



Ozempic[®] (*semaglutide*)¹

Version 3.0



¹ Image source: <https://www.ozempic.com/how-to-take/ozempic-dosing.html>

Table of contents

Document version history.....	3
Review summary.....	4
Rubric considerations	6
Review background.....	7
Drug information	8
Health inequities.....	9
Residents prescribed.....	9
Price for the drug	9
Estimated average monetary price concession	13
Estimated total amount of the price concession.....	16
Estimated price for therapeutic alternatives.....	16
Estimated average price concession for therapeutic alternatives	17
Estimated costs to health insurance plans	18
Impact on enrollee access to the drug	21
Relative financial impacts to health, medical or social services costs.....	22
Estimated average patient copayment or other cost-sharing.....	23
Clinical information based on manufacturer material	25
Input from specified stakeholders	33
Appendix	38

Document version history

Version	Date	Description
v1.0	8/13/2025	Original Release
v1.5	9/15/2025	Added new public comment to the appendix table. Updated table numbers and table references.
v1.6	9/23/2025	Added new public comment to the appendix table.
v2.0	10/9/1025	Added new survey comment
v3.0	10/30/2025	Updated table formats and footnotes.

Review summary

Therapeutic alternatives^{2,3,4}

Ozempic (*semaglutide*) has the following therapeutic alternatives: **Bretta, Rybelsus, Trulicity,** and **Victoza**.

Proprietary name	Non-proprietary name	Manufacturer	Year approved	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
Ozempic	<i>semaglutide</i>	Novo Nordisk Inc.	2017	19	2025-2028	2028	Yes (2027)
Byetta⁵	<i>Exenatide synthetic</i>	Astrazeneca Ab	2005				No
Rybelsus⁶	<i>semaglutide</i>	Novo Nordisk Inc.	2017	13	2026-2039		Yes (2027)
Trulicity⁷	<i>dulaglutide</i>	Eli Lilly and Co.	2014				No
Victoza⁸	<i>liraglutide</i>	Novo Nordisk Inc.	2010	4	2025-2037		No

²Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book. U.S. Food & Drug Administration, Aug. 8, 2025. <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

³Frequently Asked Questions on Patents and Exclusivity, U.S. Food & Drug Administration, Feb. 5, 2020. [https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What is the difference between patents a](https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What%20is%20the%20difference%20between%20patents%20a).

⁴Selected Drugs and Negotiated Prices. Centers for Medicare & Medicaid Services. <https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices>.

⁵Byetta was discontinued in 2025. Drug approvals and databases. U.S. Food & Drug Administration, Aug. 8, 2022. <https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases>.

⁶No exclusivity was listed for Rybelsus in the U.S. Food & Drug Administration Orange Book Database. <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

⁷No patent or exclusivity information was listed for Trulicity in the U.S. Food & Drug Administration Purple Book Database. <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

⁸No exclusivity was listed for Victoza in the U.S. Food & Drug Administration Orange Book Database. <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

Price history^{9,10}

Ozempic® (semaglutide) rose at an average annual rate of **4.8 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
 - Byetta: **3.1 percent**
 - Rybelsus: **4.4 percent**
 - Trulicity: **5.0 percent**
 - Victoza: **-2.3 percent**

Additionally, the average annual rate of Ozempic exceeded inflation in **2019, 2020, 2023, and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 0.3 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions¹¹

Based on data received from healthcare carriers, Ozempic in 2023 had the **gross spend of \$1,070 per claim**, while the **spend net of discount was \$562 per claim**. Price concession per claim was reported to be **\$508**.

Cost to the payers¹²

Table 1 2023 APAC payer annual total expenditure, utilization, and cost per enrollee

Proprietary name	Total expenditure	Utilization	Cost per enrollee	Cost per enrollee, median
Ozempic	\$173,071,290	170,729	\$6,121	\$897
Byetta	\$418,695	375	\$5,234	\$826
Rybelsus	\$15,574,551	11,524	\$6,023	\$973
Trulicity	\$114,173,339	104,682	\$8,277	\$909
Victoza	\$26,835,206	20,794	\$6,963	\$1,089

⁹ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

¹⁰ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

¹¹ Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.

¹² Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

Cost to enrollees¹³

Table 2 2023 gross APAC annual enrollee out-of-pocket (OOP) cost

Proprietary name	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Ozempic	\$494	\$40	\$86	\$30
Byetta	\$297	\$35	\$76	\$4
Rybelsus	\$530	\$47	\$121	\$40
Trulicity	\$499	\$25	\$76	\$10
Victoza	\$367	\$10	\$78	\$4

Rubric considerations

Domain	Consideration
Utilization	170,729
Price evaluation	Avg percent change in WAC of 4-4.99%, outpaced inflation for three years
Price concessions	25-50% of claims discounted
System & payer costs	Total gross spend >\$50M, total net spend >\$10M
Enrollee burden	Total APAC OOP \$200-\$700
Equity impact	Yes
Access restrictions	Yes
Therapeutic alternative fail to reduce system spending	Yes
Stakeholder input identify access or financial hardship?	Yes
Patent expirations more than 18 months from time of review?	Yes
Excluded from CMS Maximum Fair Price List (MFP)	No

¹³ Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

Review background

This review incorporates supporting information from Medi-Span, FDA databases (e.g., Orange Book, Purple Book), and other publicly available data where applicable.

Two primary data sources inform this review: the Oregon All Payers All Claims (APAC) database and the commercial carrier data call. APAC aggregates utilization data across all payer types in Oregon, including Medicaid, Medicare, and commercial plans, and presents gross cost estimates. In contrast, the data call reflects submissions from 11 commercial health insurers and reports primarily net costs after manufacturer rebates, PBM discounts, and other price concessions. As a result, APAC generally reflects larger total utilization and cost figures due to broader reporting, while the data call offers insight into actual expenditures from private payers in the commercial market.

This review addresses the affordability review criteria to the extent practicable. Due to limitations in scope and resources, some criteria receive minimal or no consideration.

In accordance with OAR 925-200-0020, PDAB conducts affordability reviews on prioritized prescription drugs selected under OAR 925-200-0010. The 2023 drug affordability review selection included the following criteria: orphan-designated drugs were removed; drugs were reviewed based on payer-paid cost data from the data call submissions; and drugs reported to the APAC program across Medicare, Medicaid, and commercial lines of business were included. To ensure broader public impact, drugs with fewer than 1,000 enrollees reported in APAC reports were excluded from consideration.

Senate Bill 844 (2021) created the Prescription Drug Affordability Board (PDAB) to evaluate the cost of prescription drugs and protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon and other stakeholders within the health care system from the high costs of prescription drugs.

Drug information¹⁴

Drug proprietary name(s)	Ozempic®
Non-proprietary name (active ingredients)	<i>semaglutide</i>
Manufacturer	Novo Nordisk
Pharmacologic category	Glucagon-like Peptide 1 (GLP-1) Receptor Agonist
Treatment	Improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise; reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease; reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with T2DM and chronic kidney disease (CKD).
Dosage strength	2 mg/3 mL (0.68 mg/mL) available in: Single-patient-use pen that delivers 0.25 mg or 0.5 mg per injection 4 mg/3 mL (1.34 mg/mL) available in: Single-patient-use pen that delivers 1 mg per injection 8 mg/3 mL (2.68 mg/mL) available in: Single-patient-use pen that delivers 2 mg per injection
Form/Route	Subcutaneous Injection
Physician administered	No

FDA approval

Ozempic was first approved by the FDA on Dec. 5, 2017.¹⁵

The drug qualified for the following expedited forms of approval: None

At time of review, the drug had no approved designations under the Orphan Drug Act.

¹⁴ U.S. Food & Drug Administration. Ozempic (*semaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.

¹⁵ FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, the earliest approval date across all related FDA applications was used. <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

Health inequities

ORS 646A.694(1)(a) and OAR 925-200-0020 (1)(a) & (2)(a)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source through APAC.

Despite strong cardio-renal risk-reduction signals in guidelines for GLP-1 RAs, uptake skews toward patients with higher income and from majority groups. There is **lower uptake and higher discontinuation among minoritized/low-income patients**, which risks widening complications gaps.^{16,17} Storage requirements (refrigeration before first use; limited room-temperature window) may pose practical barriers for patients with unstable housing or limited refrigeration access.^{18,19} FDA declared the semaglutide injection shortage was resolved in February 2025, but affordability and plan controls still drive uneven access.²⁰

Residents prescribed

ORS 646A.694(1)(b) and OAR 925-200-0020(1)(b) & (2)(b). Data source from APAC.

Based on APAC claims, **170,729** Oregonians filled a prescription for Ozempic in 2023.²¹

Price for the drug

ORS 646A.694(1)(c) and OAR 925-200-0020(1)(c) & (2)(e), (f), & (g). Data source from Medi-Span, APAC, and carrier data call.

This section examines the pricing dynamics of Ozempic, drawing on multiple data sources to characterize its historical price trends and implications for affordability. It includes an analysis of the drug's wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), compared to its therapeutic alternatives. Together, the data provides a comprehensive view of Ozempic's list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts costs.

¹⁶ Moore, Josiah, et al. "Factors and Disparities Influencing Sodium-Glucose Cotransporter 2 Inhibitors and Glucagon-like Peptide 1 Receptor Agonists Initiation in the United States: A Scoping Review of Evidence." *Pharmacy (Basel)*. March 19, 2025;13(2):46. <https://pubmed.ncbi.nlm.nih.gov/40126319/>.

¹⁷ Rodriguez, Patricia J., et al. "Discontinuation and Reinitiation of Dual-Labeled GLP-1 Receptor Agonists Among US Adults With Overweight or Obesity." *JAMA Netw Open*. 2025 Jan 2;8(1):e2457349. <https://pubmed.ncbi.nlm.nih.gov/39888616/>.

¹⁸ U.S. Food & Drug Administration. Ozempic (*semaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.

¹⁹ Northwell Health. Jan. 4, 2024. How to use and inject an Ozempic pen. YouTube. https://youtu.be/IJgRd_OsWik.

²⁰ FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize. U.S. Food & Drug Administration, April 28, 2025. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize>.

²¹ Number of 2023 enrollees in APAC database across commercial insurers, Medicaid, and Medicare. For more information regarding APAC data: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

Price history

WAC per 30-day supply was calculated with package and unit WAC from Medi-Span and was reviewed as an indication of historic price trends for the drug. However, WAC does not account for discounts, rebates, or other changes to the drug's cost throughout the supply chain.

Table 3 30-day supply for Review Drug and its therapeutic alternatives

	Ozempic	Byetta	Rybelsus	Trulicity	Victoza
30-day supply	1 package (1 pen of 3 ml)	1 package (1 pen of 2.4 ml)	30 units (30 pills)	1 package (4 pens of 0.5 ml)	1 package (3 pens of 9 ml)

Table 4 Drug vs therapeutic alternatives for 2018-2024 WAC per 30-day supply²²

Year	Ozempic	Byetta	Rybelsus	Trulicity	Victoza
2018	\$729	\$708		\$730	\$870
2019	\$772	\$730		\$759	\$922
2020	\$811	\$752		\$797	\$968
2021	\$852	\$778	\$852	\$844	\$1,016
2022	\$892	\$801	\$892	\$887	\$1,065
2023	\$936	\$825	\$936	\$931	\$1,117
2024	\$969	\$850	\$969	\$977	\$677
Avg. Annual % Change	4.8%	3.1%	4.4%	5.0%	-2.3%
% change 2018 between 2024	32.8%	20.0%		33.9%	-22.2%

The WAC of Ozempic, averaged across five NDCs reported, was approximately **\$322.84 per unit** at the end of 2024.²³ Between 2018-2024, the unit WAC increased at an average annual rate of **4.8 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2018-2019, 2019-2020, and 2022-2023 (see Figure 1 and Table 5).²⁴

²² Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

²³ Ibid.

²⁴ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

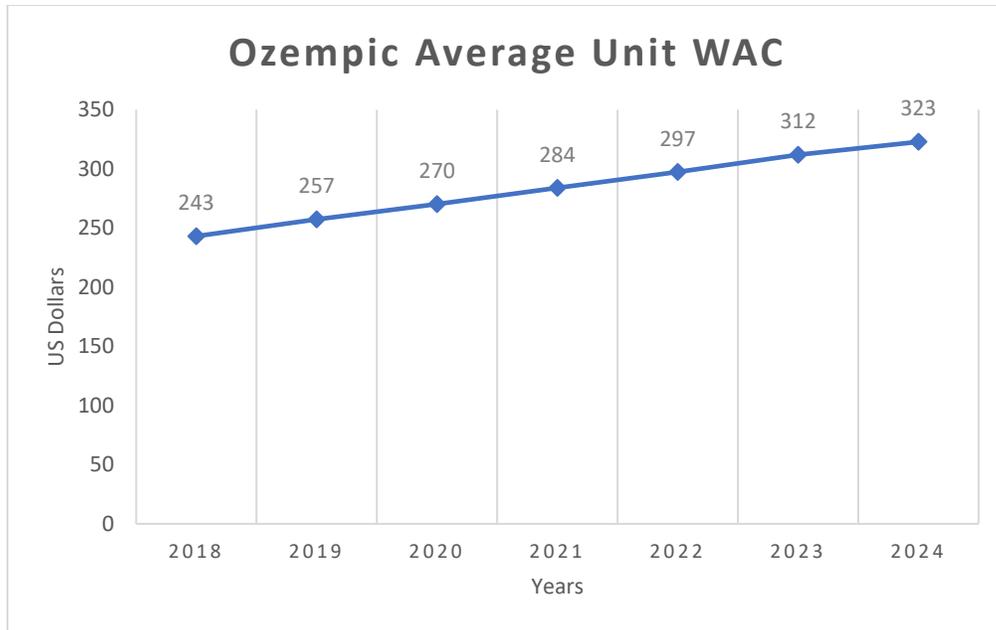


Figure 1 Ozempic average unit WAC from 2018-2024

Table 5 Percent change of unit WAC of drug and therapeutic alternatives with CPI comparison²⁵

Year	Ozempic	Byetta	Rybelsus	Trulicity	Victoza	CPI-U
2018-2019	5.9%			4.0%	5.9%	1.7%
2019-2020	5.0%	3.0%		5.0%	5.0%	0.7%
2020-2021	5.0%	3.5%		5.9%	5.0%	5.3%
2021-2022	4.8%	3.0%	4.8%	5.0%	4.8%	9.0%
2022-2023	4.9%	3.0%	4.9%	5.0%	4.9%	3.1%
2023-2024	3.5%	3.0%	3.5%	5.0%	-34.1%	3.0%

²⁵ Percentages might differ from Table 4 as Table 5 percentages are based on unit WAC only.

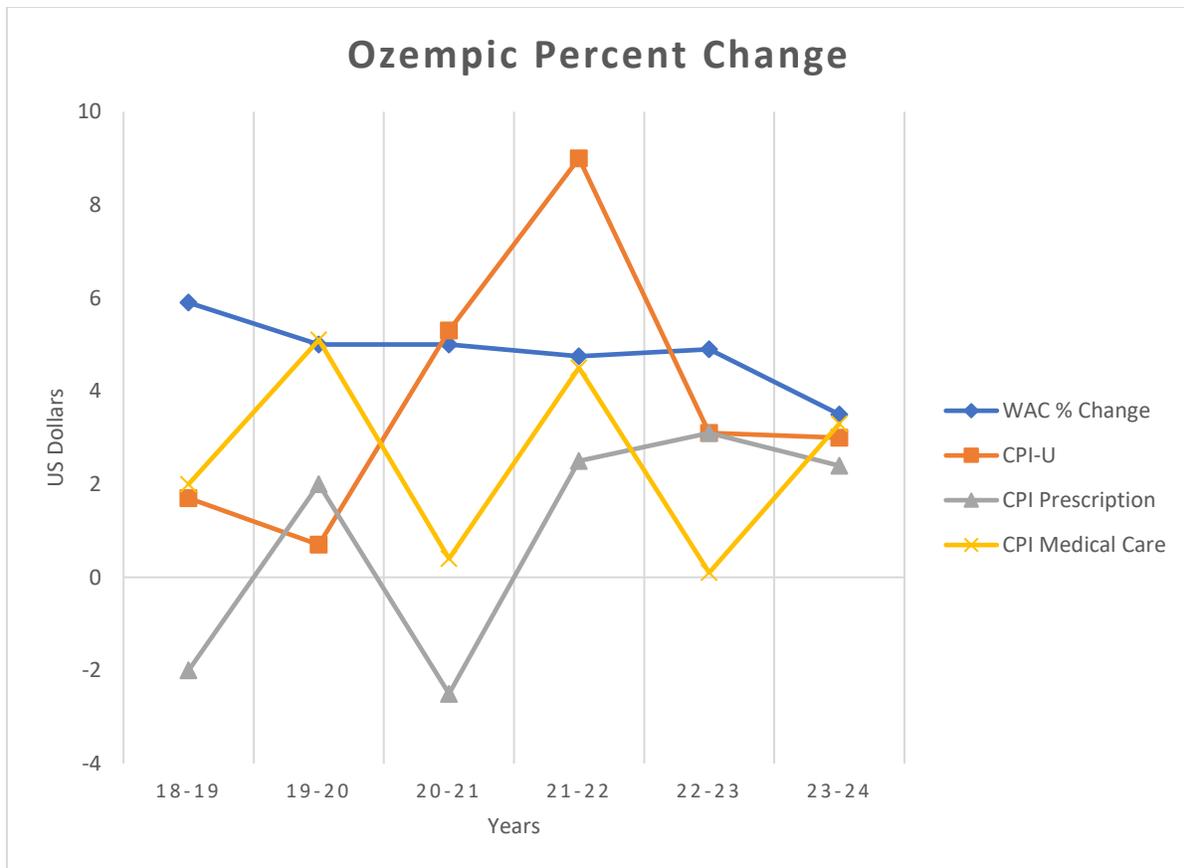


Figure 2 Year over year change in WAC compared to inflation rates²⁶

Pharmacy acquisition costs

The AAAC, which reflects pharmacies’ actual purchase prices for Medicaid fee-for-service claims, rose from **\$386.65 per unit in Quarter 1 of 2020 to \$387.93 per unit in Quarter 4 of 2024**, an approximate **0.3 percent increase** over the period (see Table 6).²⁷ Relative to the **\$290.56 WAC** in end-of-year 2024, an **AAAC increase of 33.5 percent** is indicated.

While WAC provides a standardized benchmark of list price, it does not account for negotiated price concessions. In contrast, the AAAC offers a more representative estimate of the net price incurred by Medicaid payers in Oregon, derived from regular pharmacy surveys conducted by the Oregon Health Authority. Monitoring these trends over time contextualizes Ozempic’s price trajectory relative to inflation and affordability for public and private payers.

²⁶ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

²⁷ This data was compiled using the first weekly AAAC chart of each month from January 2020 to December 2024, available at <https://myersandstauffer.com/client-portal/oregon/>.

Table 6 2020-2024 AAAC Medicaid FFS quarterly purchase prices for Ozempic

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC Average	Average unit WAC
2020	\$387	\$389	\$389	\$390	\$389	\$270
2021	\$404	\$408	\$380	\$363	\$389	\$284
2022	\$379	\$381	\$377	\$357	\$374	\$297
2023	\$370	\$371	\$367	\$357	\$366	\$312
2024	\$372	\$379	\$388	\$388	\$382	\$323

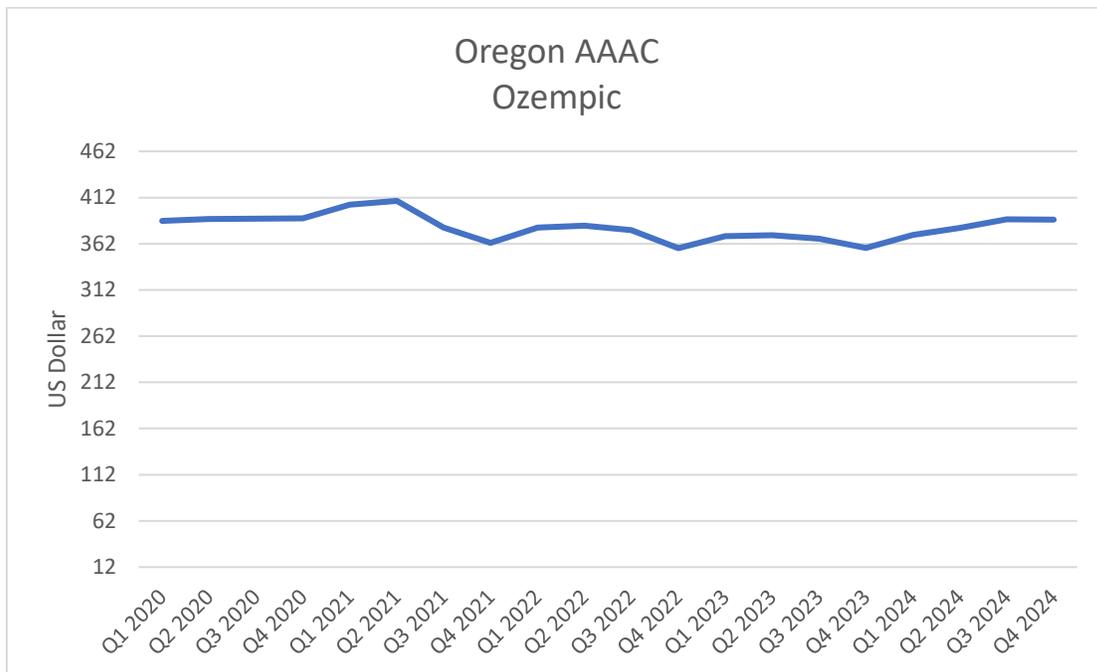


Figure 3 AAAC For Ozempic from Q1 2020 to Q4 2024

Estimated average monetary price concession

ORS 646A.694(1)(d) and OAR 925-200-0020(1)(d) & (2)(d) & (2)(L)(A-B). Data source information provided from data call.

This section provides an analysis of the average monetary discounts, rebates, and other price concessions applied to Ozempic claims in the commercial market. Drawing on 2023 data submitted through the carrier data call, it evaluates the extent to which these concessions reduced gross drug costs and estimates the average net costs to payers after adjustments. The analysis includes claim-level data on the proportion of claims with applied discounts, and the breakdown of the total concession amounts by type, offering insight into the reduced costs provided through manufacturer, PBM, and other negotiated price reductions.

Based on carrier-submitted data for 2023, the **average gross cost of Ozempic per enrollee in the commercial market was approximately \$3,167**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately \$1,664**, reflecting an **estimated mean discount of 47.5 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Ozempic before concessions was \$51,483,857**, with total reported **price concessions amounting to approximately \$24,437,818**, as detailed in Table 7. Notably, **85.8 percent of claims benefited from some form of price concession**, leaving **14.2 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	16,254
Total number of claims	48,107
Total number of claims with price concessions applied	41,258
Percentage of claims with price concessions applied	85.8%
Percentage of cost remaining after concessions	52.5%
Percentage of discount	47.5%
Manufacturer price concessions for all market types	\$21,165,105
PBM price concessions for all market types	\$3,269,305
Other price reductions for all market types	\$3,408
Cost before price concessions across all market types	\$51,483,857
Total price concessions across all market types	\$24,437,818
Cost of after price concessions across all market types	\$27,046,039
Avg. payer spend per enrollee without price concessions	\$3,167
Avg. payer spend per enrollee with price concessions	\$1,664

Including all market segments, the **gross spend of Ozempic per claim for commercial carriers was \$1,070** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **\$562**, meaning that insurers reported a price concession of **\$508** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types from data call²⁸

	Average	Individual market	Large market	Small market
Spend per claim, gross	\$1,070	\$1,128	\$1,058	\$1,073
Spend per claim, net	\$562	\$583	\$569	\$528
Price concessions per claim	\$508	\$545	\$489	\$545

Figure 4 shows manufacturer concessions comprised the largest share, supplemented by PBM discounted price arrangements and other adjustments across the payer types.

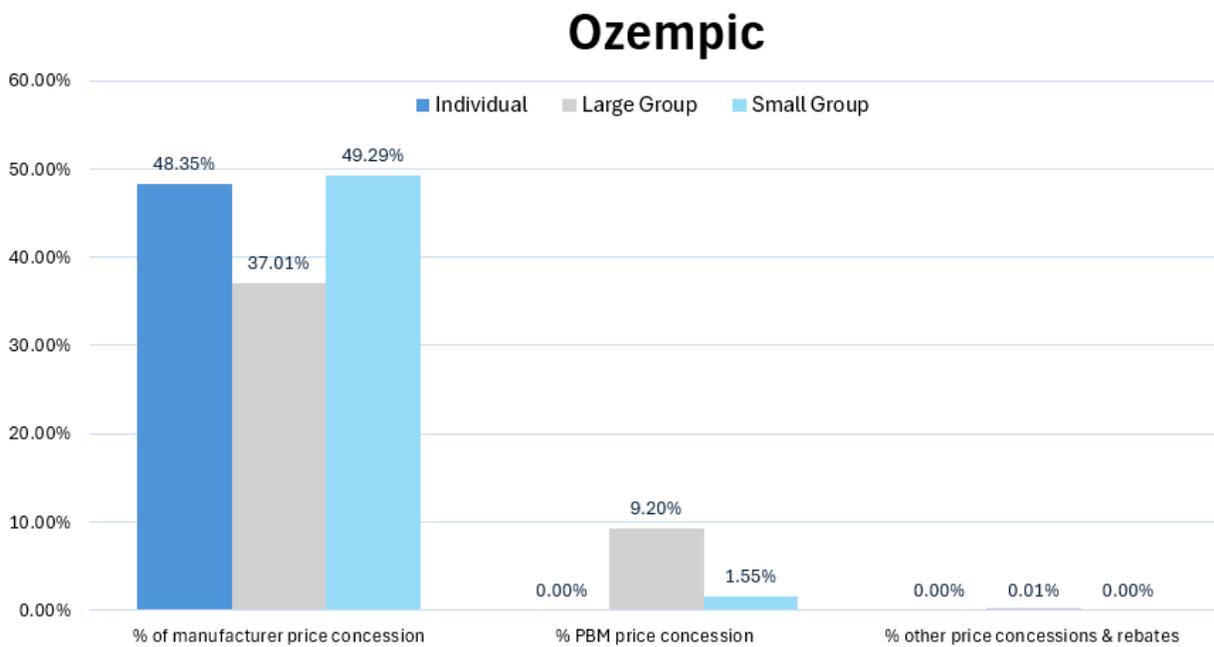


Figure 4 Percent of price concession in each market type^{29, 30}

²⁸ Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon’s commercial insurance carriers.

²⁹ Price concession refers to any form of discount, directed or indirect subsidy, or rebate received by the carriers or its intermediary contracting organization from any source that serves to decrease the costs incurred under the health plan by the carriers. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on purchase agreement, coupons, free or reduced-price services, and goods in kind. Definition adapted from Code of Federal Regulations, Title 42, Chapter IV, Subchapter B, Part 423, Subpart C. See more at: [CFR-2024-title42-vol3-sec423-100.pdf](https://www.ecfr.gov/current/title-42-chapter-iv-subchapter-b-part-423-subpart-c).

³⁰ Rebate refers to a discount that occurs after drugs are purchased from a pharmaceutical manufacturer and involves the manufacturer returning some of the purchase price of the purchaser. When drugs are purchased by a managed care organization, a rebate is based on volume, market share, and other factors. Academy of Managed Care Pharmacy. <https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary>.

Estimated total amount of the price concession

ORS 646A.694(1)(e) and OAR 925-200-0020(1)(e) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source carrier data call.

This section is intended to quantify the total discounts, rebates, or other price concessions provided by the manufacturer of Ozempic to each pharmacy benefit manager, expressed as a percentage of the drug's price. At the time of this review, there was no specific data available to PDAB to determine the total amount of such price concessions in the Oregon market.

The statutory and regulatory criteria calls for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through improved reporting or additional disclosures from manufacturers, PBMs, and payers.

Estimated price for therapeutic alternatives³¹

ORS 646A.694(1)(f) and OAR 925-200-0020(1)(f), (2)(c) & (2)(m). Data source information provided from APAC.

This section presents information on the estimated spending associated with Ozempic and its therapeutic alternatives using 2023 data from APAC and the data call. APAC data reflects gross spending across Medicare, Medicaid, and commercial health plans in Oregon, while the data call includes net spending submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concession or rebates.

Ozempic's gross total payer paid, based on APAC data, **was \$173.1 million**, while total net payer paid received from the **carriers indicated a cost of \$48.6 million. Ozempic has the highest gross total pay** in consideration with its therapeutic alternatives. The second highest is Trulicity with **\$114.2 million**. Notably, Ozempic has the **most utilization among the drugs, at 170,729 claims**, as compared to the second highest utilization of Trulicity, at 104,682 claims. **Ozempic has the lowest payer paid per claim at \$1,014**. The highest payer paid per claim is Rybelsus at \$1,351.

Ozempic also has the highest total enrollee paid at \$13.2 million and Trulicity follows behind with \$6.0 million. Rybelsus has the highest patient paid per claim of \$111, which is higher than both Ozempic at \$77 and Trulicity at \$57. The drug with the lowest patient paid per claim is Byetta, which is \$49.

Ozempic and Rybelsus have been designated by the FDA as being in shortage from March 31, 2022, to February 21, 2025. Victoza is currently experiencing a drug shortage that began on July 19, 2023. These shortages affect the availability of these medications for patients.

³¹ Therapeutic alternative means a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. [ORS 925-200-0020\(2\)\(c\)](#).

Table 9 Average healthcare and average patient OOP costs vs therapeutic alternatives³²

Proprietary name	No. of enrollees ³³	No. of claims	Total payer paid	Total enrollees paid ³⁴	Payer paid/claim	Enrollee paid/claim ³⁵
<i>Subject Drug</i> Ozempic (Data call) ³⁶	16,254	47,862	\$48,558,612	\$3,922,274	\$1,015	\$82
<i>Subject Drug</i> Ozempic (APAC)	28,273	170,729	\$173,071,290	\$13,164,970	\$1,014	\$77
Byetta	80	375	\$418,695	\$18,421	\$1,117	\$49
Rybelsus	2,586	11,524	\$15,574,551	\$1,282,285	\$1,351	\$111
Trulicity	13,794	104,682	\$114,173,339	\$6,011,513	\$1,091	\$57
Victoza	3,854	20,794	\$26,835,206	\$1,213,145	\$1,291	\$58

Estimated average price concession for therapeutic alternatives

ORS 646A.694(1)(g) and OAR 925-200-0020(1)(g) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement.

This section addresses the estimated average of discounts, rebates, or other price concessions associated with therapeutic alternatives to Ozempic, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

The statutory and regulatory criteria calls for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was

³² The therapeutic alternative information is based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.asp>.

³³ The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 9, as compared to other totals indicated in this report.

³⁴ The cost includes all lines of business.

³⁵ Ibid.

³⁶ Information from the data call with the cost information after price concessions.

not performed. Future reviews may incorporate this data as it becomes available through carrier reporting, manufacturer disclosures, or other sources.

Estimated costs to health insurance plans

ORS 646A.694(1)(h) and OAR 925-200-0020(1)(h) & (2)(h) & (m). Data source information provided from APAC and data call.

This section quantifies the financial impact of Ozempic on health insurance plans in Oregon, based on claims and expenditure data from APAC and the carrier data call. Costs are delineated by payer type—including commercial, Medicaid, and Medicare—as well as by market segment within the commercial population. These estimates highlight the distribution of expenditures across different health coverage lines and inform assessments of the drug’s budgetary implications for public and private payers.

In 2023, the Oregon APAC database recorded **170,729 total claims for Ozempic among 30,305 total enrollees**, corresponding to a **total payer expenditure of nearly \$173.1 million**.

Table 11 provides gross cost estimates by the total APAC payer spend across all lines of business:

- **Commercial** accounted for the largest share of utilization, with **80,483** claims from **13,297** enrollees and a total spend of **\$78.0 million**.
- **Medicare** and **Medicaid** payers also reported notable expenditures of approximately **\$78.2 million** and **\$16.9 million**, respectively.

Table 10 Estimated 2023 APAC total annual gross payers’ expenditure for total enrollees and total claims ³⁷

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	13,297	80,483	\$77,957,476	\$5,863	\$969
Medicaid	3,248	18,927	\$16,872,401	\$5,195	\$891
Medicare	13,760	71,319	\$78,241,414	\$5,686	\$1,097
Totals³⁸	30,305	170,729	\$173,091,290		

Table 12 provides utilization for the healthcare system for Ozempic and its therapeutic alternatives, distinguished by lines of business. **Ozempic has the most utilization** among the drugs, with **170,729 claims**. Trulicity has a higher utilization in Medicaid, with 25,337 claims,

³⁷ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

³⁸ The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

while Ozempic has higher utilization in other lines of business. **Trulicity is the second most utilized at 104,682 claims.**

Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives³⁹

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims ⁴⁰
Ozempic	80,483	18,927	71,319	170,729
Byetta	56	132	187	375
Rybelsus	4,571	962	5,991	11,524
Trulicity	35,415	25,337	43,930	104,682
Victoza	6,379	5,180	9,235	20,794

Table 13 shows the overall payer expenditure of Ozempic and its therapeutic alternatives, distinguished by lines of business. Ozempic has a **total expenditure of \$173.1 million with Medicare being the biggest portion at \$78.2 million.** The therapeutic alternative with the **least expenditure is Byetta, at \$252,059.**

Table 12 Estimated 2023 APAC payer annual gross expenditures of the review drug and its therapeutic alternatives from all lines of business⁴¹

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total ⁴²
Ozempic	\$77,957,476	\$16,872,401	\$78,241,414	\$173,071,290
Byetta	\$61,211	\$105,425	\$252,059	\$418,695
Rybelsus	\$5,975,209	\$1,099,301	\$8,500,041	\$15,574,551
Trulicity	\$35,871,104	\$22,574,441	\$55,727,793	\$114,173,339
Victoza	\$7,708,332	\$5,519,972	\$13,606,902	\$26,835,206

Table 14 compares the overall payer cost per enrollee of Ozempic and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the highest total cost per enrollee at \$8,277.** Trulicity has **highest cost per enrollee in all lines of business.** **Rybelsus and Victoza have a higher median cost per enrollee as compared to Ozempic, at \$973 and \$1,089 respectively.**

³⁹ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁴⁰ Total is the sum of all utilization for the drug across all lines of business.

⁴¹ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁴² Total is the sum of all expenditure for the drug across all lines of business.

Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives⁴³

Proprietary name	Commercial Cost/Enrollee	Medicaid Cost/Enrollee	Medicare Cost/Enrollee	Total ⁴⁴ Cost per Enrollee	Cost per Enrollee, Median	IQR	Cost per Enrollee, 75 th percentile	Cost per Enrollee, 95 th percentile
Ozempic	\$5,863	\$5,195	\$5,686	\$6,121	\$897	\$698	\$1,448	\$2,777
Byetta	\$4,372	\$3,905	\$5,251	\$5,234	\$826	\$1,453	\$2,241	\$2,673
Rybelsus	\$6,036	\$5,336	\$5,870	\$6,023	\$973	\$1,650	\$2,502	\$2,925
Trulicity	\$6,873	\$6,673	\$7,936	\$8,277	\$909	\$1,507	\$2,356	\$2,932
Victoza	\$5,542	\$5,349	\$6,876	\$6,963	\$1,089	\$1,209	\$2,182	\$3,514

Data for plan year 2023 submitted via the carrier data call further stratifies commercial expenditures by market segment. The collected **total net cost from reporting market types was around \$52.5 million**, with payers paying **\$48.6 million**, and enrollees out-of-pocket estimated to be **\$3.9 million**. Table 15 includes the average plan costs per enrollee in the commercial market, ranging from **\$3,192 (small group)** to **\$3,429 (individual)** annually.

Table 14.a Estimated 2023 annual total net costs to the healthcare system, payers and OOP/enrollee⁴⁵

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of-pocket cost
Individual	6,351	2,058	\$7,057,664	\$6,132,651	\$925,013
Large Group	31,665	10,842	\$34,717,389	\$32,471,917	\$2,245,471
Small Group	9,846	3,354	\$10,705,833	\$9,954,043	\$751,789
Total	47,862	16,254	\$52,480,885	\$48,558,612	\$3,922,274

Table 14.b Estimated 2023 annual total net costs to the healthcare system, payers and OOP/enrollee

Market	Avg. plan spend/claim	Avg. payer paid/claim	Avg. enrollee paid/claim	Avg. plan spend/enrollee	Avg. payer paid/enrollee	Avg. OOP/enrollee
Individual	\$1,111	\$966	\$146	\$3,429	\$2,980	\$449
Large Group	\$1,096	\$1,025	\$71	\$3,202	\$2,995	\$207
Small Group	\$1,087	\$1,011	\$76	\$3,192	\$2,968	\$224

⁴³ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁴⁴ The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

⁴⁵ Cost information from the data call is the cost of the drug after price concessions.

As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (66% of total), followed by individual markets and small group.

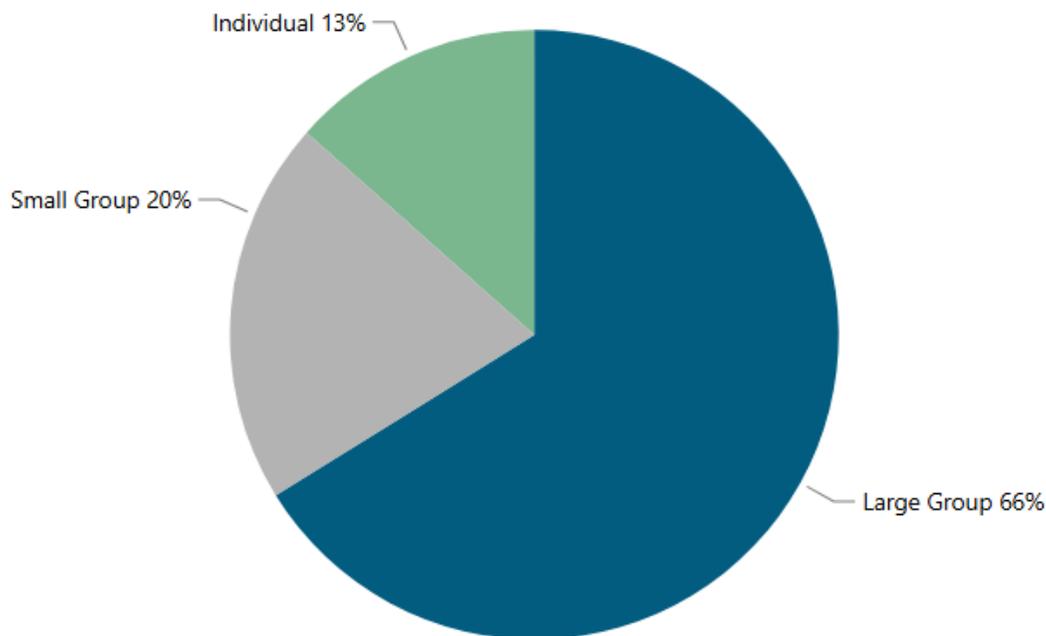


Figure 5 Data call total annual percent spend (payer paid) by market

Table 16 indicates CCOs reported Ozempic as having an annual greatest increase from 2022-2023 (rebates not included) with a **\$8.3 million year-over-year increased cost growth**.

Table 15 Medicaid CCOs greatest increase in share to total cost from 2022-2023 (rebates not included)⁴⁶

Medicaid CCOs			
2022	2023	YoY change in spending	Percent of total CCO cost 2023
\$6,037,356	\$14,376,076	\$8,338,719	0.7%

Impact on enrollee access to the drug

ORS 646A.694(1)(i) and OAR 925-200-0020(1)(i). Data source information provided from carrier data call.

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Ozempic, including prior authorization requirements, step therapy protocols, and formulary placement. The data describes how the drug is positioned within

⁴⁶ CCO pharmacy spend provided by: Oregon State University Drug Use and Research Management DUR utilization reports 2023. College of Pharmacy, Oregon State University. <https://pharmacy.oregonstate.edu/research/pharmacy-practice/drug-use-research-management/dur-reports>.

insurance benefit designs and the extent to which utilization management processes were applied during the reporting period.

Based on information reported through the carrier data call, the following plan design features were observed for Ozempic. In 2023, approximately **70.6 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **19.9 percent of plans required step therapy** before approving its use.

For formulary placement, **no plans categorized Ozempic as a non-preferred drug, and no plans excluded it entirely from the formulary.**

Table 16 Plan design analysis from 2023

Percentage of plans	
Required prior authorization	70.6%
Required step therapy	19.9%
On a non-preferred formulary	0.0%
Not covered	0.0%

Note: percentages can equal over 100 percent as some carrier and market combos may have multiple plans that fall under different designs. For example: Carrier A may have three plans in the small group market that require prior authorization but two other plans in the small group market that do not require prior authorization.

Relative financial impacts to health, medical or social services costs

ORS 646A.694(1)(j) and OAR 925-200-0020(1)(j) & (2)(i)(A-B). Limitations in scope and resources available for this statute requirement.

GLP-1 drugs like Ozempic and Trulicity have been beneficial for patients with type 2 diabetes, preventing serious complications and reducing the burden on health and social services costs. However, recent restrictions by insurers have made it significantly more challenging for patients to get reimbursed. In a study of 24 diabetes patients, 13 reported recent problems getting their health plans to cover GLP-1 drugs despite their doctors prescribing these drugs.⁴⁷

The price of Ozempic is notably higher in the U.S., at around \$800 per month, than in other countries like Canada and the U.K., where it can cost around \$300 per month.⁴⁸ The cost of

⁴⁷ Beasley, Deena. Focus: US diabetes patients face delays as insurers tighten Ozempic coverage. Reuters, Dec. 13, 2023. <https://www.reuters.com/business/healthcare-pharmaceuticals/us-diabetes-patients-face-delays-insurers-tighten-ozempic-coverage-2023-12-12/>.

⁴⁸ Ozempic Costs: Pricing, Coverage, and Affordability. Concierge MD 2024. <https://conciierge.mdla.com/blog/ozempic-costs-pricing-coverage->

uncontrolled diabetes is estimated to be \$327 billion annually in the U.S., including \$237 billion in direct medical costs and \$90 billion in reduced productivity.⁴⁹ Out-of-pocket expenses for a monthly supply of Ozempic can range from \$300 to \$800, depending on factors like insurance coverage, copayments, and deductibles.⁵⁰ Copayments for Ozempic can vary, with patients typically paying a percentage of the drug's total cost, often ranging from \$30 to \$100.⁵¹ Although most U.S. health plans cover GLP-1s for type 2 diabetes, not all patients have affordable access to the medication they need to manage their condition effectively.

Estimated average patient copayment or other cost-sharing

ORS 646A.694(1)(k) and OAR 925-200-0020(1)(k) & (2)(j)(A-D). Data source information provided from APAC and carrier data call. Data limitations with patient assistance programs

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Ozempic in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC).⁵² These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance lines of business of Medicare and commercial health care carriers.

Tables 17 and 18 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs. For example, **Medicare enrollees recorded higher, average, annual OOP costs**. Due to the absence of Medicaid OOP costs, the insurance type has been omitted entirely from the following tables.

[affordability/#:~:text=In%20the%20USA%2C%20Ozempic's%20price,involves%20evaluating%20its%20cost%2Deffe](#)
[ctiveness.](#)

⁴⁹ American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2017. National Library of Medicine, March 22, 2018. <https://pubmed.ncbi.nlm.nih.gov/29567642/>.

⁵⁰ Ozempic Costs: Pricing, Coverage, and Affordability. Concierge MD 2024.

<https://conciergemdla.com/blog/ozempic-costs-pricing-coverage-affordability/#:~:text=In%20the%20USA%2C%20Ozempic's%20price,involves%20evaluating%20its%20cost%2Deffe>
[ctiveness.](#)

⁵¹ Ibid.

⁵² Gross costs from the APAC database are prior to any price concessions such as discounts or coupons. Net cost information from the data call is the cost of the drug after price concessions.

Table 17 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee⁵³

Proprietary name	Annual Medicare OOP cost/enrollee	Annual Commercial OOP cost/enrollee	Total ⁵⁴	Median	IQR	75 th percentile	95 th percentile
Ozempic	\$531	\$441	\$494	\$40	\$128	\$128	\$727
Byetta	\$362	\$75	\$297	\$35	\$146	\$146	\$455
Rybelsus	\$560	\$476	\$530	\$47	\$161	\$165	\$828
Trulicity	\$552	\$409	\$499	\$25	\$114	\$114	\$763
Victoza	\$432	\$257	\$367	\$10	\$120	\$120	\$750

Table 18 Review drug vs. therapeutic alternatives and out-of-pocket cost per claim

Proprietary name	Medicare OOP cost/claim	Commercial OOP cost/claim	Total ⁵⁵	Median	IQR	75 th percentile	95 th percentile
Ozempic	\$102	\$73	\$87	\$30	\$75	\$75	\$425
Byetta	\$93	\$19	\$76	\$4	\$89	\$89	\$441
Rybelsus	\$135	\$103	\$121	\$40	\$101	\$105	\$606
Trulicity	\$88	\$60	\$76	\$10	\$50	\$50	\$396
Victoza	\$93	\$56	\$78	\$4	\$60	\$60	\$400

⁵³ Based on 2023 Oregon APAC data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁵⁴ The total is the overall cost per enrollee across commercial insurers and Medicare.

⁵⁵ The total is the overall cost per claim across commercial insurers and Medicare.

Clinical information based on manufacturer material⁵⁶

ORS 646A.694(1)(L) and OAR 925-200-0020(1)(L). Information provided from manufacturers and information with sources from contractor(s).

Drug indications

- FDA Approved:
 - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
 - To reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease.
 - To reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with T2DM and chronic kidney disease (CKD)
 - To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.
- Limitations of Use:
 - Includes warnings of pancreatitis and gallbladder events.
 - Evidence is insufficient to make recommendations in type 1 diabetes (T1DM) and it is currently not recommended in this population.
- Off Label Uses:
 - Type 1 diabetes mellitus (T1DM)
 - Chronic Weight Management
 - GLP-1s have been used off label for both pediatric and adult Type 1 diabetes mellitus patients to manage their diseases. GLP-1s are used as adjunctive therapy to insulin therapy for these patients, though T1DM has not been approved by FDA as an indication for semaglutides, and have been reported to improve glycemic control with automated insulin delivery.^{57, 58}
 - Semaglutide is a glucose-dependent insulinotropic polypeptide (CIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist. GLP-1

⁵⁶ U.S. Food & Drug Administration. Ozempic (*semaglutide*) Prescribing information, May 2022.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.

⁵⁷ Pasqua, MR., et al. Subcutaneous weekly semaglutide with automated insulin delivery in type 1 diabetes: a double-blind, randomized, crossover trial. *Nat Med* 31, 1239–1245 (2025).

<https://www.nature.com/articles/s41591-024-03463-z>.

⁵⁸ Gallagher, Mary Pat, et al. Understanding Off-Label Use of GLP-1 (Glucagon-Like Peptide-1 Receptor) Agonists among Providers Participating in the T1D Exchange Quality Improvement Collaborative (T1DX-QI). *Diabetes* 14 June 2024; 73 (Supplement_1): [804-P: Understanding Off-Label Use of GLP-1 \(Glucagon-Like Peptide-1 Receptor\) Agonists among Providers Participating in the T1D Exchange Quality Improvement Collaborative \(T1DX-QI\) | Diabetes | American Diabetes Association](#).

agonists have effects such as decreased appetite because it enhances satiety and reduces hunger by stimulating insulin and inhibiting glucagon secretions. The decreased appetite leads to weight loss despite obesity not being part of the FDA indications. Similar to other semaglutide products, Ozempic is used for the off-label for weight loss.^{59, 60, 61}

Clinical efficacy

- Injectable semaglutide (Ozempic) was FDA-approved based on three, phase 3, double-blind, placebo-controlled, randomized controlled trials (RCTs) in patients with T2DM both as monotherapy, as add-on therapy to background metformin with or without additional oral agents, and as add-on to basal insulin. These studies compared semaglutide subcutaneous (SC) 0.5 mg and 1.0 mg weekly to placebo. The primary outcome in all trials was changed in hemoglobin A1c (HbA1C) from baseline to week 30 or 52.⁶²
- These initial studies provided moderate quality evidence that semaglutide SC 0.5 mg and 1.0 mg weekly reduces short term HbA1c from baseline in a dose-dependent manner, ranging from -1.32% to -1.85% as monotherapy or as add-on therapy.⁶³ Semaglutide SC resulted in a dose-dependent weight loss of 3.5 to 6.5 kg in clinical trials.⁶⁴
- In January 2020, the FDA labeling of semaglutide SC (Ozempic) was expanded to include the reduction of risk of major adverse CV events.⁶⁵ This indication was added based on data from the SUSTAIN-6 study, a double-blind, randomized, placebo-controlled trial comparing semaglutide SC to placebo in 3,297 adults with T2DM and CV disease, chronic heart failure, or chronic kidney disease on background therapy for glycemic control.⁶⁶ Over a median follow-up of 2 years, there was a reduction in the primary composite CV outcome (nonfatal myocardial infarction, nonfatal stroke, CV death) of 2.3% (6.6% in the semaglutide SC group and 8.9% in the placebo group; hazard ratio [HR] 0.74; 95% CI 0.58 to 0.95; p<0.02; number needed to treat [NNT] 44) and an absolute difference of 1.1% in

⁵⁹ Understanding Unapproved Use of Approved Drugs Off Label. U.S. Food & Drug Administration, Feb. 5, 2018. <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>.

⁶⁰ FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss. U.S. Food & Drug Administration, Aug. 8, 2025. <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss>.

⁶¹ Blundell, J., et al. "Effects of once-weekly semaglutide on appetite, energy intake, control of eating, food preference and body weight in subjects with obesity." *Diabetes, obesity & metabolism*, 19(9), 1242–1251. <https://dom-pubs.pericles-prod.literatumonline.com/doi/10.1111/dom.12932>.

⁶² FDA Center for Drug Evaluation and Research. Semaglutide Clinical Review. Application Number: 209637Prog1s000: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000MedR.pdf.

⁶³ Knop FK, Aroda VR, do Vale RD, et al. Oral semaglutide 50 mg taken once per day in adults with overweight or obesity (OASIS 1): a randomized, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2023 Aug 26;402(10403):705-719. <https://pubmed.ncbi.nlm.nih.gov/37385278/>.

⁶⁴ Ibid.

⁶⁵ Ozempic Prescribing Information. Novo Nordisk. Plainsboro, NJ 09/2023. <https://www.novo-pi.com/ozempic.pdf>.

⁶⁶ Marso SP, Bain SC, Consoli A, Eliaschewitz FG, et al. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med*. 2016 Nov 10;375(19):1834-1844. <https://pubmed.ncbi.nlm.nih.gov/27633186/>.

the risk of stroke (HR 0.61; 0.38 to 0.99).⁶⁷ There was no significant difference in the individual outcomes of myocardial infarction, CV death, or all-cause death. There was a significant reduction in body weight with semaglutide SC 0.5 mg (-3.6 kg), semaglutide SC 1.0 mg (-4.9 kg) compared to placebo (-0.5 kg).⁶⁸

- In January 2025, the FDA approved semaglutide SC (Ozempic) to reduce the risk of worsening kidney disease, kidney failure, and death from CVD in adults with T2DM and chronic kidney disease (CKD), the first GLP-1 agonist to be approved for renal benefits. Approval was based on data from the FLOW study, which resulted in a reduced risk of the composite of major kidney disease events, reduction in eGFR from baseline, and death from kidney related or CV causes with semaglutide 1.0 mg weekly compared to placebo (HR 0.71; 95%CI 0.56 to 0.89).

Clinical safety

- FDA safety warnings and precautions:
 - Risk of Thyroid C-Cell Tumors
 - Pancreatitis
 - Diabetic Retinopathy complications
 - Hypoglycemia in combination with insulin or an insulin secretagogue
 - Hypersensitivity
 - Acute kidney injury
 - Acute gallbladder disease
- Contraindications:
 - Personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2.
 - Serious hypersensitivity reaction to semaglutide
- Common side effects:
 - Gastrointestinal effects (32 to 41%), including diarrhea (8 to 9%), nausea (15 to 20%), and vomiting (5 to 9%), abdominal pain (6 to 11%), and constipation (3 to 6%)
- Safety advantages or disadvantages:
 - The most common side effects associated with GLP-1 receptor agonists include gastrointestinal side effects. These are dose-related and likely due to delayed gastric emptying or activation of centers involved in appetite regulation, satiety, and nausea. These are most common soon after initiation and during dose escalation. Rapid titration is associated with higher risk of GI symptoms. There is no evidence that one GLP-1 is associated with higher rates of GI symptoms than

⁶⁷ FDA Center for Drug Evaluation and Research. Semaglutide Clinical Review. Application Number: 209637Prog1s000. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000MedR.pdf.

⁶⁸ Ibid.

others. This is likely to result in higher rates of discontinuation in real world use than in clinical trials.

- Overall risk of hypoglycemia of GLP-1 agonists when used as monotherapy is low and there is no meaningful difference in risk between individual agents. The risk of hypoglycemia is increased when used in combination with insulin or sulfonylureas.
- There is high quality evidence of an association with GLP-1 receptor agonists and an increased risk of a composite assessment of gallbladder or biliary diseases (including cholelithiasis, cholecystitis, and biliary disease) compared to active treatments or placebo (relative risk [RR] 1.37; 95% CI, 1.23 to 1.52).⁶⁹ The risk was increased with higher doses, longer durations and when used for weight loss. There was a statistically significant increased risk with liraglutide and dulaglutide, a nonsignificant increased risk with exenatide and injectable semaglutide and no increased risk seen with oral semaglutide.⁷⁰ Despite, an increased risk compared to placebo, the absolute risk remains small (additional 27 cases per 10,000 persons treated per year).⁷¹

⁶⁹ He L, Wang J, Ping F, et al. Association of Glucagon-Like Peptide-1 Receptor Agonist Use With Risk of Gallbladder and Biliary Diseases: A Systematic Review and Meta-analysis of Randomized Clinical Trials. *JAMA Intern Med.* 2023;182(5):513–519. <https://pubmed.ncbi.nlm.nih.gov/35344001/>.

⁷⁰ Marso SP, Bain SC, Consoli A, Eliaschewitz FG, et al. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med.* 2016 Nov 10;375(19):1834-1844. <https://pubmed.ncbi.nlm.nih.gov/27633186/>.

⁷¹ Ibid.

Therapeutic alternatives^{72,73,74,75,76}

Table 19 FDA-approved indications

Drug	Formulation	Dosing Frequency	Indications (per label)		
			T2DM	CV Risk Reduction	CKD
Semaglutide (Ozempic)	SubQ	Weekly	Yes	Yes	Yes
Semaglutide (Rybelsus)	Oral	Daily	Yes	No	No
Dulaglutide (Trulicity)	SubQ	Weekly	Yes	Yes	No
Liraglutide (Victoza)	SubQ	Daily	Yes	Yes	No
Exenatide (Byetta)	SubQ	Twice Daily	Yes	No	No
Tirzepatide (Mounjaro)	SubQ	Weekly	Yes	No	No

Abbreviations: CKD: chronic kidney disease; CV: cardiovascular; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus

⁷² U.S. Food & Drug Administration. *Ozempic (semaglutide) Prescribing Information*. Teva Pharms., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf

⁷³ U.S. Food & Drug Administration. *Byetta (exanatide) Prescribing Information*. Teva Pharms., Action year 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf

⁷⁴ U.S. Food & Drug Administration. *Rybelsus (semaglutide) Prescribing Information*. Teva Pharms., Action year 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf

⁷⁵ U.S. Food & Drug Administration. *Trulicity (dulaglutide) Prescribing Information*. Teva Pharms., Action year 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf

⁷⁶ U.S. Food & Drug Administration. *Victoza (liraglutide) Prescribing Information*. Teva Pharms., Action year 2022. *Victoza* https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf

Table 20 Efficacy: Comparative clinical efficacy (selected label trials)

Drug	~A1C Decrease	Short term weight loss	Rates of nausea	Cardiovascular Benefits
Semaglutide (Ozempic)	1.0%- 1.7%	4.0 – 6.0 kg	15% - 20%	↓ MACE (NNT 44)
Dulaglutide (Trulicity)	1.0% - 1.8 %	2.5 – 4.6 kg	12% - 20%	↓ MACE (NNT 71)
Exenatide (Byetta)	1.0%	2 kg	8% - 11%	
Liraglutide (Victoza)	1.0% - 1.3%	2.5 kg	18% - 20%	↓ MACE (NNT 53)
Semaglutide (Rybelsus)	1.0%	2.5 kg	11% - 20%	↓ MACE (NNT 56)
Tirzepatide (Mounjaro)	1.7%-2.5%	5.0-12.0 kg	12% - 29%	↓ MACE*

Abbreviations: CV: cardiovascular; ER: extended release; kg: kilogram; MACE: major adverse cardiovascular events; NNT: number needed to treat; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus

*Unpublished data. Pending publication of CV outcomes trial.

Comparative clinical efficacy (selected labeled trials)

- Clinical guidelines recommend GLP-1 agonists as a first line option for patients with T2DM and compelling indications with evidence of benefit, including atherosclerotic cardiovascular disease (ASCVD) and those at high risk for ASCVD.⁷⁷ Agents with proven CV benefits are recommended, including dulaglutide (Trulicity), liraglutide (Victoza), and subcutaneous semaglutide (Ozempic). There are no published studies directly comparing GLP-1 agonists on CV outcomes. A large randomized, double-blind, phase 3 trial comparing tirzepatide to dulaglutide in adults with T2DM and CV disease evaluating CV outcomes is expected to be published in early 2026. Preliminary results suggest tirzepatide decreased major adverse cardiovascular events.
- Within the GLP-1 agonists, semaglutide is considered to have very high efficacy in lowering HgA1c and very high efficacy for weight loss. It is a long acting GLP-1 agonist and is available as weekly dosing which may be preferred by some patients. Tirzepatide is the only GLP-1/GIP agonist and has the highest efficacy for weight loss and similar HgA1c lowering ability to semaglutide

⁷⁷ American Diabetes Association Professional Practice Committee. “9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2024.” Diabetes Care, January 2024, 47 (Supplement_1): S158–S178. <https://doi.org/10.2337/dc24-S009>.

- Compared to dulaglutide, exenatide and liraglutide, semaglutide SC (Ozempic) was shown to be superior in reduction in HgA1C (-1.5% to -1.8%), and in reduction in body weight (-5.6 kg to -6.5 kg).
- Compared to liraglutide, oral semaglutide (Rybelsus) is noninferior in reduction in HgA1C (estimated treatment difference -0.2%; 95% CI -0.3 to -0.1) and superior in reduction in body weight (-4.4 kg vs. -3.1 kg; p=0.003), with no known effects on CV outcomes.⁷⁸
- In addition to the in-class (GLP-1 agonists) therapeutic alternatives included in above table, additional first line drug classes used for the treatment of T2DM include metformin, sodium-glucose cotransporter 2 inhibitors (SGLT2i), and inhibitors of dipeptidyl peptidase 4 (DPP-4).⁷⁹

Table 21 Safety & therapeutic considerations (from warnings/precautions & highlights)

Drug	Boxed warning	Notable warnings/precautions (selected)
Semaglutide (Ozempic)	Thyroid C-cell tumors	Pancreatitis; diabetic retinopathy complications; AKI/dehydration; gallbladder disease; hypoglycemia with SU/insulin; delayed gastric emptying affecting oral meds.
Semaglutide (Rybelsus)	Thyroid C-cell tumors	Pancreatitis; diabetic retinopathy complications; AKI; severe GI effects; gallbladder disease; aspiration risk under anesthesia; oral-drug absorption interactions; strict empty-stomach dosing.
Dulaglutide (Trulicity)	Thyroid C-cell tumors	Pancreatitis; retinopathy complications (monitor if hx); AKI with severe GI events; severe GI disease caution; gallbladder disease; hypoglycemia with SU/insulin.
Liraglutide (Victoza)	Thyroid C-cell tumors	Pancreatitis; renal impairment cautions; hypersensitivity; gallbladder disease; daily injection/titration requirements.
Exenatide (Byetta)	No thyroid C-cell boxed warning on label.	Pancreatitis; avoid in severe renal impairment/ESRD; caution in moderate renal impairment; GI disease caution; immunogenicity; drug-induced thrombocytopenia warning added.

⁷⁸ Pratley R, Amod A, Hoff ST, Kadowaki T, et al. Oral semaglutide versus subcutaneous liraglutide and placebo in type 2 diabetes (PIONEER 4): a randomised, double-blind, phase 3a trial. *Lancet*. 2019 Jul 6;394(10192):39-50.

⁷⁹ American Diabetes Association Professional Practice Committee. "9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2024." *Diabetes Care*, January 2024, 47 (Supplement_1): S158–S178. <https://doi.org/10.2337/dc24-S009>.

Table 22 Strengths, dosing & route

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
Semaglutide (Ozempic)	SC, once weekly	Start 0.25 mg weekly ×4 wk to 0.5 mg; may increase to 1 mg then 2 mg (≥4 wk steps).	Pens delivering 0.25/0.5 mg (2 mg/3 mL), 1 mg (4 mg/3 mL), 2 mg (8 mg/3 mL).
Semaglutide (Rybelsus)	Oral, once daily (empty stomach with ≤4 oz water; wait ≥30 min)	R1: 3 mg to 7 mg to 14 mg; R2: 1.5 mg to 4 mg to 9 mg (formulations not mg-for-mg substitutable).	Tablets: R1 3/7/14 mg; R2 1.5/4/9 mg.
Dulaglutide (Trulicity)	SC, once weekly	Adults: start 0.75 mg to 1.5 mg; may increase in 1.5-mg steps to max 4.5 mg. Peds (≥10 y): start 0.75 mg; max 1.5 mg.	Single-dose pens: 0.75 mg/0.5 mL; 1.5 mg/0.5 mL; 3 mg/0.5 mL; 4.5 mg/0.5 mL.
Liraglutide (Victoza)	SC, once daily	Start 0.6 mg daily ×≥1 wk to 1.2 mg; may increase to 1.8 mg if needed; same titration in pediatrics (≥10 y).	6 mg/mL pen delivering 0.6, 1.2, or 1.8 mg doses.
Exenatide (Byetta)	SC, twice daily (≤60 min before morning & evening meals)	Start 5 mcg BID ×1 mo to 10 mcg BID as tolerated.	Prefilled pens: 5 mcg/dose (60 doses); 10 mcg/dose (60 doses).

Input from specified stakeholders

ORS 646A.694(3) and OAR 925-200-0020(2)(k)(A-D)

See appendix page for all stakeholder feedback.

Patients and caregivers:

Note: The information presented is based on self-reported survey responses from individuals prescribed certain medications. Participation in the survey was voluntary, and the responses reflect the individual's personal understanding and interpretation of the question asked. As such, the data may contain inconsistencies or inaccuracies due to varying levels of comprehension, recall bias, or misinterpretation of question intent. These limitations should be considered when interpreting the responses.

Survey information was **collected from 26 individuals** taking or having an association with Ozempic. According to the survey results, **65 percent of respondents had Ozempic covered under the insurance**, regardless of the type of insurance used.

Zero patients were on Medicaid, 17 patients were on Medicare, and nine patients had private health insurance. **Five patients** reported that their prescription was **not covered**, although they were under **private health insurance**. Three patients reported being on patient assistance programs.

Below are written answers from Oregon patients who responded to the PDAB survey in April and May 2025, edited for readability, length and to protect patient privacy.

”” Ozempic ””

- ✚ I've been overweight for over 40 years, in and out of diet programs, including Weight Watchers, and many others, and nothing worked long term. I finally found a medicine that helps me lose weight. (I've lost 30 pounds) and used it for two years, and then they cut it off with little to no explanation. I've already gained part of the weight back. It's very discouraging and depressing.
- ✚ Because I'm over 65 and on Medicare, I'm excluded from patient assistance programs. On Medicare, my out-of-pocket expenses have increased so much that I now have to rely on food banks for food I can no longer afford. In addition to paying out-of-pocket drug costs, I now have copays for visits to specialists, emergency ambulance transport, and non-emergency transportation to medical appointments. I'm partially disabled and survive only on my Social Security retirement. If Social Security and Medicare are cut, I will be homeless and without medical care. I feel like my life is at risk; no home and no medical care is an almost certain death for me. Sadly, I'm one of millions in this country in the same situation. Thank you for your efforts to help!

- ✚ The FDA announcement preventing pharmacies from compounding semaglutide and tirzepatide at a lower cost than the name brand is going to bankrupt people who need it to prevent or remediate worsening health conditions. I am lucky enough to have some maneuverability in my budget to afford the name brand but it's my single largest monthly expense and I still need to make sacrifices to afford it going forward.
- ✚ Reducing weight led to lower blood pressure and reduced cholesterol and general better health. Stopping the drug will likely lead to increase in weight, blood pressure and cholesterol; but I cannot afford to continue paying \$300/month out of pocket.
- ✚ One Medicare patient has been on Ozempic .25 mg weekly for the past two or three years to help control blood sugar for diabetes, paying \$250 per month out of pocket.

Here is a letter submitted by a retired patient who planned to speak at the May 21 board meeting but was unable to because of a scheduling conflict. This patient also submitted a letter to the board included in this report as Exhibit B.

- ✚ I've been overweight for 40 years and on many diets and programs for weight loss. None have worked for me until Ozempic. I took Ozempic for one year and lost 30 pounds. My doctor prescribed Mounjaro to help me continue to lose weight. Then my insurance decided not to cover it. I couldn't afford it without insurance as it was between \$300-349/mo. Since I could not afford that, and have had no meds since, I've gained 20 pounds back. This has caused me extreme anguish and depression. I think about my extra weight everyday. I need these medications as they are the only thing that has worked for me. Please consider reducing the cost of these medications. I was prediabetic before the weight loss meds and Ozempic helped me to go off these meds. However, I just had a blood test recently and it appears my prediabetes has returned. Weight loss drugs are key to my health, but I need to be able to afford them.

Individuals with scientific or medical training

Surveys were posted on the PDAB website to collect drug information from individuals with scientific and medical training. There were no reports for Ozempic to determine the impact of the disease, benefits or disadvantages, drug utilization, or input regarding off label usage.

Safety net providers

The information reported by safety net providers describes their experience dispensing Ozempic, particularly in relation to the federal 340B Drug Pricing Program. The survey collected information on utilization, if the drug was eligible for 340B discounts, dispensing arrangements, and payment and reimbursement levels.

A total of **11 safety net clinics** responded to the survey. Among respondents, **ten clinics indicated that Ozempic was covered as a 340B-eligible prescription** within their programs. Most clinics (91%) reported operating an internal pharmacy for dispensing 340B-eligible medications, and 64 percent reported using one or more contract pharmacies for this purpose.

Additionally, **82 percent of clinics reported having a prescription savings program**, and all respondents (100%) reported employing a staff member dedicated to 340B compliance.

Regarding expenditures under the 340B program, respondents reported a range of total amounts paid for Ozempic: 27 percent reported paying between **\$0–\$100,000**, 18 percent reported between **\$100,001–\$300,000**, while **55 percent declined to report, citing trade secret protections**.

Reported reimbursement for dispensing under 340B also varied: 18 percent of respondents reported reimbursement between **\$0–\$100,000**, 9 percent between **\$100,001–\$500,000**, and 18 percent between **\$500,000–\$10,000,000**.

Without additional detail on the volume of patients treated or the per-claim costs, it is difficult to interpret the figures in terms of clinic financial risk or access outcomes. The wide range may reflect differing clinic sizes, patient populations, or inventory management practices. Notably, the absence of full reporting by 55 percent of clinics makes it challenging to assess how 340B drug costs affect long-term affordability or sustainability for safety-net providers.

These results suggest that while Ozempic is incorporated into many safety-net programs, further data would be necessary to understand how reimbursement aligns with acquisition cost and whether 340B discounts adequately mitigate financial exposure for patients and the healthcare system.

Table 23 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	9
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340B compliance requirements	100%
Reported total amount paid for drug under 340B was between \$0-\$100,000	27%
Reported total amount paid for drug under 340B was between \$100,001-\$300,000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between \$0-\$100,000	18%

Survey information	Response
Reported total reimbursement for drugs dispensed under 340B was between \$100,001-\$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between \$500,000-\$10,000,000	18%

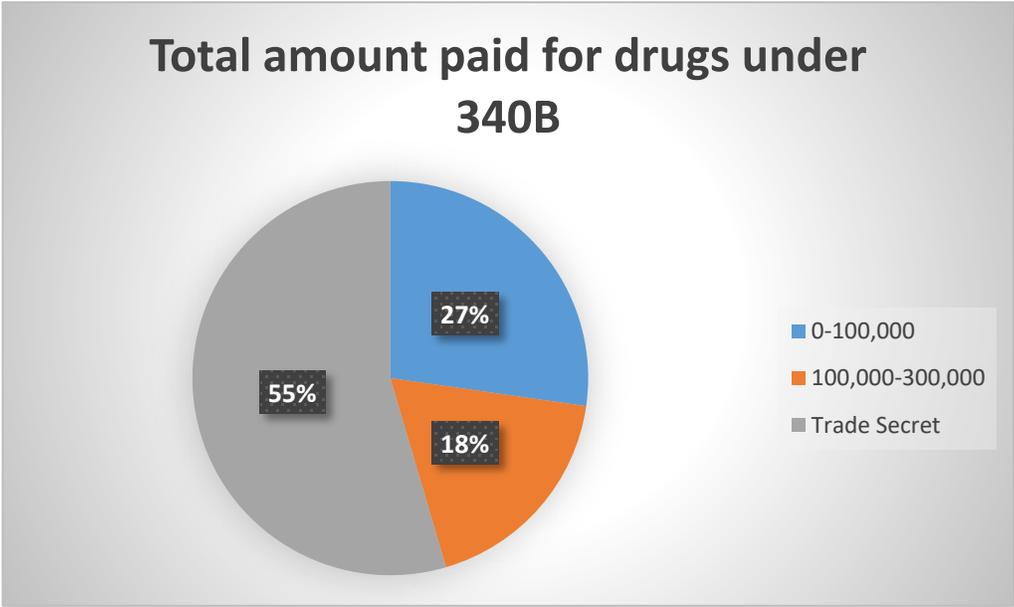


Figure 6 Amounts paid for drug under 340B discount program

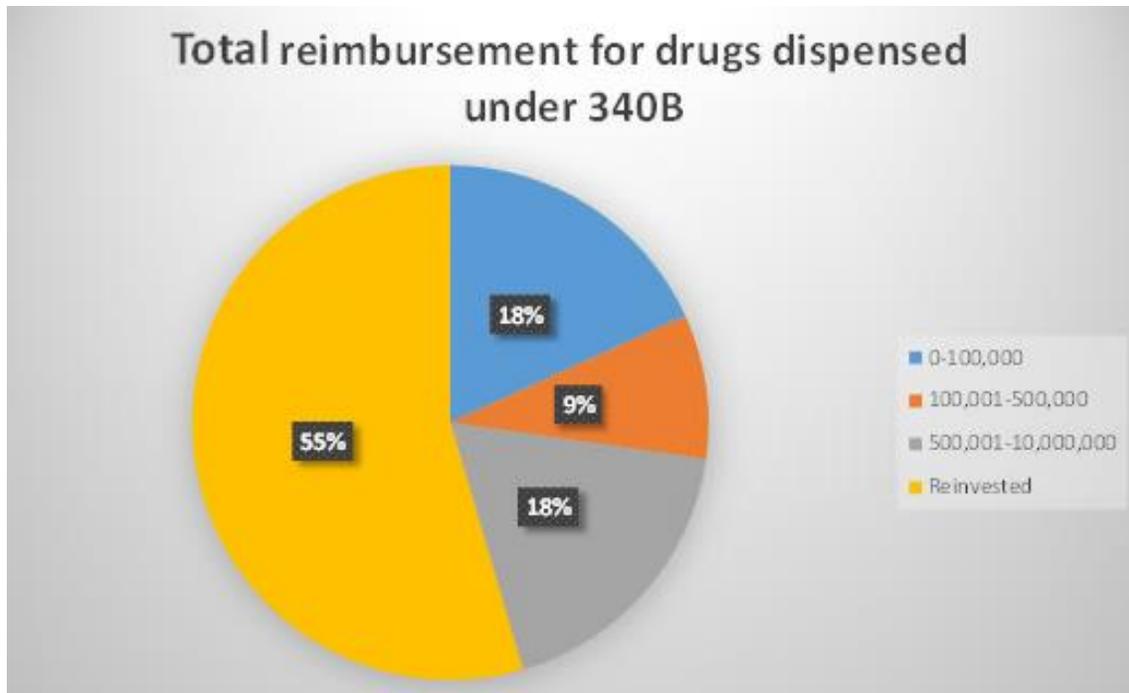


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

Payers

Relevant information from payers is incorporated throughout the material packed based on the data submitted through the formal data call process. This includes details on the total cost of care for the disease, the cost and utilization of the prescription drug, the availability and formulary placement, therapeutic alternatives, as well as reported impacts to member costs.

The data provided through the carrier data call serves as a comprehensive source of payer input and reflects aggregate insights across participating organizations. No separate qualitative feedback or narrative statements were requested or received from individual payers for inclusion in the section.

Appendix

Stakeholder feedback:

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Suzanna Masartis	Community Liver Alliance	Ozempic	Letter	5/21/2025	Exhibit A
Carol Elkins	Retired, patient	Ozempic	Letter	6/18/25	Exhibit B
Dr. Harry Gewanter	Let My Doctors Decide Action Network	Ozempic	Letter	5/15/2025	Exhibit C
Mary Anne Cooper	Regence BlueCross BlueShield	Ozempic	Letter	5/12/2025	Exhibit D
Kelsey Lovell	Novo Nordisk	Ozempic	Letter	9/15/2025	Exhibit E