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Rybelsus ®
(*semaglutide*)[1]

Version 2.1

[1] Image source: https://www.rybelsus.com/taking-rybelsus/what-to-expect-with-rybelsus.html

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Document version history

Version	Date	Description
v1.0	08/13/2025	Original Release
v1.1	09/15/2025	Added new public comment to the appendix table. Updated table numbers and table references.
v1.2	09/23/2025	Added new public comment to the appendix table.
v2.0	10/30/2025	Updated table formats and footnotes
v2.1	12/05/2025	Exclusivity information updated.

Review summary

Therapeutic alternatives[2,3,4]

Rybelsus (*semaglutide*) has the following therapeutic alternatives:

Proprietary name	Non-proprietary name	Manufacturer	Approved year	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
Rybelsus[5]	*semaglutide*	Novo Nordisk Inc.	2017	13	2026-2039	2028	Yes (2027[6])
Byetta[7]	*Exenatide synthetic*	Astrazeneca Ab	2005				No
Ozempic	*semaglutide*	Novo Nordisk Inc.	2017	19	2025-2028	2028	Yes (2027[6])
Trulicity[8]	*dulaglutide*	Eli Lilly and Co.	2014				No
Victoza[9]	*liraglutide*	Novo Nordisk Inc.	2010	4	2025-2037		No

[2] Approved 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.

[3] Frequently 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.

[4] Selected Drugs and Negotiated Prices. Centers for Medicare & Medicaid Services, May 23, 2025. https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices.

[5] New exclusivity date found on Dec. 5, 2025. Approved 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.

[6] The year the Maximum Fair Price (MFP) becomes effective.

[7] Byetta 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.

[8] No patent or exclusivity information was listed for Trulicity in the U.S. Food & Drug Administration Purple Book Database. https://purplebooksearch.fda.gov/.

[9] No 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[10,11]

Rybelsus rose at an **average annual rate of 4.6 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
    - Byetta: **3.1** percent
    - Ozempic: **4.8** percent
    - Trulicity: **5.0** percent
    - Victoza: **-2.3** percent

Additionally, the average annual rate of Rybelsus exceeded inflation **in 2020, 2023, and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 17.7 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions [12]

Based on data received from healthcare carriers, Rybelsus in 2023 had the **gross spend of $1,237 per claim**, while the **spend net of discount was $607 per claim**. Price concession per claim was reported to be **$630**.

Cost to the payers[13]

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
Rybelsus	$20,042,008	15,787	$5,682	$940
Byetta	$418,695	375	$5,234	$826
Ozempic	$81,017,647	78,032	$4,427	$902
Trulicity	$114,173,339	104,682	$8,277	$909
Victoza	$26,835,206	20,794	$6,963	$1,089

[10] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[11] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[12] 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.
[13] 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 enrollees[14]

Table 2 2023 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
Rybelsus	$509	$47	$116	$40
Byetta	$297	$35	$76	$4
Ozempic	$360	$40	$89	$30
Trulicity	$499	$25	$76	$10
Victoza	$367	$10	$78	$4

Rubric considerations

Domain	Consideration
Utilization	15,787
Price evaluation	change in WAC between 0% to 3.99% for four years, outpaces inflation for three years
Price concessions	50-75% of discounted
System & payer costs	Total gross spend $15M-$50M and total net spend $3M-$10M
Enrollee burden	Total APAC OOP annual cost $200-$700
Equity impact	Yes
Access restrictions	Yes
Therapeutic alternative fail to reduce system spending	Yes
Stakeholder input identify access or financial hardship?	No
Patent expirations more than 18 months from time of review?	Yes
Excluded from CMS Maximum Fair Price List (MFP)	No

[14] 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 information[15]

Drug proprietary name(s)	Rybelsus®
Non-proprietary name (active ingredients)	*semaglutide*
Manufacturer	Novo Nordisk
Pharmacologic category	Glucagon-like Peptide 1 (GLP-1) Receptor Agonist
Treatment	Used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM)
Dosage strength	3mg, 7mg, and 14mg
Route of administration	Tablet/Oral
Physician administered	No

FDA approval

Rybelsus was first approved by the FDA on Sept. 20, 2019.[16]

The drug qualified for the following expedited forms of approval: Priority

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

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.

Rybelsus requires strict administration such as taking it on an empty stomach with less than 4 oz of water and waiting more than 30 minutes before eating, drinking, or taking other oral meds. This can be challenging for shift workers, people with food insecurity, having multiple drugs to take, or limited health literacy.[17] These schedule demands may affect adherence in populations already facing barriers, potentially reducing its benefit. The American Diabetes Association's 2025 Standards emphasize screening for social needs, tailoring education, and addressing health literacy as critical supports when choosing an oral GLP-1 option.[18] Persistent

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

[16] 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.

[17] U.S. Food & Drug Administration. Rybelsus *(semaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.

[18] American Diabetes Association Professional Practice Committee; 5. Facilitating Positive Health Behaviors and Well-being to Improve Health Outcomes: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S86–S127. https://doi.org/10.2337/dc25-S005.

disparities in GLP-1 initiation further underscores the need for targeted diabetes self-management education, support and coverage navigation.[19, 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, **15,787** Oregonians filled a prescription for Rybelsus 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 Rybelsus, 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 its list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts cost.

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

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

[19] Moore, J., Iheme, N., Rebold, N. S., Kusi, H., Mere, C., Nwaogwugwu, U., Ettienne, E., Chaijamorn, W., & Rungkitwattanakul, D. (2025). 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, Switzerland)*, *13*(2), 46. https://doi.org/10.3390/pharmacy13020046.

[20] Rodriguez PJ, Zhang V, Gratzl S, et al. Discontinuation and Reinitiation of Dual-Labeled GLP-1 Receptor Agonists Among US Adults With Overweight or Obesity. *JAMA Netw Open.* 2025;8(1):e2457349. doi:10.1001/jamanetworkopen.2024.57349.

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

Table 4 Drug vs therapeutic alternatives and 2018-2024 WAC per 30-day supply[22]

Year	Rybelsus	Byetta	Ozempic	Trulicity	Victoza
2018		$708	$729	$730	$870
2019	$772	$730	$772	$759	$922
2020	$818	$752	$811	$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	4.6%	3.1%	4.8%	5.0%	-2.3%
% change 2018 between 2024		20.0%	32.8%	33.9%	-22.2%

The WAC of Rybelsus, averaged across six NDCs reported, was approximately **$32.28 per unit** at the end of 2024.[23] Between 2018-2024, the unit WAC increased at an average annual rate of **4.6 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2019-2020, 2022-2023, and 2023-2024** (see Table 5 and Figure 2).[24]

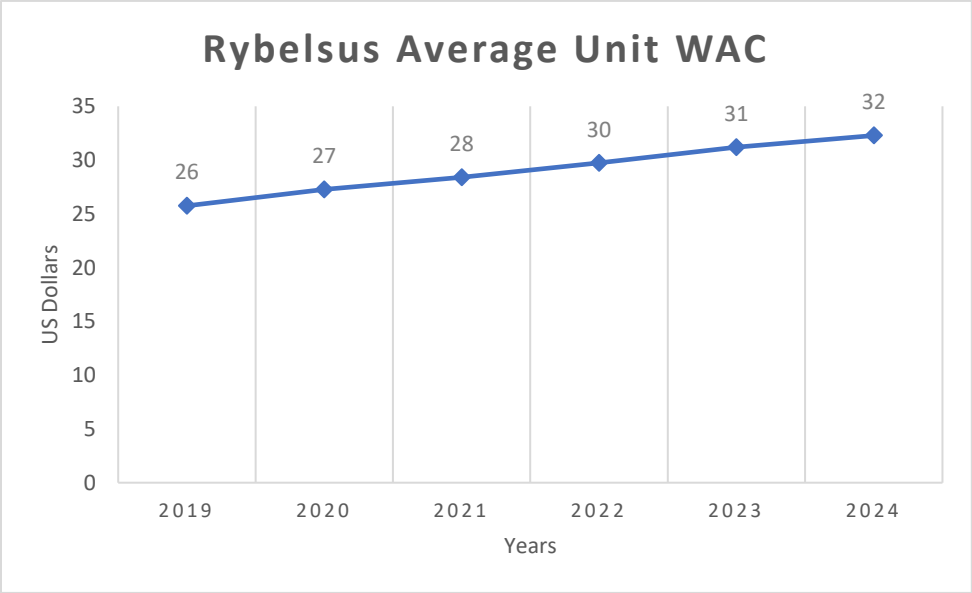

Figure 1 Rybelsus average unit WAC from 2018-2024

[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/.

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison[25]

Year	Rybelsus	Byetta	Ozempic	Trulicity	Victoza	CPI-U
2018-2019			5.9%	4.0%	5.9%	1.7%
2019-2020	6.0%	3.0%	5.0%	5.0%	5.0%	0.7%
2020-2021	4.1%	3.5%	-21.3%	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%

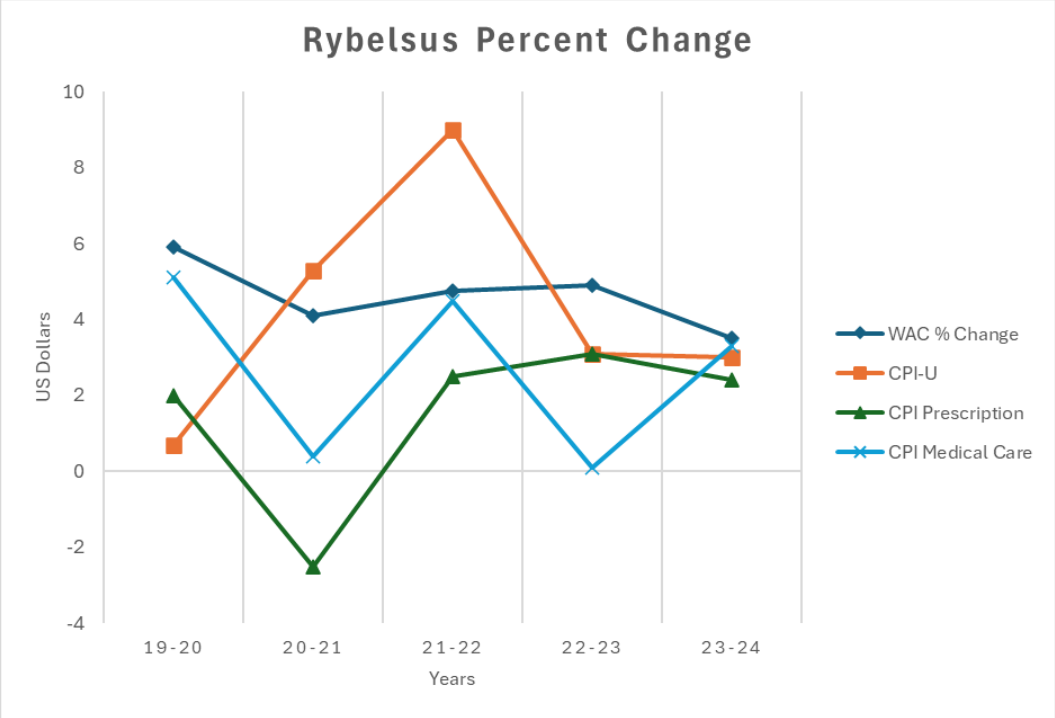

Figure 2 Year over year change in WAC compared to inflation rates[26]

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$26.34 per unit in Quarter 1 of 2021 to $31.01 per unit in Quarter 4 of 2024**, an approximate **17.7 percent increase** over the period (see Table 6).[27] Relative to the **$32.28** WAC in end-of-year 2024, an **AAAC discount of 3.9 percent** is indicated.

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

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 the Rybelsus price trajectory relative to inflation and affordability for public and private payers.

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

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC Average	Average unit WAC
2021	$26	$26	$27	$27	$27	$28
2022	$29	$29	$29	$29	$29	$30
2023	$30	$30	$30	$30	$30	$31
2024	$31	$31	$31	$31	$31	$32

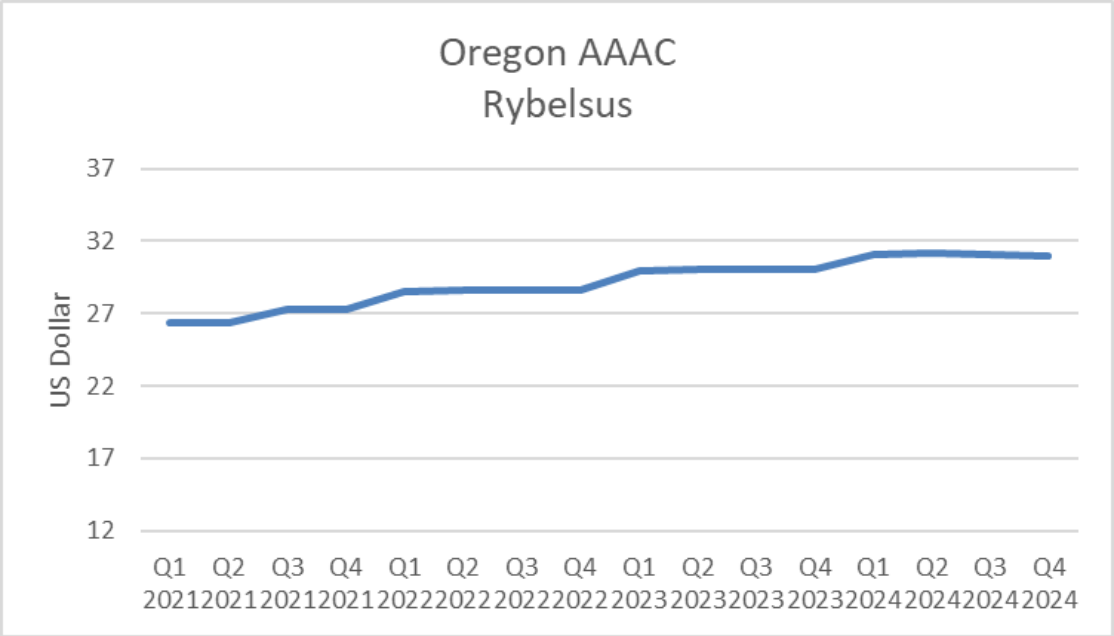

Figure 3 AAAC For Rybelsus from Q1 2021 to Q4 2024

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 Rybelsus 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 Rybelsus per enrollee in the commercial market was approximately $3,023**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $1,483**, reflecting an **estimated mean discount of 50.9 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Rybelsus before concessions was $4,304,075**, with total reported **price concessions amounting to approximately $2,192,282**, as detailed in Table 7. Notably, **81.1 percent of claims benefited from some form of price concession,** leaving **18.9 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	1,424
Total number of claims	3724
Total number of claims with price concessions applied	2,821
Percentage of claims with price concessions applied	81.1%
Percentage of cost remaining after concessions	49.1%
Percentage of discount	50.9%
Manufacturer price concessions for all market types	$1,698,088
PBM price concessions for all market types	$493,767
Other price reductions for all market types	$428
Cost before price concessions across all market types	$4,304,075
Total price concessions across all market types	$2,192,282
Cost of after price concessions across all market types	$2,111,793
Avg. payer spend per enrollee without price concessions	$3,023
Avg. payer spend per enrollee with price concessions	$1,483

Including all market segments, the **gross spend of Rybelsus per claim for commercial carriers was $1,237** before any discounts, rebates, or other price concessions. The net cost per enrollee

discounts, rebates, and other price concessions was **$607**, meaning that insurers reported a price concession of **$630** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types from Data Call[28]

	Average	Individual market	Large market	Small market
Spend per claim, gross	$1,237	$1,242	$1,189	$1,361
Spend per claim, net	$607	$599	$596	$641
Price concessions per claim	$630	$643	$593	$720

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

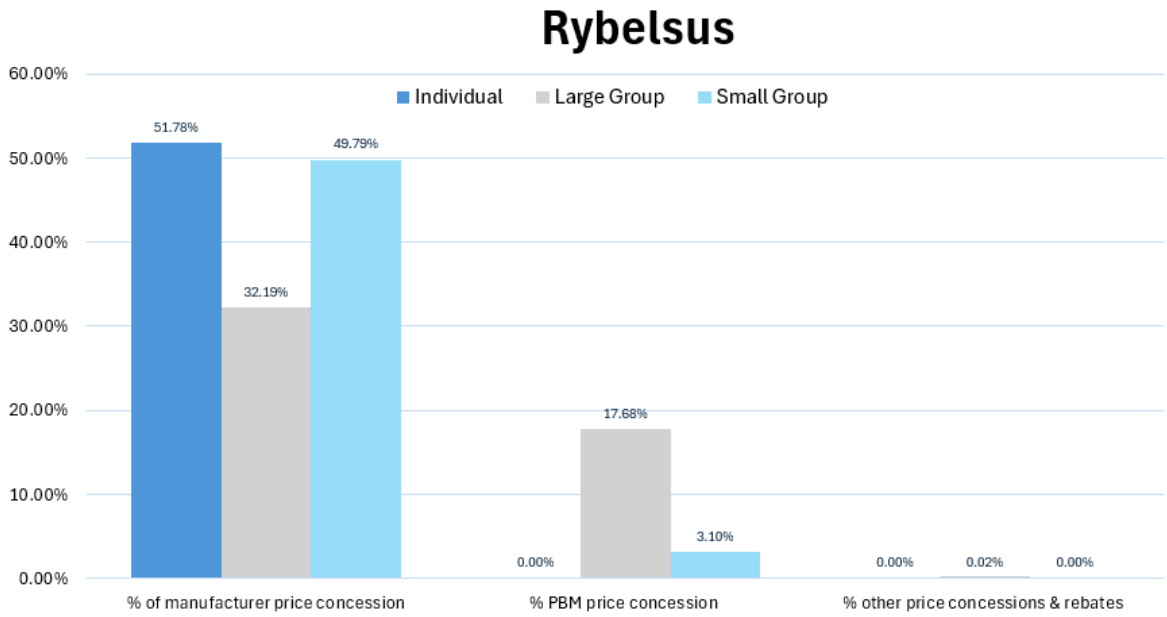

Figure 4 Percent of price concession in each market type[29, 30]

[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.

[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

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 Rybelsus 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 alternatives[31]

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 Rybelsus 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.

Rybelsus's gross total payer paid, based on APAC data, **was $20.0 million**, while total net payer paid received from the **carriers indicated a cost of $4.7 million.** Rybelsus has the second to lowest gross total pay. **Trulicity has the highest gross total pay in consideration** with **$114.2 million** The second highest is Ozempic with **$81.0** million. Notably, Trulicity has the **most utilization among the drugs, at 104,682 claims**, compared to the second highest utilization of Ozempic, at 78,032 claims. **Rybelsus has the second highest payer paid per claim at $1,270,** which is only lower than Trulicity at $1,091 and Victoza at $1,291.

Ozempic also has the highest total enrollee paid at $6.2 million and Trulicity follows behind with $6.0 million. Rybelsus is the third highest total enrollee paid with $1.7 million. **Rybelsus has the highest patient paid per claim of $107**, which is higher than both Ozempic at $80 and Trulicity at $57. The drug with the lowest patient paid per claim is Byetta, which is $49.

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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.

[31] Therapeutic alternative to mean 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).

Neither the drug nor the therapeutic alternatives were reported by the FDA for drug shortage, thus availability is assumed to be unaffected.

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.

Table 9 Average healthcare and average patient OOP costs for Rybelsus vs therapeutic alternatives[32]

Proprietary name	No. of enrollees[33]	No. of claims	Total payer paid	Total enrollees paid[34]	Payer paid/ claim	Patient paid/ claim[35]
Subject Drug **Rybelsus (Data call)**[36]	**1,424**	**3,724**	**$4,722,455**	**$331,150**	**$1,268**	**$89**
Subject Drug **Rybelsus (APAC)**	**3,527**	**15,787**	**$20,042,008**	**$1,683,793**	**$1,270**	**$107**
Byetta	80	375	$418,695	$18,421	$1,117	$49
Ozempic	18,301	78,032	$81,017,647	$6,223,820	$1,038	$80
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 Rybelsus, as compared to the subject drug itself. At

[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.
[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.

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 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 Rybelsus 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 **15,787 total claims for Rybelsus among 3,612 total enrollees**, corresponding to a **total payer expenditure of $20.0 million.**

Table 10 provides gross cost estimates by the total APAC payer spend across all lines of business:

- **Medicare** accounted for the largest share of utilization, with **8,512** claims from **2,068** enrollees and a total spend of **$11.2 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **$7.4 million** and **$1.4 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	1,273	6,014	$7,408,395	$5,820	$1,232
Medicaid	271	1,261	$1,412,331	$5,212	$1,120
Medicare	2,068	8,512	$11,221,283	$5,426	$1,318
Totals[38]	**3,612**	**15,787**	**$20,042,008**		

[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.

Table 11 provides utilization for the healthcare system for Rybelsus and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the most utilization** among the drugs, with **104,682 claims**. In all lines of business, Trulicity is the most utilized aside from commercial, which had Ozempic with the highest utilization.

Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives [39]

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims[40]
Rybelsus	6,014	1,261	8,512	15,787
Byetta	56	132	187	375
Ozempic	37,201	8,338	32,493	78,032
Trulicity	35,415	25,337	43,930	104,682
Victoza	6,379	5,180	9,235	20,794

Table 12 shows the overall payer expenditure of Rybelsus and its therapeutic alternatives, distinguished by lines of business. Rybelsus has a **total expenditure of $20.0 million** with **Medicare being the biggest portion at $11.2 million**. The therapeutic alternative with the **least expenditure is Byetta, at $418,695.**

Table 12 Estimated APAC payer 2023 annual gross expenditure of the review drug and its therapeutic alternatives from all lines of business [41]

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total[42]
Rybelsus	$7,408,395	$1,412,331	$11,221,283	$20,042,008
Byetta	$61,211	$105,425	$252,059	$418,695
Ozempic	$36,494,230	$7,438,499	$37,084,917	$81,017,647
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 13 compares the overall payer cost per enrollee of Rybelsus and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the highest total cost per enrollee**

[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.

at $8,277. Trulicity has **highest cost per enrollee in all lines of business. The median cost per enrollee for Trulicity is $909**, which is comparable to the median cost per enrollee for Ozempic at $902. **Rybelsus and Victoza have higher median cost per enrollee as compared to Trulicity**, at $940 and $1,089 respectively.

Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives [43]

Proprietary name	Commercial Cost/ Enrollee	Medicaid Cost/ Enrollee	Medicare Cost/ Enrollee	Total[44] Cost per Enrollee	Cost per Enrollee, Median	IQR	Cost per enrollee, 75th percentile	Cost per enrollee, 95th percentile
Rybelsus	$5,820	$5,212	$5,426	$5,682	$940	$1,621	$2,436	$2,898
Byetta	$4,372	$3,905	$5,251	$5,234	$826	$1,453	$2,241	$2,673
Ozempic	$4,117	$3,736	$4,288	$4,427	$902	$952	$1,719	$2,782
Trulicity	$6,873	$6,673	$7,936	$8,277	$909	$1,507	$2,356	$2,935
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 **total net cost from reporting market types was around $5.1 million**, with payers paying **$4.7 million**, and enrollees out-of-pocket estimated to be **$331,150**. Table 14 includes the average plan costs per enrollee in the commercial market, ranging from **$3,673 (small group)** to **$3,335 (individual)** annually.

Table 14.a Estimated 2023 total net costs to the healthcare system, payers and OOP/enrollee [45]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	202	460	$673,756	$607,145	$66,611
Large group	907	2,426	$3,222,765	$3,046,037	$176,727
Small group	315	838	$1,157,083	$1,069,272	$87,811
Total	**1,424**	**3,724**	**$5,053,604**	**$4,722,455**	**$331,150**

[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.

Table 14.b Estimated 2023 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	$1,465	$1,320	$145	$3,335	$3,006	$330
Large group	$1,328	$1,256	$73	$3,553	$3,358	$195
Small group	$1,381	$1,276	$105	$3,673	$3,395	$279

As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (64% of total), followed by small group and individual markets.

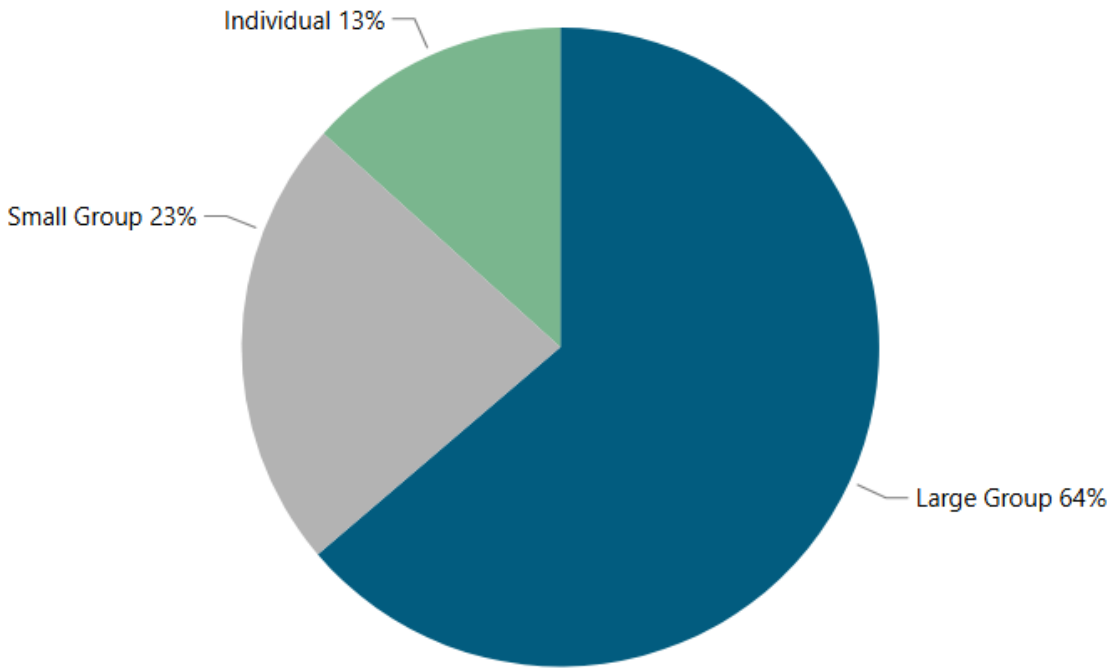

Figure 5 Data call total annual percent spend (payer paid) by market

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.

Review of rejected claims and drug benefit designs

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Rybelsus, including prior authorization requirements, step therapy protocols, and formulary placement. The data describes how the drug is positioned within 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 Rybelsus. In 2023, approximately **67.3 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **33.1 percent of plans required step therapy** before approving its use.

For formulary placement, **60.7 percent of plans categorized Rybelsus as a non-preferred drug**, and **no plans excluded it entirely from the formulary**.

Table 15 Plan design analysis from 2023

Percentage of Plans	
Required prior authorization	67.3%
Required step therapy	33.1%
On a non-preferred formulary	60.7%
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.

This section addresses the extent to which the use of Rybelsus may affect broader health, medical, or social service costs, as compared to alternative treatments or no treatment. At the time of this review, there was no quantifiable data available to PDAB to assess these relative financial impacts in the Oregon population.

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 carrier reporting, manufacturer disclosures, or other sources.

Future reviews may incorporate findings from real-world evidence, health technology assessments, or economic modeling as such data become available.

Estimated average enrollee 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 Rybelsus in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Tables 16 and 17 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.

Table 16 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee [46]

Proprietary name	Annual Medicare OOP cost/ enrollee	Annual commercial OOP Cost/ enrollee	Total[47]	Median	IQR	75th percentile	95th percentile
Rybelsus	$524	$471	$509	$47	$156	$165	$848
Byetta	$362	$75	$297	$35	$146	$146	$455
Ozempic	$399	$313	$360	$40	$115	$115	$673
Trulicity	$552	$409	$499	$25	$110	$114	$763
Victoza	$432	$257	$367	$10	$120	$120	$750

[46] 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.
[47] The total is the overall cost per enrollee across commercial insurers and Medicare.

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

Proprietary name	Medicare OOP cost/ claim	Commercial OOP cost/ claim	Total[48]	Median	IQR	75th percentile	95th percentile
Rybelsus	$127	$100	$116	$40	$96	$100	$538
Byetta	$93	$19	$76	$4	$89	$89	$441
Ozempic	$106	$75	$89	$30	$75	$75	$454
Trulicity	$88	$60	$76	$10	$50	$50	$396
Victoza	$93	$56	$78	$4	$60	$60	$400

Clinical information based on manufacturer material

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:
  - Rybelsus 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 T2DM.
- Limitations of Use
  - Rybelsus is not indicated for use in patients with type 1 diabetes mellitus
- Off Label Uses:
  - Chronic weight management
  - Type 1 diabetes mellitus

Clinical efficacy

- The oral formulation of *semaglutide* (Rybelsus) was FDA approved for glycemic control based on clinical trials resulting in a significant reduction in HbA1c from baseline as monotherapy, in combination with metformin, insulin and additional oral agents of 0.8% to 1% compared to placebo.[8] It also resulted in weight loss of approximately 1 to 4 kg.
- A phase 3, double-blind, placebo-controlled randomized controlled trial (PIONEER 6) compared oral semaglutide 14 mg to placebo in patients 50 years of age or older with CV disease, chronic kidney disease, with CV risk factors (n=3183).[9] Oral semaglutide was

[48] The total is the overall cost per claim across commercial insurers and Medicare.

noninferior but not superior to placebo in the primary CV outcome (4.8% vs. 3.8%; HR 0.79; 95% CI 0.57 to 1.00; p=0.17) over a median duration of 15.9 months.[8]

- In a more recent double-blind, placebo-controlled study (SOUL), oral semaglutide 14 mg daily resulted in a significant reduction in major adverse CV events compared to placebo (12% vs. 13.8%; HR 0.86; 95% CI 0.77 to 0.96) in patients with T2DM and atherosclerotic cardiovascular disease, chronic kidney disease, or both.

Clinical safety

- FDA safety warnings and precautions:
    - Risk of Thyroid C-Cell Tumors
    - Pancreatitis
    - Diabetic Retinopathy Complications
    - Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin
    - Acute Kidney Injury
    - Hypersensitivity
    - Acute Gallbladder Disease

- Contraindications:
    - Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
    - Prior serious hypersensitivity reaction to semaglutide or to any of the excipients in Rybelsus.

- Common side effects:
    - Gastrointestinal effects (32 to 41%), including diarrhea (8 to 9%), nausea (11 to 20%), and vomiting (6 to 8%), abdominal pain (6 to 20%), and constipation (5 to 6%)

Therapeutic alternatives[49,50,51,52,53]

Table 18 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		
Dulaglutide (Trulicity)	SubQ	Weekly	YES	YES	
Liraglutide (Victoza)	SubQ	Daily	YES	YES	
Exenatide (Byetta)	SubQ	Twice Daily	YES		
Tirzepatide (Mounjaro)	SubQ	Weekly	YES		
Abbreviations: CKD: chronic kidney disease; CV: cardiovascular; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus					

Table 19 Efficacy: A1C, weight, and cardiovascular benefits

Drug	~A1C Decrease	Short term weight loss	Rates of nausea	Cardiovascular Benefits
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)

[49] U.S. Food & Drug Administration. *Ozempic (semaglutide) Prescribing Information*. Teva Pharms., Action year 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.
[50] 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.
[51] 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.
[52] 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.
[53] U.S. Food & Drug Administration. *Victoza (liraglutide) Prescribing Information*. Teva Pharms., Action year 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf.

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)
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.[54] 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

- 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

[54] American Diabetes Association Professional Practice Committee. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2024. Diabetes Care. 2024 Jan 1;47(Suppl 1):S158-S178. https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment.

reduction in body weight (-4.4 kg vs. -3.1 kg; p=0.003), with no known effects on CV outcomes.[55]

- 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).[56]

Table 20 Safety & therapeutic considerations

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.

[55] 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.
[56] American Diabetes Association Professional Practice Committee. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2024. Diabetes Care. 2024 Jan 1;47(Suppl 1):S158-S178. https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment.

Table 21 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 four individuals taking or having an association with Rybelsus. According to the survey results, 25 percent of respondents had Rybelsus covered under the insurance, regardless of the type of insurance used.

Zero patients were on Medicaid, two patients were on Medicare, and two patients had private health insurance. One patient reported that their prescription was not covered, although they were under private health insurance. No patients reported being on patient assistance programs.

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 Rybelsus 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 Rybelsus, 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 Rybelsus 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: 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 details 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 Rybelsus 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 22 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	10
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%
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%

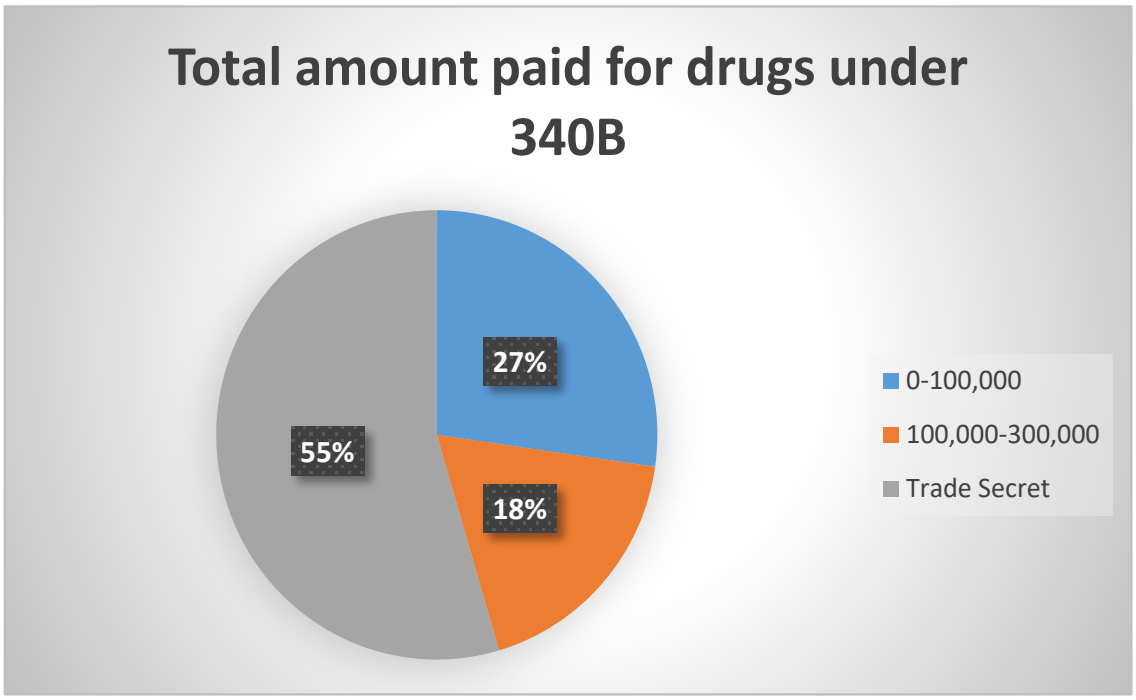

Figure 6 Amounts paid for drug under 340B discount program

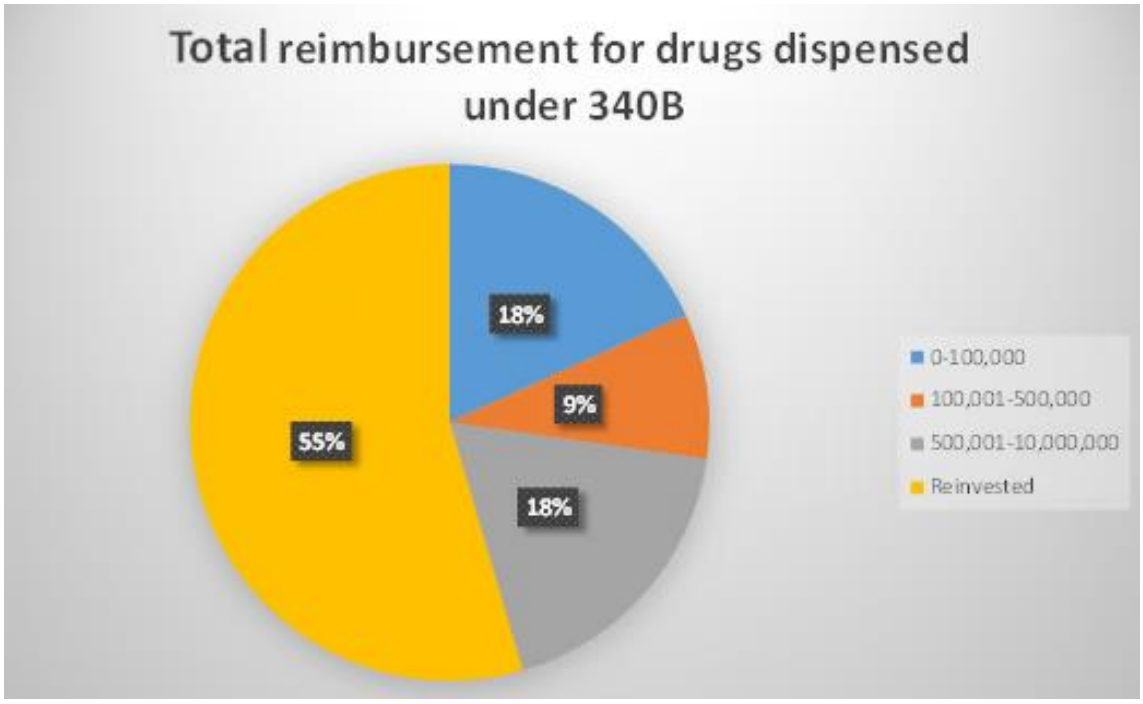

Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

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	Rybelsus	Letter	5/21/2025	Exhibit A
Dr. Harry Gewanter	Let My Doctors Decide Action Network	Rybelsus	Letter	5/15/2025	Exhibit B
Mary Anne Cooper	Regence BlueCross BlueShield	Rybelsus	Letter	5/12/2025	Exhibit C
Kelsey Lovell	Novo Nordisk	Rybelsus	Letter	9/15/2025	Exhibit D