# Ozempic (semaglutide)-Dossier

Maryland Prescription Drug Affordability Board

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MARYLAND
Prescription Drug Affordability Board

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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 |

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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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## 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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### 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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**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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Blank spaces indicate that no data was provided.

**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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^^^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 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) | | | | | | |

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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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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] | *** | | *** | *** |

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

Blank spaces indicate that no data was provided.

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

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

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 | *** | *** | *** | *** |

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

## Factor 7.4: The average cost share

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

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

**Table 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 | *** | *** | |

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

## Factor 7.5: 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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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 | *** | *** | | *** |

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# Section 8: Other Information

## Factor 8.1: Input from the Public

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

**INITIAL 60-DAY COMMENT PERIOD**

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

In accordance with COMAR 14.01.04.05C(2)(a), the public may provide written comments concerning the prescription drug product within 60 days of the date the drug selected for a cost review study is posted on the Board's website. The 60-day Public Comment period for 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.**