management, following a surge in costs from $485,000 to over $3.6 million quarterly. Coverage for diabetes treatment remains unaffected, but new weight-loss prescriptions will not be approved after Dec. 1, 2025.

**Key Details Regarding the Decision**

- **Coverage Cutoff:** Weight loss coverage ends March 31, 2026, with no new approvals after December 1, 2025.
- **Diabetes Exception:** Employees using GLP-1 drugs for diabetes management will continue to have coverage.
- **Financial Impact:** The rising cost of these drugs threatened to increase employee health premiums by nearly 20%. Despite cutting this coverage, employees still face a 13% premium increase, according to the Baltimore Sun.
- **Recommendation:** The HCPSS Benefits Advisory Committee recommended this change to manage overall benefits costs, say the staff.hcpss.org.

The decision reflects a broader trend among large employers struggling with the high costs of weight-loss drugs. Employees affected by the change are encouraged to discuss alternative treatment options with their

providers.

**2 attachments**

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1K

**img-89b31923-81e1-4746-aa89-4f75f29c976e**
1K

May 1, 2026

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

**VIA ELECTRONIC MAIL TO** COMMENTS.PDAB@MARYLAND.GOV

**Re: Novo Nordisk Ozempic – Cost Review Study Report Public Written Comments**

Dear Members of the Maryland Prescription Drug Affordability Board:

Novo Nordisk (NN) is a global healthcare company committed to preventing, treating, and ultimately curing diabetes and improving the lives of those living with other serious chronic conditions, including hemophilia, growth disorders, and obesity. The Novo Nordisk Foundation, our majority shareholder, is among the top five largest charitable foundations in the world. Accordingly, our company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and the sustainability of society.

We strongly support the Maryland Prescription Drug Affordability Board's efforts to improve patient access and affordability. The Board's current process, however, is unlikely to lead to meaningful results for patients. Therefore, we respectfully submit this letter in response to the Draft Cost Review Study Report, highlighting our key concerns including 1) the lack of recognition of the transformative value of Ozempic®, 2) deficient data and questionable source reliability included in the Board's cost review processes, and 3) a fundamental disregard for the evolving pricing landscape that has impacted Ozempic® significantly.

## I. The Board has consistently ignored the qualitative value of Ozempic® as a unique and transformative medicine, relying on flawed metrics that could put patients at risk.

Novo Nordisk has concerns about the Board determination that use of Ozempic® has created an affordability challenge for Maryland's health care system. As reflected in the preparatory materials for previous meetings of the Board, this determination was based on the total gross spend for state and local governments, which was reported as "exceeding 4.87%," and not on patient-related out-of-pocket metrics. Using gross spend, as the Board has done here, is not an accurate representation of actual cost to the system as it disregards rebates, other discounts, and price concessions manufacturers make to payers, all of which ensure that patients are not

paying the list price that the Board is using to determine whether affordability is, in fact, a challenge. As stated in previous comment letters to the Board, 80% of US patients with insurance coverage—and 82.5% of Maryland patients, specifically—are paying $25 or less per prescription for Ozempic®, and 90% are paying $50. Clinicians with expertise in this therapeutic area recognize the significant value of Ozempic®. In it's 2026 Guideline pharmacotherapy recommendations, the American Diabetes Association stated that "in adults with Type 2 diabetes…treatment plan should include medications…like GLP-1 RA", the class of drugs to which Ozempic® belongs.[1] Despite these facts, the Board has determined that Ozempic® has created an "affordability challenge" based on flawed metrics.

Importantly, evaluating affordability by aggregate gross spending penalizes treatments for chronic disease and subjects them to continual scrutiny, even when they deliver strong clinical value for patients and generate long-term cost offsets and savings. For people living with type 2 diabetes—particularly those at higher risk of complications—Ozempic® offers a highly-effective treatment option and is frequently found to be cost-effective as compared to other glucose lowering agents in published models that consider long-term benefits and cost offsets.[2] Rather than targeting broadly used chronic disease therapies with excellent outcomes that provide good value, the Board should adopt a more holistic view of affordability and, for example, pinpoint low-value drivers of spending. Under its current narrow assessment of affordability, the Board risks setting a UPL that could undermine access to clinically effective treatments for patients who need them.

## II. The Cost Review Study Report, which will impact the Board's final affordability determination, relies on deficient data and affordability metrics that are not rooted in market realities for Ozempic®.

First, reliance on non-saleable NDCs raises the risk that the resulting analysis does not accurately capture the costs relevant to Maryland patients. Saleable NDCs designate the "unit of sale"—the specific individual package of a drug that is purchased, stocked, dispensed, and ultimately reaches the patient. Other NDCs may refer to bulk components, sample packaging, or configurations not reflective of actual market transactions. Therefore, the credibility and utility of the Board's analysis depend on its focus on saleable NDCs, which represent the true point of patient access and expense.

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[1] American Diabetes Association, Standards of Care in Diabetes ---2026 accessed at standards-of-care-2026.pdf (April 28, 2026).

[2] See, for example, results of a systematic review and meta-analysis: Cost-effectiveness of Semaglutide Compared With Other Glucose-Lowering Medications in Treating Type 2 Diabetes: A Comprehensive Systematic Review and Meta-analysis accessed at Cost-effectiveness of Semaglutide Compared With Other Glucose-Lowering Medications in Treating Type 2 Diabetes: A Comprehensive Systematic Review and Meta-analysis | Diabetes Care | American Diabetes Association (April 28, 2026).

Moreover, the Board's affordability assessment relies on cost analyses that materially mischaracterize the prices actually paid for Ozempic and the drivers of patient cost burden. Much of the analysis is based on outdated, incomplete data that does not reflect current contracting arrangements or new pricing models. In addition, the Board's assessment remains implicitly anchored to Wholesale Acquisition Cost (WAC) and gross spending metrics, rather than the net prices paid by payors after statutory rebates, supplemental rebates, and negotiated discounts—particularly in state and local government channels. Because the difference between list and net price for Ozempic is substantial, analyses grounded in WAC materially overstate real-world costs and distort conclusions about affordability.

## III. This Cost Review Study Report ignores the realities of the significant changes to Ozempic® pricing as a result of the currently evolving drug pricing landscape.

Novo Nordisk will offer lower prices and expanded patient access and affordability for Ozempic® in Medicaid as part of an agreement with the White House, announced in November 2025. Assessments of the affordability of Ozempic® that fail to account for substantial net price reductions and other recent actions to expand access ignore the complete picture and are constrained by stale data, rather than reflecting current market conditions. The Board's decision-making then risks prompting restrictive policies—like UPLs—that may have negative unintended consequences.

Novo Nordisk also announced significant changes to provide cost savings to patients without insurance coverage or with inadequate coverage, or those who choose to pay without using their insurance. In mid-2025, Novo Nordisk announced that Ozempic® would be made available to self-paying patients with type 2 diabetes with a prescription through NovoCare® Pharmacy. Ozempic® is now available for as low as $199 per month from NovoCare® Pharmacy and other partner direct-to-patient platforms.

*****

In sum, Novo Nordisk remains concerned that the Board's Cost Review Study Report fails to consider key contextual information and relies on outdated data that does not reflect the actual out of pocket costs to patients or the unique clinical value that Ozempic offers.

Thank you for the opportunity to provide comments and for your consideration of the issues raised in this letter. Should you have any questions or concerns, please contact Stephanie Kutler, Head of Policy, at NSTK@novonordisk.com for additional information.

PhRMA
RESEARCH • PROGRESS • HOPE

670 Maine Ave SW WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

***By Electronic Submission***

May 1, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

**RE: Draft Ozempic Cost Review Study Report for Comment**

Dear Members of the Maryland Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Maryland Prescription Drug Affordability Board's (the "PDAB's" or "Board's") request for written comments on its draft Cost Review Study Report for Ozempic ("Draft Report").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA

[1] *See* Ozempic (semaglutide) – Draft Cost Review Study Report ("Draft Report") (Apr. 22, 2026), *available at* https://pdab.maryland.gov/Documents/Cost%20Review/2026/Final%20Ozempic%20Cost%20Review%20Study%20Report%20with%20Appendix%204.22.2026%20%281%29.pdf; In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Md. Code, Health-Gen. §§ 21-2C-01–16 (the "PDAB Statute") and the Board's implementation of the PDAB Statute. PhRMA also incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Board's implementation of the PDAB Statute. *See, e.g.*, Letter from PhRMA to Board Regarding Draft Regulation – New Regulation COMAR 14.01.07.02 (Upper Payment Limit); Letter from PhRMA to Board Regarding Draft Regulations – New Regulation COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits); New Regulation – COMAR 14.01.07 (Upper Payment Limit) (Mar. 30, 2026); Letter from PhRMA to Board Regarding Draft Cost Review Study Reports for Comment (Mar. 30, 2026); Letter from PhRMA to Board Regarding UPL Amount and Methodology Documents (Mar. 4, 2026); Letter from PhRMA to Board Regarding Cost Review Study Process and Policy Review Process (Feb. 10, 2026); Letter from PhRMA to Board Regarding Proposed Rules – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Feb. 10, 2025); Letter from PhRMA to Board Regarding Proposed Regulation – Amendments to COMAR § 14.01.04.05 (Cost Review Study Process) (Dec. 2, 2024); Letter from PhRMA to Board Regarding Draft Regulations – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter - COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Nov. 8, 2024); Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024); Letter from PhRMA to Board Regarding Selected Drug List (July 16, 2024); Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024); Letter from PhRMA to Board Regarding Cost Review Study Process (Apr. 24, 2024); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade- Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Draft Regulations on Public Information Act (May 4, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023); Letter from PhRMA to Board Regarding Cost Review: Additional Metrics for Identifying Potential Drugs Presentation (Sept. 12, 2022).

member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

PhRMA recognizes the Board's ongoing work to implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] PhRMA has previously expressed in detail various concerns regarding the cost review process, and we encourage the Board to consider these prior comments.[3] In addition, we provide below select comments and concerns in response to this request for comment.

## I. Clear, Specific, and Meaningful Standards

Consistent with our prior comments, PhRMA continues to have concerns with the lack of sufficiently clear, specific, and meaningful standards provided by the Board to govern its cost review process.[4] PhRMA urges the Board to adopt, publish, and consistently apply clear and meaningful standards for conducting cost reviews and considering all cost review criteria to limit the risk of arbitrary decision-making.[5]

The following are examples of areas for which the Board should develop clearer standards:

- **Cost Review Process.** PhRMA continues to be concerned with the lack of clarity regarding the specific data and standards used in the Board's cost review process.[6] The Board offers only a summary of the various factors involved in its decision-making, without explaining how it weighs or balances those factors.[7] As a result, stakeholders do not have meaningful insight into the Board's process and decision-making. Moreover, the Board has not developed an adequate record of reasoning to support its decision-making, including how it evaluated the statutory and regulatory factors for each drug. The Maryland Administrative Procedure Act ("APA") requires the Board to provide a "reasoned analysis" that shows the "basis of the agency's action" and adequate "factual findings . . . to support the agency's conclusions."[8] Accordingly, PhRMA requests that the Board adopt a systematic, reasoned, and unbiased review methodology to comply with the Maryland APA and ensure the Board transparently and consistently applies review criteria in the PDAB Statute and the Board's regulations.[9]

- **"Affordability Challenge" Definition.** As we have stated in our prior comment letters, the definition of "affordability challenge" is circular, as it refers in part to "*an affordability challenge* for the State health care system," but does not identify specific criteria or a methodology for

[2] *See* Md. Code, Health Gen. §§ 21-2C-01–16.
[3] *See supra* note 1.
[4] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3; Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 5-6; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 4-5.
[5] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 5-6; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 4-5.
[6] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3; Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 5-6.
[7] *See* Draft Report (Apr. 22, 2026); *see also* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3.
[8] *Elbert v. Charles Cnty. Plan. Comm'n*, 259 Md. App. 499, 509 (2023); *see, e.g.*, *Mortimer v. Howard Rsch. and Dev. Corp.,* 83 Md. App. 432, 442 (1990).
[9] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3; Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 5-6.

making an affordability determination.[10] Absent concrete criteria, the Board risks conducting inconsistent drug evaluations , which may impact the Board's cost reviews. PhRMA continues to urge the Board to adopt clear, workable standards to guide the cost review process to limit the risk of arbitrary and inconsistent decision making.

- **Use of Public Input.** As PhRMA has previously requested, the Board should provide further detail about when and how public comment informs specific decisions in the cost review process.[11] Under the PDAB Statute and Board regulations,[12] the Board is required to provide the public with notice and opportunity to comment on each meeting and pending decision of the Board, and the Board's regulations explicitly provide for consideration of public comments in the Board's cost reviews.[13] However, the Board has not meaningfully explained in the Draft Report how public comments were considered and how they impacted its decision-making. For example, the Board has yet to adequately address and account for the clinical and economic benefits of a drug, including by considering the overall disease burden.[14] PhRMA therefore urges the Board to provide additional transparency into its decision-making process and develop clear standards regarding how public comments are considered and how they impact the Board's decisions.[15]

## II. Transparency Concerns

The Board should provide additional insight into its cost review process, including by revising the non-exhaustive list of processes below:

- **Data Review Process.** As noted above, PhRMA is concerned about the data review process that informs the Board's cost reviews.[16] Because the Board's processes require compiling and considering voluminous data from diverse sources, there is an inherent risk of including data that may be inaccurate, incomplete, or misleading. As expressed in prior letters, the Board should establish a process that provides manufacturers opportunity to review, evaluate, confirm, and meet with the Board about the data on which it is relying prior to the Board rendering any final decisions.[17] The Board should also ensure confidential, proprietary, and trade secret information is protected from disclosure during this process.[18]

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[10] COMAR § 14.01.05.01C (emphasis added). *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 2; Letter from PhRMA to Board (Feb. 10, 2026) *supra* note 1 at 4; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 5.

[11] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 2; Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 6; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 5.

[12] *See* Md. Code, Health-Gen. § 21-2C-03 (e)(2), (4)–(5); COMAR §§ 14.01.01.03(B), 14.01.01.05, 14.01.04.03(D)(4).

[13] *See* COMAR § 14.01.05(C)(1)(g)(xvi)-(xvii), (C)(2), (D)(1)-(2).

[14] *See* Ozempic (semaglutide) – Draft Cost Review Study Report (Apr. 22, 2026) at 109, 120-21, 141-42; *see also* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 2.

[15] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 2; Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 6; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 5.

[16] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3; Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 4; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 5.

[17] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3; Letter from PhRMA to Board (July 16, 2024) supra note 1 at 4; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 5.

[18] *See* Md. Code, Health Gen. § 21-2C-10 (statutory protections for confidential, proprietary, and trade secret information). For additional discussion of confidentiality issues, *see, e.g.,* Letter from PhRMA to Board (May 1, 2023) *supra* note 1 at 18-19.

- **Process for Identifying Therapeutic Alternatives.** PhRMA remains concerned about the Board's consideration of therapeutic alternatives in its cost review process, including the Board's definition of "therapeutic alternative" and how it determines which drugs meet that definition for a particular drug under review.[19] To ensure the Board's decisions are consistent with clinical evidence, PhRMA reiterates its request that the Board engage with manufacturers about potential therapeutic alternatives and publish criteria for identifying therapeutic alternatives .[20] PhRMA continues to urge caution in how the Board defines therapeutic alternatives for a particular drug, as some therapies that could be identified as therapeutic alternatives under the Board's definition are not appropriate for all patients using the therapy.[21]

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns with the cost review process, we continue to stand ready to be a constructive partner in this dialogue. Please contact Kristin Parde at Kparde@phrma.org with any questions.

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Alexandra Hussey
Senior Director – Law

[19] *See* COMAR § 14.01.01.01(B)(61) (defining "[t]herapeutic alternative" as "a drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug"); Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3-4; Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 4-5; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 3.

[20] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3; Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 4-5; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 3.

[21] *See* Letter from PhRMA to Board Regarding Draft Cost Review Study Reports (Mar. 30, 2026) *supra* note 1 at 3-4.

Maryland

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

# Re: public comments needed for semaglutide/Ozempic

**Dr. Benna Z Sherman** [redacted] Fri, Apr 24, 2026 at 11:30 AM
To: comments.pdab@maryland.gov

Dear Prescription Affordability Board Members,

As a licensed psychologist practicing in Maryland since 1993, I urge you to work to make Ozempic affordable for my patients. Many patients suffering from mental disorders and disabilities have gained weight due to their symptoms, their required medications, and their life experiences. Their physical and mental health then worsens because of the well documented effects of obesity on both. It is unacceptable that a solution to this cycle exists but is out of reach because of the astronomical cost and the fact that many insurance plans and Medicare do not cover GLP-1s. Please work to make this medication and other GLP-1s affordable to patients in Maryland who already struggle with numerous mental and physical challenges. Thank you.

Benna Z Sherman, PhD
Licensed Psychologist
Severna Park MD 21146
[redacted]
General email:
[redacted]
Patient email:
[redacted]

Http://www.DrBennaSherman.com
Author of "How to Get and Give Love-- Relationship Maps"

Facebook: @ Dr. Benna Sherman



"Three things in human life are important. The first is to be kind. The second is to be kind. The third is to be kind." -- Henry James

Maryland

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

# Maryland Coverage for Ozempic

**Dr. Stemberger** [redacted] Thu, Apr 23, 2026 at 5:18 PM
To: comments.pdab@maryland.gov

Dear Prescription Affordability Board Members,

As a licensed psychologist practicing in Maryland since 1993, I urge you to work to make Ozempic affordable for my patients. Many patients suffering from mental disorders and disabilities have gained weight due to their symptoms, their required medications, and their life experiences. Their physical and mental health then worsens because of the well documented effects of obesity on both. It is unacceptable that a solution to this cycle exists but is out of reach because of the astronomical cost and the fact that many insurance plans and Medicare do not cover GLP-1s. Please work to make this medication and other GLP-1s affordable to patients in Maryland who already struggle with numerous mental and physical challenges. Thank you.

Kind regards,

Ruth Stemberger, Ph.D.
Licensed Psychologist
[redacted]
https://drstemberger.com
[redacted]