



Oregon Prescription Drug Affordability Board

350 Winter Street NE, Salem, OR 97309-0405 | 971-374-3724 | pdab@dcbs.oregon.gov | dfr.oregon.gov/pdab

Agenda

This is a regular meeting. **Date: September 17, 2025** | **Time: 8 a.m.**

This is a draft agenda and subject to change

Board Members:

Chair Shelley Bailey
Vice Chair Dr. Amy Burns
Dr. Daniel Hartung
Dr. Christopher Laman
John Murray
Dan Kennedy
Lauri Hoagland

Meeting name

Prescription Drug Affordability Board

Meeting location

Virtual

Zoom link

[Register for meeting](#)

Staff: Cortnee Whitlock, senior policy analyst; Stephen Kooyman, project manager, Heather Doyle, data analyst; Pei-Chen Choo, research analyst; Melissa Stiles, administrative specialist; Pramela Reddi, counsel

Purpose	Subject	Presenter
<i>Informational and vote</i>	Call to order and roll call	Chair Shelley Bailey
<i>Informational</i>	Board declarations of conflict of interest and meetings with entities or individuals related to board activities	Chair Shelley Bailey
<i>Discussion and vote</i>	Board approval of 8/20/2025 minutes	Chair Shelley Bailey
<i>Informational</i>	PDAB program update	Cortnee Whitlock, senior policy analyst
<i>Informational</i>	General public comment: limited to 3 minutes	Chair Shelley Bailey
<i>Discussion</i>	Volunteered trade secret information	Cortnee Whitlock
<i>Review and discussion</i>	Policy recommendations for including in the 2025 annual legislative report	Cortnee Whitlock
<i>Review and discussion</i>	Methodology for drug reviews and scoring rubric and worksheet	Cortnee Whitlock
<i>Review and discussion</i>	Drug review: Jardiance – Antidiabetics ¹	Cortnee Whitlock

¹ The board is conducting drug reviews per ORS 646A.694 and OAR 925-200-0020. There will be a public comment period for the prescription drug selected for cost review. Each speaker will have 3 minutes. Board members may have follow-up questions for the speakers. The board chair has the discretion to extend a speaker's time. The board will hear from patients, caregivers, and individuals with scientific or medical background, per ORS 646A.694(3).

Purpose	Subject	Presenter
<i>Review and discussion</i>	Drug review: Mounjaro – Antidiabetics ¹	Cortnee Whitlock
<i>Review and discussion</i>	Drug review: Ozempic – Antidiabetics ¹	Cortnee Whitlock
<i>Review and discussion</i>	Drug review: Rybelsus – Antidiabetics ¹	Cortnee Whitlock
<i>Review and discussion</i>	Drug review: Trulicity – Antidiabetics ¹	Cortnee Whitlock
<i>Break</i>	The board will take a break around 10:30	Chair Shelley Bailey
<i>Informational</i>	Announcements	Chair Shelley Bailey
<i>Vote</i>	Adjournment	Chair Shelley Bailey

Accessibility

Anyone needing assistance due to a disability or language barrier can contact Melissa Stiles at least 48 hours ahead of the meeting at pdab@dcbs.oregon.gov or 971-374-3724. American sign language will be available during the September 17 board meeting.

How to provide testimony to the board

The Prescription Drug Affordability Board invites people to provide testimony. **Oral:** To speak to the board during the public comment portion of the agenda, please submit the [PDAB public comment form](#) no later than 24 hours before the PDAB meeting. **Written:** to provide written comments to the board, please submit the [PDAB public comment form](#) with attachments no later than 48 hours before the PDAB meeting. The board reviews all written comments. All written comments are posted on the website.

Open and closed sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed to everyone but board members, designated staff, and members of the news media. No action will be taken in executive session. Members of the media are directed not to report on or otherwise disclose anything said during executive session.

¹ The board is conducting drug reviews per ORS 646A.694 and OAR 925-200-0020. There will be a public comment period for the prescription drug selected for cost review. Each speaker will have 3 minutes. Board members may have follow-up questions for the speakers. The board chair has the discretion to extend a speaker's time. The board will hear from patients, caregivers, and individuals with scientific or medical background, per ORS 646A.694(3).



Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting
Wednesday, August 20, 2025
Draft Minutes

Web link to the meeting video: <https://youtu.be/wAl1u10eAM4>

Web link to the meeting materials: <https://dfr.oregon.gov/pdab/Documents/20250820-PDAB-document-package.pdf>

Call to order: Chair Shelley Bailey called the meeting to order at 9:00 a.m. and roll was called.

Board members present: Chair Shelley Bailey, Dan Hartung, Dan Kennedy, Chris Laman, John Murray

Absent: Vice Chair Amy Burns, Lauri Hoagland

Declaration of conflict of interest, meetings with entities or individuals related to board activities, or testifying before the Legislature: John Murray provided a statement. View at video minute [00:00:38](#).

Approval of board minutes: Chair Bailey asked for a motion and second to approve the board minutes as shown on [Pages 3-8](#) of the agenda materials. Dan Kennedy made a motion to approve the minutes and John Murray provided a second. View the vote at video minute [00:01:44](#).

MOTION to approve the July 16, 2025, minutes

Board Vote:

Yes: Dan Hartung, Dan Kennedy, Chris Laman, John Murray, Chair Shelley Bailey

No: None

Absent: Vice Chair Amy Burns, Lauri Hoagland

Motion passed 5-0

Executive session for legal advice pursuant to ORS 192.660(2)(f): The board adjourned to executive session. No decisions were made in closed session. View at video minute [00:02:48](#) The board returned to open session and called roll to confirm a board quorum. View at video minutes [00:03:45](#).

PDAB program update: Cortnee Whitlock, PDAB senior policy analyst, provided a program update. View the video at minute [00:04:12](#).

General public comment: Chair Bailey called on the people who signed up in advance to speak to the board: Lorren Sandt, Caring Ambassadors, Ranier Simons, CANN, Tiffany Westrich-Robertson, EACH/PIC Coalition, Dharia McGrew, PhRMA, Derek Flowers, Value of Care Coalition, Silas Martin, Johnson and Johnson, Jessica McBride, OCAP.

The board received 12 written comments, which are posted on the [PDAB website](#). View the speakers at video minute [00:06:00](#) and [00:30:14](#).

Board review of methodology for drug reviews and scoring rubric and worksheet: Cortnee Whitlock, senior policy analyst, led the board in a discussion about the drug review process. View the slide presentation on [Pages 6-17](#). View the discussion at video minute [00:23:43](#).

Round 2 drug reviews: The board began discussions about drug reviews for Trelegy, Eliquis, Xarelto, Cosentyx, and Creon.



Drug review for Trelegy - Antiasthmatic and bronchodilator: View the Trelegy report on [Pages 18-46](#) posted on the PDAB website. View the discussion at video minute [01:27:34](#). View the public comment for Trelegy at [01:27:47](#).

Drug review for Eliquis – Anticoagulants: View the Eliquis report on [Page 48-79](#). View the discussion at video minute [02:06:26](#). View the public comment for Eliquis at [02:06:39](#).

Drug review for Xarelto – Anticoagulants: View the Xarelto report on [Pages 80-110](#). View the discussion at video minute [02:24:19](#). View the public comment for Xarelto at [02:24:19](#).

Drug review for Cosentyx - Dermatological: View the Cosentyx report on [Page 111-144](#). View the discussion at video minute [02:43:33](#). View the public comment for Cosentyx at video minute [02:55:14](#).

Drug review for Creon –Digestive Aids: View the Creon report on [Pages 145 - 175](#). View the discussion at video minute [02:58:51](#). View the public comment for Creon at video minute [02:59:08](#).

Drug review public comment periods: Chair Bailey announced public comment periods for people who signed up in advance to speak specifically about the drugs under review. The chair also read the list of letters received regarding the drugs under review. See table below for list of public comment speakers.

Announcements: Chair Bailey announced the next meeting will be Sept. 17, 2025, at 8 a.m. View at video minute [03:10:52](#).

Adjournment: Chair Bailey adjourned the meeting at 11:30 a.m. with all board members in agreement. View at minute [03:11:01](#).



Table of public comment letters and speakers for Group 2 drugs

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Harmeet Dhillon	GSK	Trelegy	Letter	5/21/2025	Exhibit A
Linda Nelson	Oregon Coalition for Affordability Prescriptions	Trelegy	Letter	5/21/2025	Exhibit B
Molly Burich	GSK	Trelegy	Letter	8/15/2025	Exhibit C
Tom Corbridge	GSK	Trelegy	Speaker	8/20/2025	Exhibit D
Anne Murray	Bristol Myers Squibb	Eliquis	Letter Speaker Letter Letter	5/21/2025 5/21/2025 7/13/2025 8/18/2025	Exhibit E Exhibit F Exhibit G Exhibit H
Sarah Hoffman	Partnership to Advance Cardiovascular Health	Eliquis	Letter	5/21/2025	Exhibit I
Sue Koob	Preventive Cardiovascular Nurses Association	Eliquis	Letter	7/14/2025	Exhibit J
John Mullin and board members	Oregon Coalition for Affordable Prescriptions	Eliquis	Letter	8/15/2025	Exhibit K
Sarah Hoffman	Partnership to Advance Cardiovascular Health	Xarelto	Letter	5/21/25	Exhibit L
Silas Martin	Johnson & Johnson	Xarelto	Speaker	5/21/25	Exhibit M
Michael Valenta	Johnson & Johnson	Xarelto	Letters	3/30/25 6/16/25 8/14/25	Exhibit N Exhibit O Exhibit P
Sue Koob	Preventive Cardiovascular Nurses Association	Xarelto	Letter	7/14/25	Exhibit Q
Lisa Pulver	Johnson & Johnson	Xarelto	Speaker	8/20/25	Exhibit R
Courtney Piron	Novartis	Cosentyx	Letters	5/1/2025 8/12/2025	Exhibit S Exhibit T
Gabrielle Draper	Derma Care Access Network	Cosentyx	Letter	8/17/2025	Exhibit U
Kim Sanders	OHSU	Cosentyx	Letter	8/17/2025	Exhibit V
Tiffany Westrich-Robertson	Patient living with arthritis and on Cosentyx for four years	Cosentyx	Speaker	8/20/2025	Exhibit W
Albert Faro et al	Cystic Fibrosis Foundation	Creon	Letter	5/21/2025	Exhibit X
Lindsay Silva	Mother/primary care giver to someone living with Cystic Fibrosis	Creon	Speaker	5/21/2025	Exhibit Y



Oregon Prescription Drug
Affordability Board



Trade secret/confidentiality concerns

PDAB efforts and authority in other states

Sept. 17, 2025

Overview

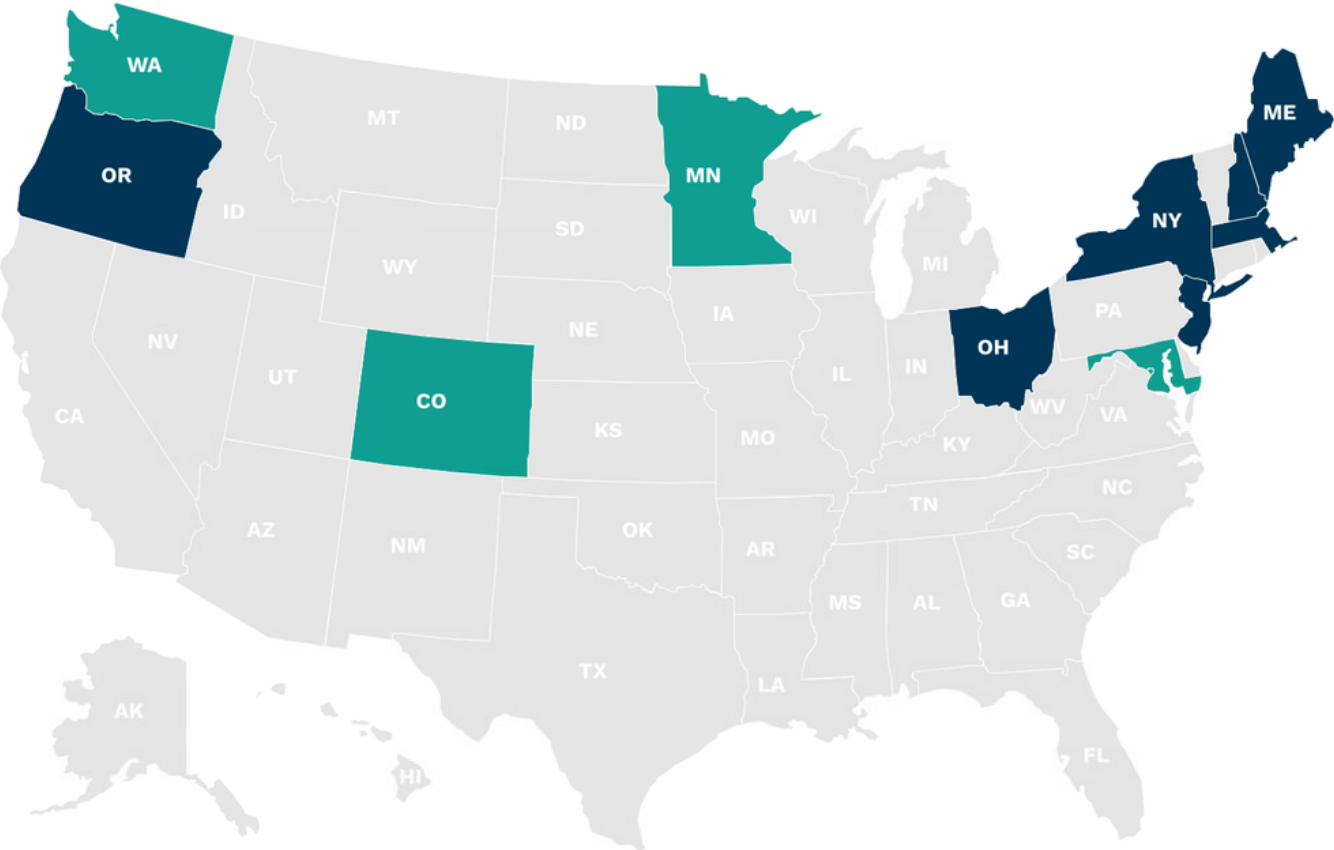
- According to Oregon Revised Statute (ORS) 646A.693 (12) (b), Oregon PDAB may meet in executive session to discuss trade secret information.
- **However**, according to ORS [192.660 \(4\)](#), representatives of the news media shall be allowed to attend executive sessions (with few exceptions that do not apply to PDAB).
- Questions regarding what other state PDABs are allowed to do regarding receiving, handling and discussing trade secret information led to this comparison presentation, which focuses on states that currently have UPL-setting authority (Colorado, Maryland, Minnesota and Washington state) and trade secret policies.
- What steps should be considered for Oregon to draft similar policies.



PDAB Map

Prescription Drug Affordability Boards with Upper Payment Limit Authority

■ State has a PDAB ■ State has a PDAB with UPL authority ■ No PDAB



Source: MultiState. Data as of 4/28/2025.

<https://s3.amazonaws.com/multistate.us/producton/articles/aSk4y4SMOJJYIV2rW/body/upload-f86ec7.png> Accessed 09.05.2025.



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Comparison

Issue	Oregon	Colorado	Maryland	Minnesota	Washington
State law allows an executive session for board to discuss confidential or trade secret information	Yes	Yes	Yes	Yes	Yes
Media inclusion is mentioned in state law or board bylaws	Yes	No	No	No	No
Has a documented process or guidance for handling confidential, trade secret, and/or proprietary information	No	Yes	Yes	Yes (draft)	Yes
PDAB has authority to set upper payment limits (UPLs)	No*	Yes	Yes	Yes	Yes

* OR PDAB approved UPL report to Legislature in December 2024. The report outlined a structured methodology and current insights for considering upper payment limits (UPLs) to address prescription drug affordability in Oregon.



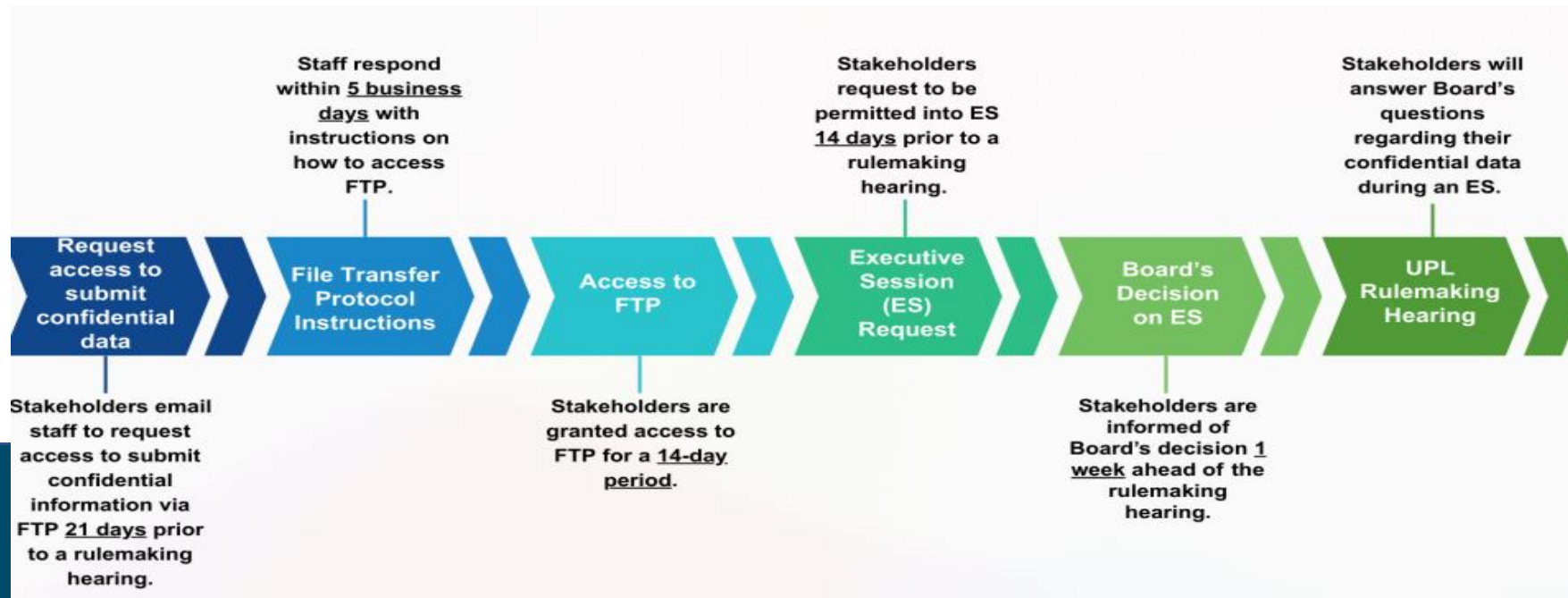
Colorado PDAB

- **Closed/executive sessions**

“The Board may, at any time, retire into executive session to consult with the assigned Assistant Attorney(s) General at the Colorado Department of Law or as permitted by section 24-6-402, C.R.S. The Board must retire into executive session to discuss proprietary, trade secret, or confidential information pursuant to section 10-16-1404(3), C.R.S.” Adopted policies.

- **Receipt of confidential, trade secret or proprietary information**

Confidential Information Submission Process



Maryland PDAB

- **Closed/executive sessions**

According to [bylaws](#), “All Board meetings shall be conducted in accordance with the Open Meetings Act, Title 10, Subtitle 5 of the State Government Article” ... with one exception:

- In accordance with [§ 21-2C-03\(e\)\(1\)\(iv\)](#) of the Health General Article, the Board may meet in closed session to discuss trade secrets or confidential and proprietary data and information.

- **Receipt of confidential, trade secret or proprietary information**

[Code of Maryland Regulations \(COMAR\) 14.01.01.04](#)

Identification

Submitter:

- Clearly designate specific information considered confidential, trade secret or proprietary
- Submit form certifying the info not to be publicly available

Board:

- Can determine if info received is confidential, trade secret or proprietary
- May seek additional information



Minnesota PDAB

- **Closed/executive sessions**

According to [bylaws](#), “Upon review of proprietary information, the Board may meet in closed session as provided in Minnesota Statutes, sections [62J.87, subdivision 7](#); [62J.90, subdivision 2](#); and section [62J.91, subdivision 3](#). The Board may develop and adopt additional policies regarding proprietary information as provided in section [62J.91, subdivision 3](#).”

- **Collection of confidential, trade secret or proprietary information:**

[Sec. 62J.91 MN Statutes](#)

- “(a) Any submission made to the board related to a drug cost review must be made available to the public with the exception of information determined by the board to be proprietary and information provided by the commissioner of health classified as not public data under section 13.02, subdivision 8a, or as trade secret information under section 13.37, subdivision 1, paragraph (b), or as trade secret information under the Defend Trade Secrets Act of 2016, United States Code, title 18, section 1836, as amended.



Washington PDAB

- **Closed/executive sessions**

According to the board [policies and procedures](#), “The Board may, at any time, retire into executive session to consult with the assigned Assistant Attorney(s) General at the Washington Office of the Attorney General as permitted by § 42.30 RCW. The Board may retire into executive session to discuss confidential information pursuant to section § 70.405 RCW”

- **Collection of confidential, trade secret or proprietary information**

“The board may examine publicly available information as well as collect confidential and proprietary information from the prescription drug manufacturer and other relevant sources.”
RCW [70.405.040](#) (2)





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Prescription Drug Affordability Board

2025 Policy recommendations

Sept. 17, 2025

2022 PDAB policy recommendations

PDAB recommendation	Legislative action
Implement upper payment limit (UPL)	Senate Bill 192 (2023): PDAB will develop a plan to implement UPL. Notes: PDAB submitted UPL report to the Oregon Legislature 12/2024. PDAB alternates became full members 9/2023.
Require pharmacy benefit managers (PBMs) and GOPs to report aggregated rebates and other payments from manufacturers annually to DPT	Senate Bill 192 (2023): directs the state to begin collecting information from PBMs
Require manufacturers to report to DPT annually on all patient assistance programs they maintain or fund.	Senate Bill 404 (2023) did not move out of committee
Require all state regulated health insurance carriers in Oregon to report to the DPT program.	Senate Bill 404 (2023) did not move out of committee
Require patient advocacy organizations to publicly disclose funding sources.	No action



2023 PDAB policy recommendations

PDAB recommendation	Legislative action
Lower insulin co-pay limit to \$35 and/or decouple from inflation index	Senate Bill 1508 (2024): Legislature passed a bill that caps the cost of insulin at \$35 a month and limits the cost to \$105 for a 90-day supply.
Expand PBM report requirements for more transparency	<p>Senate Bill 192 (2023): directs the state to begin collecting information from PBMs.</p> <p>Notes: DCBS received its first batch of information in June 2024 from 59 companies operating in Oregon. The information included total rebates, fees, price protection payments, other payments from manufacturers related to managing benefits for insurance companies in Oregon, rebate amounts passed on to insurers, patients, and rebate amounts retained by PBMs.</p>
Change Oregon's statute language regarding substitution requirements for biological products and biosimilars, updating ORS 689.522	No action



2024 PDAB policy recommendations

PDAB recommendation	Legislative action
Senate Bill 844 cleanup: <ul style="list-style-type: none">• Language change from 9 drugs a year for affordability reviews to up to 9 drugs a year.• Remove requirement that DCBS provide PDAB with a list of prescription drugs each quarter.• Replace the generic drug report annual requirement with a new provision that relevant content would be incorporated into the affordability review report.	Senate Bill 289 (2025): Signed by the governor May 27, 2025, will implement three housekeeping changes for PDAB on behalf of DCBS, effective Jan. 1, 2026.
Expand patient assistance programs reporting to the Drug Price Transparency Program (DPT).	No action
Require pharmacy benefit managers and insurers to report on copay accumulators and maximizers to the DPT Program Implement mandatory reporting on copay.	No action
Require payers to provide a pharmacy dispensing fee equal to or greater than the dispensing fee used in Oregon's medical assistance programs. <ul style="list-style-type: none">• Require reimbursement of the dispensing fee.	No action
Require Oregon Health Plan FFS and coordinated care organizations to purchase through a statewide purchasing group.	No action
Extend Oregon Health Plan's preferred drug list for all classes of prescription drugs.	No action



2025 policy concepts for discussion

From John Murray, RPh

1. Eliminate spread pricing in Medicaid and Managed care programs. All patients would benefit from this.
2. Base reimbursement drug cost figures on objective, verifiable data sources, not PBM owned and managed lists which can be manipulated for increased PBM profitability.
3. Work toward the ability to use NADAC cost basis in Oregon (this may require a constitutional change).
4. Delink PBM fees from the price of a drug or other fees/rebates and instead institute service fees for PBMs. This will remove an incentive for PBMs to prefer high-priced drugs, saving money for taxpayers and on insurance premiums.
5. Allow any willing pharmacy provider to participate, which would require plans to contract with any pharmacy that wants to join their network.



2025 policy concepts for discussion

From John Murray, RPh

6. Increase commercial PBM transparency.

7. Institute one PBM for all Medicaid and managed care patients in Oregon, to be selected through a bid process which emphasizes efficiency, reduced tax-payer costs, access for all Oregonians and maximum transparency.

8. Outlaw the PBM requirement that pharmacies must contractually dispense medications below their cost to dispense.

9. Base pharmacy reimbursement on an objective, verifiable cost figure plus percentage plus the OHA Medicaid dispensing fee schedule.

10. Institute and use upper payment limits ONLY if all other changes of drug delivery system and its economics fail. For two reasons, one, UPLs at the federal level are causing serious concerns about negative impacts to the already fragile system and, yet again, PBMs cannot be the only ones who come out whole should they be implemented.



2025 policy concepts for discussion

From Dr. Dan Hartung, PharmD, MPH

1. Medicaid single state-wide PBM and/or uniform preferred drug list (PDL)

A single PBM or uniform PDL would reduce administrative burden for patients and providers through the advancement of uniform and consistent coverage policies across all 16 CCOs. A uniform PDL/single PBM model would also improve opportunities for larger supplemental rebates. Finally, single PBM model could adopt the reimbursement arrangements (e.g. FFS reimbursement approach) that are sustainable for pharmacy providers in the state.

2. Audit of 340B entities

Following up on the report from Minnesota, Oregon could benefit from greater transparency in its 340B program. The report could answer questions like these. What is the total economic impact of the 340B program to eligible entities in the state? What institutions are garnering the largest economic impact and what types of patients do they serve? What payer types are providing these revenue (e.g. Medicare, commercial, Medicaid)? To what extent does the state forego rebate dollars because of 340B discounts provided to Medicaid?



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2025 policy concepts for discussion

From Board Chair Shelley Bailey, MBA

1. Cost Plus reimbursement for public employees: states with such programs include Montana, Colorado, New Mexico, Iowa, Arkansas, West Virginia, Kentucky, Tennessee, Alabama, Georgia, with legislation in Illinois, Ohio, and Pennsylvania.
2. Public sector benefit program for reverse auctions.
3. [Vermont law S.30 \(2025\)](#) – Pages 9-13 reference conflicts for health insurance brokers for contracts that involve rebates. Read S.30 (2025) text here:
<https://legislature.vermont.gov/Documents/2026/Docs/ACTS/ACT011/ACT011%20As%20Enacted.pdf>.
4. Medicaid managed care Rx based pass through states with single managed Medicaid for pass through: Ohio, Kentucky, Louisiana, Mississippi. 15 states with MCO cost plus mandate: Nevada (2026), New Mexico (2024), Nebraska (2024), Kansas (2013), Oklahoma (2024), Minnesota (2027), Iowa (2016), Louisiana (2017), Mississippi (2017), Michigan (2021), Ohio (2022), Kentucky (2021), Georgia (2023), North Carolina (2022), Virginia (2026).



2025 policy concepts for discussion

From Board Chair Shelley Bailey, MBA

5. All drugs fee for service: Alaska, Idaho, Montana, Wyoming, Colorado, South Dakota, Wisconsin, Missouri, Arkansas, Tennessee, Alabama, Vermont, Maine.

6. Full drug carve out States that went “back” to FFS: California (2022), North Dakota (2019), West Virginia (2017), New York (2023).

7. Point of sale rebates – Like West Virginia referenced in the 2024/2025 report to the Oregon Legislature.

8. Previous suggestions from UPL report to legislature 2024/2025 [pages 26-28](#). Read the suggestions here: <https://dfr.oregon.gov/pdab/Documents/reports/PDAB-upper-payment-limit-report-2024.pdf#page-26>



2025 policy concepts for discussion

From Dan Kennedy, RPh

1. Make a single pharmacy benefit manager (PBM) responsible for all state adjudication of claims and payments to pharmacies, with a mandated dispensing fee that would reimburse pharmacies appropriately. Include CCOs in this.



Domain	Statutory* and Rule** References	Packet section	Key questions
Impact & equity considerations	*(2)(a) **(1)(a)-(b)	Health inequities; Residents prescribed; Relative financial impacts to health, medical or social services costs	<ul style="list-style-type: none"> Are specific populations disproportionately affected (e.g. racial disparities, Medicaid reliance)? How many Oregonians are using this drug, and through which payer line?
Access		<u>Impact on patient access to the drug;</u>	<ul style="list-style-type: none"> <u>Is the drug non-preferred or subject to access barriers (e.g., prior authorization, step therapy)?</u>
Price evaluation	*(2)(e) **(1)(c)	Price for the drug	<ul style="list-style-type: none"> Has the WAC increased above inflation? Are pharmacy acquisition costs or net costs diverging from WAC?
Price concessions¹	*(2)(d) & (L) **(1)(d), (e) & (g)	Estimated average monetary price concessions; Estimated total amount of the price concessions; Estimated average price concession for therapeutic alternatives	<ul style="list-style-type: none"> What percentage of claims receive discounts? How do concessions affect net payer costs? Are concessions for alternatives better or worse?
System & payer costs	**(1)(h)	Estimated costs to health insurance plans; Relative financial impacts to health, medical or social services costs	<ul style="list-style-type: none"> What is the annual cost burden on Medicaid, Medicare, and commercial insurers? How concentrated is use in one line of business?
Enrollee burdens	*(2)(g) & (j) **(1)(i) & (k)	Impact on patient access to the drug; Estimated average enrollee copayment or other cost-sharing; Access and equity considerations	<ul style="list-style-type: none"> Are enrollees facing high OOP costs with the drug? Is the drug non-preferred or subject to access barriers (e.g., prior authorization, step therapy)?
Therapeutic alternatives	*(2)(c) & (i) **(1)(f), (g), (j)	Estimated price for therapeutic alternatives; clinical information based on mfr material.	<ul style="list-style-type: none"> Are there more affordable alternative that are equally or more effective? Do those alternatives have fewer access restrictions?
Specified stakeholder input	*(3) **(2)(k)	Input from stakeholders	<ul style="list-style-type: none"> What do patients and providers report about the affordability or access of the drug? Are there unique cost burdens or value perceptions?
Patent expirations			<ul style="list-style-type: none"> Are there expected date for loss of exclusivity? Have generics or biosimilars launched? Are they meaningfully priced lower? Is manufacturer seeking patent extensions?

Domain	Statutory* and Rule** References	Packet section	Key questions
			<ul style="list-style-type: none"> Any active lawsuits or FDA delays that stall generic entry? Is the market monopolized due to lack of competition?
Maximum Fair Price (MFP)			<ul style="list-style-type: none"> Is an MFP currently established for the drug? How does the current market price compare to the MFP?

* All references are to ORS 646A.694.

**All references are to OAR 925-200-0020.

1. Scoring Framework Overview

Drug is assigned a **0–3 scale** for each domain, where:

Score Interpretation

- 0 Minimal impact
- 1 Moderate impact
- 2 High impact
- 3 Severe impact

Apply 0-3 scale to each statutory domain (e.g., cost to payers, OOP burden, price trends) based on predefined criteria drawn from materials.

Total score of ~~24~~30

Suggested interpretations: ~~0-6~~0-9 minimal impact; ~~7-13~~10-19: moderate impact; ~~14-21~~20-30 high impact

2. Sample Metrics:

¹ Discounts: upfront reduction from the list price of a drug at the time of sale. Rebates: a retroactive payment from the manufacturer to a purchaser or payer (PBM or payer) after the drug is purchased and dispensed. Price concession: Encompasses any form of price reduction or adjustment provided by manufacturer, which may include discounts, rebates, chargebacks, and other negotiated reductions.

If a drug has total APAC cost of \$38M, with 4.6% change in the average price of WAC for three or more years, had 85% of reporting healthcare plans listing as non-preferred, 42% of claims discounted, two TAs, with enrollee OOP cost between APAC reported commercial and Medicare being \$1,182, and patient surveys indicating a moderate financial concern, the scoring would look as followed:

Domain	Based on	Score
Access and equity considerations	85% of reporting healthcare plans listing as non-preferred	3
Price evaluation	WAC raised at an average annual rate of 4.6 percent	2
Price concessions	42% of claims included some form of price concessions	2
System & payer costs	Total cost: \$38M	2
Enrollee burden	OOP reported APAC costs per enrollee for commercial \$800 and \$382 for Medicare	3
Therapeutic alternative	Has 2 TA/TE/Biosim	2
Specified stakeholder input	Moderate financial concerns	2
TOTAL		16

With a score of 16 the example drug reviewed would indicate a high impact to the healthcare system or patient OOP costs.

Domain	Score 0 (Low Impact)	Score 1 (Moderate Impact)	Score 2 (High Impact)	Score 3 (Severe Impact)	Updates
Impact & equity considerations	No disparities; widely preferred	Minor disparities; May affect underserved populations	Clearly identified disparities; significant impact on marginalized groups	Strong evidence of disparities; interventions to reduce inequities are lacking or nonexistent.	Separated access and equity considerations row. Updated row 2 domain to Impact & equity considerations.
Access	Minimal access barriers	Modest impact on access 25%-49% plans listed drug as non-preferred; prior auth for <25% plans	50%-74% plans listed drug as non-preferred; prior auth/step therapy >25%	75%-100% plans listed drug as non-preferred; majority of plans require prior auth/step therapy or over 50% denied prior-auth	Added Domain Access and scoring descriptions
Utilization	25,000 or more patients on drug reported in APAC	10,000 to 24,999 patients on drug reported in APAC	3,000 to 9,999 patients on drug reported in APAC	Less than 2,999 patients on drug reported in APAC	Added Domain Utilization and scoring descriptions
Price evaluation	Stable WAC changes or rising below inflation for five years; minimal divergence from net cost	Average percent change in WAC between 0% to 3.99% for four years; out paces inflation four years	Average percent change in WAC between 4% to 4.99% for three years; out paced inflation for three year	Average percent change in WAC between >5%; Outpaced inflation for four or more years	
Price concessions (PC)	High percent of rebate or PC; net costs substantially reduced	50-75% of discounted; net costs modestly reduced	25-50% claims discounted; moderate payer relief	<25% of claims receive concessions; negligible payer relief	
System & payer costs	Low total gross spend (<\$10M); costs evenly spread across payers	Total gross spend \$10M-\$15M and total net spend <\$3M	Total gross spend \$15M-\$50M and total net spend \$3M-\$10M	Total gross spend >\$50M and total net spend >\$10M	
Enrollee burden	Total APAC OOP annual cost of < \$200	Total APAC OOP annual cost \$200-\$700	Total APAC OOP \$700-\$1,200	Total APAC OOP >\$1,200; drug excluded	Moved prior authorization information to Domain Access
Therapeutic alternatives	Alternatives available; has a large number of TA/TE/Biosim	Somewhat more costly/effective; similar access; subject Rx has six or more TA/TE/Biosim	More expensive alternatives; subject Rx has 2-6 TA/TE/Biosim	No effective/affordable alternatives; subject drug has one or no TA/TE/Biosim	
Specified stakeholder input	No concerns raised; positive feedback or minimal stakeholder input	Mixed views; moderate financial concerns noted	Significant concerns from providers/patients re: cost/affordability	Broad concern or consistent reports of high burden from multiple groups	

Domain	Score 0 (Low Impact)	Score 1 (Moderate Impact)	Score 2 (High Impact)	Score 3 (Severe Impact)	Updates
Patent expirations	Patent expired or generic/bioequivalent is available and accessible; Multiple competitors in the market or therapeutic class.	Patent expired but market entry of generic/biosimilars were delayed (e.g. due to regulatory hurdles, legal tactics, or market barriers; Limited cost relief observed.	Patent is expiring in 18 months but manufacturer is actively seeking exclusivity extensions (e.g. patent evergreening, pediatric extensions, or chemical/device tweaks)	Patent expired; manufacturer has taken legal or structural steps to prevent competition. Sustained high pricing.	Added Domain Patent Expirations and scoring descriptions
Maximum Fair Price (MFP)	Drug has an established CMS MFP and the current market price aligns within 5%. Evidence the manufacturer is adopting the fair price across all markets	Drug has an MFP but current pricing is modestly above the MFP 5-20%.	The drug has an MFP and currently pricing is 20-40% above fair price estimates	No MFP or current market price is more than 40% above available fair price benchmarks.	Added Domain MFP and scoring descriptions



Oregon Prescription Drug
Affordability Board

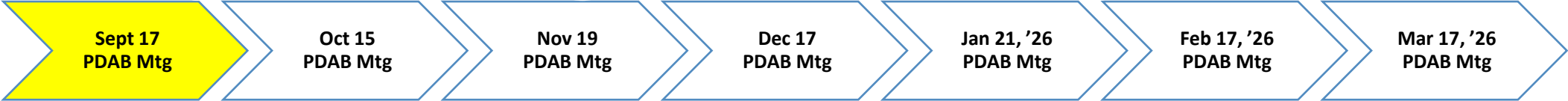


Prescription Drug Affordability Board

2025 Drug Review Roadmap

Sept. 17, 2025

2025-2026 Drug Review (DR) & Annual Report Calendar



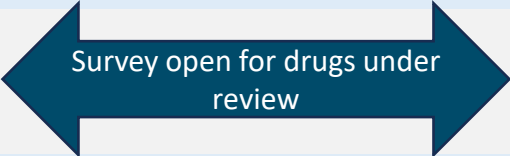
Rx Subset list
Insulin Subset list



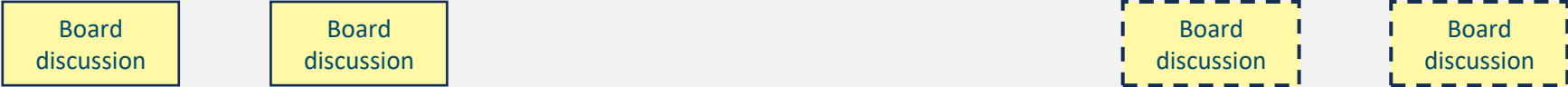
Drug Review Report



Stakeholder RFI
(Request for Information)



Recommendation



Annual Report
Price trends, drug subset list, policy recommendations, progress report



Review grouping number	Therapy class	Drug name	Non-proprietary name
1	Antipsychotics & Antimanic agents	Vraylar	Cariprazine HCl
1	Cardiovascular agents – misc.	Entresto	Sacubitril; Valsartan
1	Migraine product	Ajovy	Fremanezumab-vfrm
1	Migraine product	Emgality	Galcanezumab-gnlm
1	Migraine product	Nurtec	Rimegepant/rimegepant sulfate
1	Migraine product	Ubrelvy	Ubrogepant
2	Antiasthmatic and bronchodilator	Trelegy	Fluticasone furoate; Umeclidinum bromide; Vilanterol trifenate
2	Anticoagulants	Eliquis	Apixaban
2	Anticoagulants	Xarelto	Rivaroxaban
2	Dermatological	Cosentyx	Secukinumab
2	Digestive Aids	Creon	Pancrelipase (Amylase; Lipase; Protease)



Review grouping number	Therapy class	Drug name	Non-proprietary name
3	Antidiabetics	Jardiance	Empagliflozin
3	Antidiabetics	Mounjaro	Tirzepatide
3	Antidiabetics	Ozempic	Semaglutide
3	Antidiabetics	Rybelsus	Semaglutide
3	Antidiabetics	Trulicity	Dulaglutide
4	Insulin product	Basaglar KwikPen	Insulin Glargine
4	Insulin product	Insulin Glardine-yfgn	Insulin Glargine
4	Insulin product	Lantus	Insulin Glargine
4	Insulin product	Lantus SolorStar	Insulin Glargine
4	Insulin product	Semglee (yfgn)	Insulin Glargine
4	Insulin product	Toujeo Max SolorStar	Insulin Glargine
4	Insulin product	Toujeo SoloStar	Insulin Glargine





Jardiance® (*empagliflozin*)¹

Version 1.0



¹ Image source: <https://www.clinicaltrialsarena.com/wp-content/uploads/sites/22/2023/10/Jardiance-lmg-1.jpg>

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Review summary

Therapeutic alternatives^{2,3,4}

Jardiance® (*empagliflozin*) has the following therapeutic alternatives:

Proprietary name	Non-proprietary name	Manufacturer	Approved year	Number of patents	Patent date range	Exclusivity expiration	On the CMA drug price negotiation list (effective date)
Jardiance	<i>empagliflozin</i>	Boehringer Ingelheim Pharmaceuticals	2014	19	2028-2034	2026	Yes (2026)
Brenzavvy	<i>bexagliflozin</i>	Theracosbio LLC	2023	6	2028-2032	2028	No
Farxiga	<i>dapagliflozin</i>	Astrazeneca Ab	2014	35	2025-2041	2027	Yes (2026)
Invokana	<i>canagliflozin</i>	Janssen Pharmaceuticals	2013	8	2025-2029	2028	No
Steglatro ⁵	<i>ertugliflozin</i>	Merk Sharp and Dohme LLC	2017	1	2030		No

Price history^{6,7}

Jardiance rose at an **average annual rate of 4.7 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:

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](https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What%20is%20the%20difference%20between%20patents%20a).

⁴ 2025. <https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices>.

⁵ No exclusivity was listed for Steglatro: 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 Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

⁷ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

- Brenzavvy: **N/A**⁸
- Farxiga: **2.3** percent
- Invokana: **4.3** percent
- Steglatro: **4.6** percent

Additionally, the average annual rate of Jardiance exceeded inflation in **2019, 2020, and 2023**. Pharmacy acquisition costs for **Medicaid also increased by 17.2 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions⁹

Based on data received from healthcare carriers, Jardiance in 2023 had the **gross spend of \$973 per claim**, while the **spend net of discount was \$386 per claim**. Price concession per claim was reported to be **\$587**.

Cost to the payer¹⁰

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

Drug	Total expenditure	Utilization	Cost per enrollee	Cost per enrollee, median
Jardiance	\$141,128,924	164,419	\$4,221	\$624
Brenzavvy ¹¹				
Farxiga	\$29,820,729	37,843	\$4,037	\$589
Invokana	\$1,787,166	1,873	\$4,753	\$1,237
Stelgrato	\$8,092,496	25,425	\$3,185	\$330

⁸ Annual rate could not be calculated due to only one year of WAC being obtained for Brenzavvy.

⁹ 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.

¹⁰ 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>.

¹¹ Information is unavailable due to the NDC of Brenzavvy yielding no results in APAC database.

Cost to enrollees¹²

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

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Jardiance	\$409	\$47	\$88	\$30
Brenzavvy ¹³				
Farxiga	\$383	\$45	\$83	\$30
Invokana	\$524	\$30	\$119	\$10
Stelgrato	\$28	\$0	\$4	\$0

Rubric considerations (example)

Domain	Consideration
Impact & equity	Board discussion to determine equity impact
Access	36% of reporting health plans required prior authorization (PA); 1.1% required step therapy; no plans categorized Rx as non-preferred drug; and no plans excluded it entirely from the formulary.
Utilization	164,419 claims
Price evaluation	WAC increased at an average annual rate of 4.7%
Price concessions	60.3% discount on Rx
System & payer costs	Gross = \$141,128,924 Net = \$22,637,956
Enrollee burden	\$409
Therapeutic alternative	4 therapeutic alternatives
Stakeholder input	Board discussion to determine equity impact
Patent expirations	2026
Maximum Fair Price	On MFP to take effective in 2026

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.

¹² 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>.

¹³ Information is unavailable due to the NDC of Brenzavvy yielding no results in APAC database.

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 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)	Jardiance®
Non-proprietary name	<i>empagliflozin</i>
Manufacturer	Boehringer Ingelheim
Treatment: Jardiance is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated for:	<ul style="list-style-type: none"> • To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure. • To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression. • To reduce the risk of cardiovascular death in adults with type 2 diabetes

¹⁴ U.S. Food & Drug Administration. Jardiance (empagliflozin) Prescribing Information, Sept. 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf.

	<p>mellitus and established cardiovascular disease.</p> <ul style="list-style-type: none"> As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.
Dosage and strength	<ul style="list-style-type: none"> Recommended 10 mg, 25 mg once daily.
Form/Route	Tablet/oral

FDA approval

Jardiance was first approved by the FDA on **Aug. 1, 2014**.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.

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.

People who bear the highest burdens of diabetes, chronic kidney disease (CKD), and heart failure in the United States, including American Indian/Alaska Native, Black, Hispanic/Latino, and some Pacific Islander groups, are the same groups most likely to benefit from Jardiance (empagliflozin) for kidney and cardiovascular protection. Yet they remain less likely to receive SGLT2 inhibitors.^{16,17} The American Diabetes Association’s 2025 Standards explicitly recommend SGLT2 inhibitors to slow CKD progression and reduce cardiovascular disease (CVD) events in type-2 diabetes.¹⁸ Not adopting better prescribing for SGLT2 among minoritized groups can worsen outcome gaps.¹⁹ Cost sharing and formulary controls (e.g. prior authorization/step therapy) have improved since 2021, but still create access frictions in some Medicare plans, which can disproportionately affect lower income patients.²⁰ Rural residency is

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.

¹⁶ National Diabetes Statistics Report. U.S. Centers for Disease Control and Prevention, May 15, 2024. <https://www.cdc.gov/diabetes/php/data-research/index.html>.

¹⁷ Wang, E., Patorno, *et al.* Racial and ethnic disparities in the uptake of SGLT2is and GLP-1RAs among Medicare beneficiaries with type 2 diabetes and heart failure, atherosclerotic cardiovascular disease and chronic kidney disease, 2013–2019. *Diabetologia* **68**, 94–104 (2025). <https://doi.org/10.1007/s00125-024-06321-2>.

¹⁸ American Diabetes Association Professional Practice Committee; 11. Chronic Kidney Disease and Risk Management: *Standards of Care in Diabetes—2024*. *Diabetes Care* 1 January 2024; 47 (Supplement_1): S219–S230. <https://doi.org/10.2337/dc24-S011>.

¹⁹ Ibid.

²⁰ Wisniewski, Brady, *et al.* “Medicare formulary restrictions for glucagon-like peptide 1 receptor agonists and sodium glucose cotransporter 2 inhibitors used in type 2 diabetes mellitus: 2019-2023.” *Journal of Managed Care & Specialty Pharmacy*, Volume 30, Number 1, June 27, 2025. <https://doi.org/10.18553/jmcp.2024.30.1.34>.

also associated with higher diabetes prevalence and can intersect with pharmacy access barriers.²¹

Residents prescribed

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

Based on APAC claims, **164,419** Oregonians filled a prescription for Jardiance in 2023.²²

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.

Price history

This section examines the pricing dynamics of Jardiance, 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 Jardiance’s list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts costs.

WAC per 30-day supply was calculated with 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

	Jardiance	Brenzavvy	Farxiga	Invokana	Steglatro
30-day supply	30 units	30 units	30 units	30 units	30 units

Table 4 Drug vs therapeutic alternatives for 2018-2024 WAC per 30-day supply²³

Year	Jardiance	Brenzavvy	Farxiga	Invokana	Steglatro
2018	\$465		\$465	\$465	\$268
2019	\$493		\$492	\$494	\$281
2020	\$522		\$517	\$519	\$295
2021	\$549		\$533	\$543	\$310
2022	\$570		\$549	\$570	\$325

²¹ National Diabetes Statistics Report. U.S. Centers for Disease Control and Prevention, May 15, 2024. <https://www.cdc.gov/diabetes/php/data-research/index.html>.

²² 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>.

²³ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

Year	Jardiance	Brenzavvy	Farxiga	Invokana	Steglatro
2023	\$593		\$565	\$599	\$341
2024	\$611	\$132	\$531	\$599	\$352
Avg. Annual % Change	4.7%		2.3%	4.3%	4.6%
% change 2018 between 2024	31.4%		14.4%	28.8%	31.1%

The WAC of Jardiance, averaged across six NDCs reported, was approximately **\$20.37 per unit** at the end of 2024.²⁴ Between 2018-2024, the unit WAC increased at an average annual rate of **4.7 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2018-2019, 2019-2020, and 2022-2023** (see Figures 1 and 2).²⁵

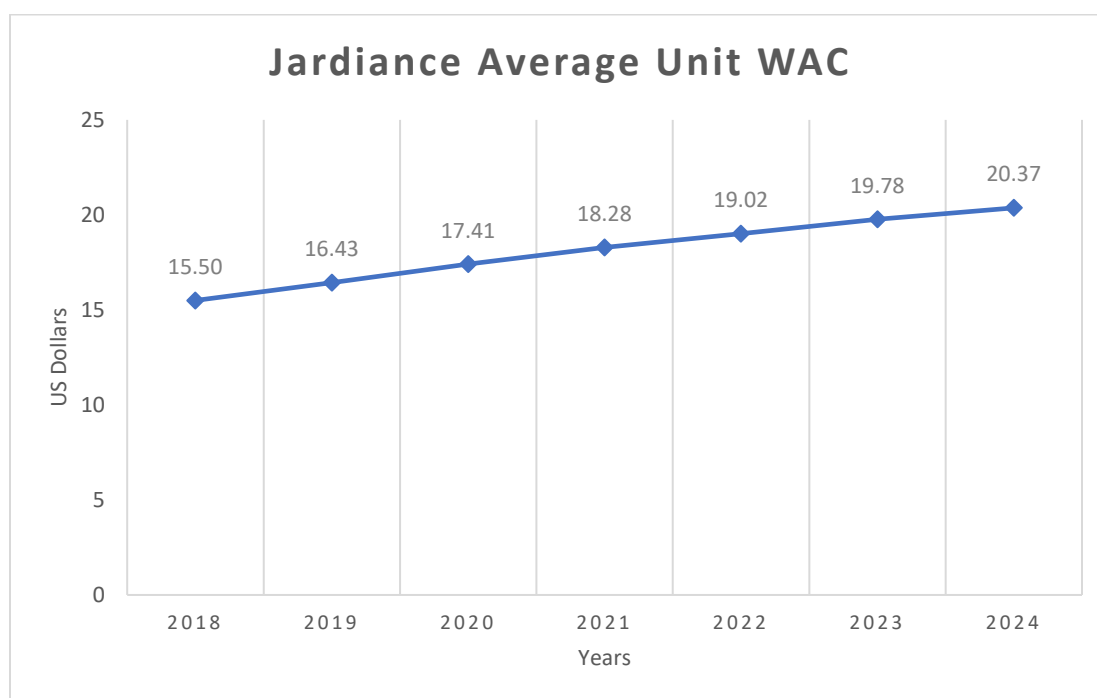


Figure 1 Jardiance average unit WAC from 2018-2024

²⁴ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

²⁵ 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 comparison²⁶

Year	Jardiance	Brenzavvy ²⁷	Farxiga	Invokana	Steglatro	CPI-U
2018-2019	6.0%		6.0%	6.4%	4.9%	1.7%
2019-2020	6.0%		5.1%	4.9%	4.9%	0.7%
2020-2021	5.0%		3.0%	4.8%	4.9%	5.3%
2021-2022	4.0%		3.0%	4.9%	4.8%	9.0%
2022-2023	4.0%		3.0%	5.0%	5.0%	3.1%
2023-2024	3.0%		-6.0%	0%	3.2%	3.0%

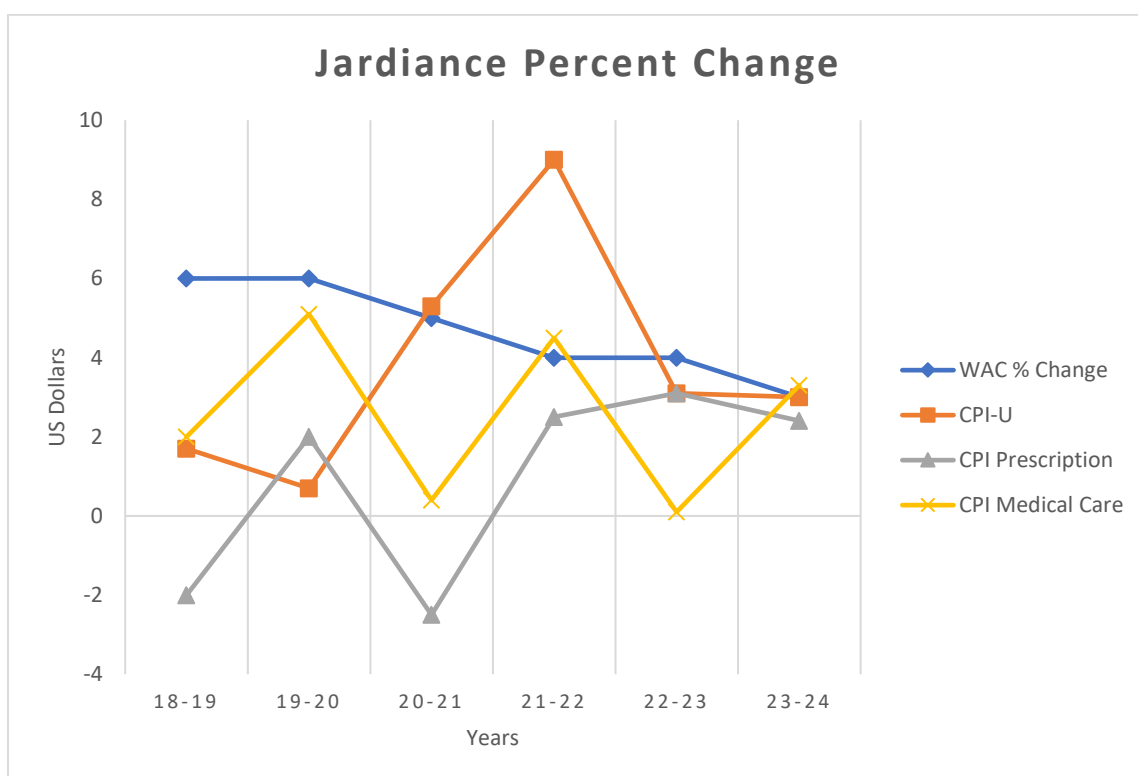


Figure 2 Year over year change in WAC compared to inflation rates²⁸

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **\$16.66 per unit in Quarter 1 of 2020 to \$19.52 per unit in Quarter 4 of 2024**, an approximate **17.2 percent increase** over the period (see Figure 3).²⁹ Relative to the **\$20.37 WAC** in end-of-year 2024, an **AAAC discount of 4.2 percent** is indicated.

²⁶ Percentages might differ from Table 4 as Table 5 percentages are based on unit WAC only.

²⁷ Annual rate could not be calculated due to only one year of WAC being obtained for Brenzavvy.

²⁸ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

²⁹ 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 Jardiance’s price trajectory relative to inflation and affordability for public and private payers.

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

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC average	Average unit WAC
2020	\$17	\$17	\$17	\$17	\$16.68	\$17.41
2021	\$18	\$18	\$18	\$18	\$17.51	\$18.28
2022	\$18	\$18	\$18	\$18	\$18.22	\$19.02
2023	\$19	\$19	\$19	\$19	\$18.98	\$19.78
2024	\$20	\$20	\$20	\$20	\$19.52	\$20.37

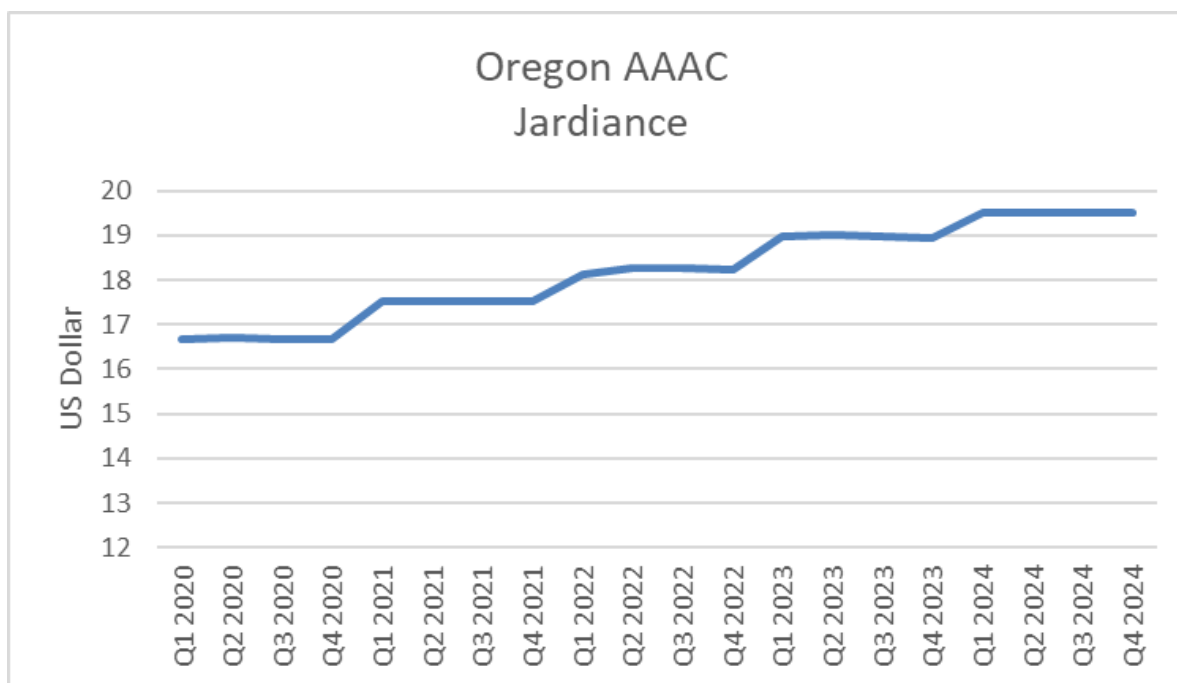


Figure 3 AAAC For Jardiance from Q1 2020 to Q4 2024

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 Jardiance 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 Jardiance per enrollee in the commercial market was approximately \$3,112**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately \$1,235**, reflecting an **estimated mean discount of 60.3 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Jardiance before concessions was \$26,732,156**, with total reported **price concessions amounting to approximately \$16,127,003**, as detailed in Table 5. Notably, **80.1 percent of claims benefited from some form of price concession**, leaving **19.9 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	8,589
Total number of claims	27,481
Total number of claims with price concessions applied	22,000

Percentage of claims with price concessions applied	80.1%
Percentage of cost remaining after concessions	39.7%
Percentage of discount	60.3%

Manufacturer price concessions for all market types	\$13,245,236
PBM price concessions for all market types	\$2,873,542
Other price reductions for all market types	\$8,225

Cost before price concessions across all market types	\$26,732,156
Total price concessions across all market types	\$16,127,003
Cost of after price concessions across all market types	\$10,605,152

Avg. payer spend per enrollee without price concessions	\$3,112
Avg. payer spend per enrollee with price concessions	\$1,235

Including all market segments, the **gross spend of Jardiance per claim for commercial carriers was \$973** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **\$386**, meaning that insurers reported a price concession of **\$587** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types

	Average	Individual Market	Large Market	Small Market
Spend per Claim, gross	\$973	\$1,031	\$940	\$1,064
Spend per Claim, net	\$386	\$404	\$379	\$401
Price Concessions per Claim	\$587	\$627	\$561	\$664

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

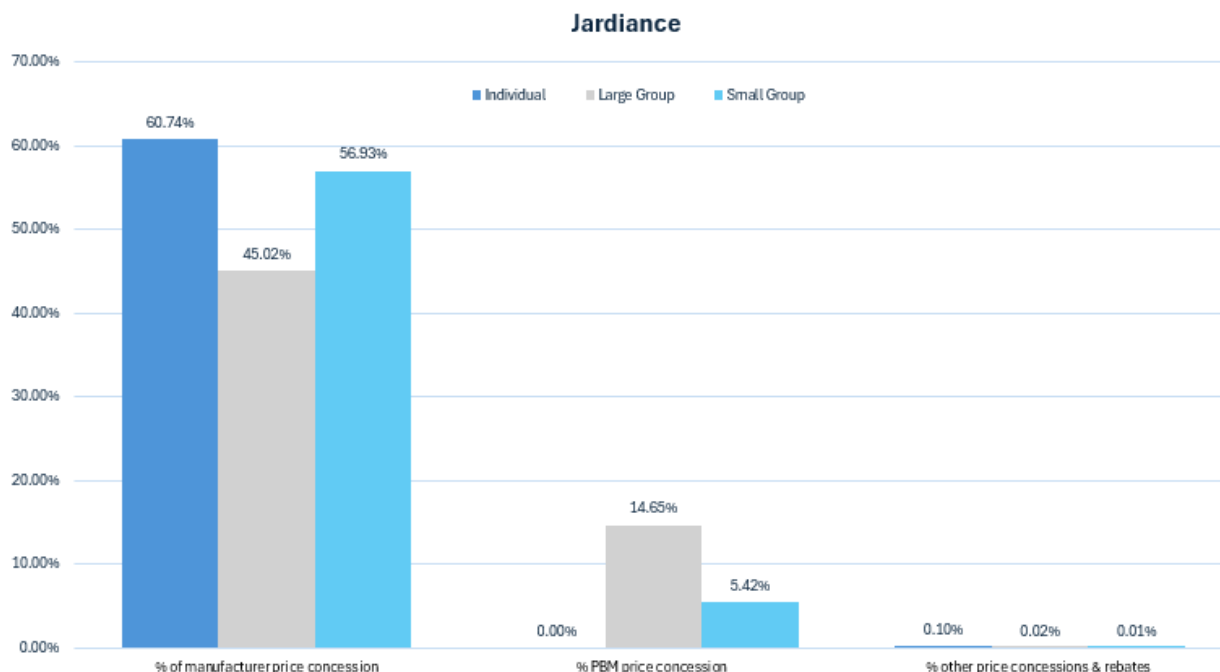


Figure 4 Percent of price concession in each market type^{30, 31}

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 Jardiance to each pharmacy benefit managers, 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.

³⁰ 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.federalregister.gov/documents/2024/01/24/2024-0124-cfr-423-100).

³¹ 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 price for therapeutic alternatives

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 Jardiance 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.

Jardiance' gross total payer paid, based on APAC data, **was \$141.1 million**, while total net payer paid received from the **carriers indicated a cost of \$22.6 million. Jardiance has the highest gross total pay in consideration** with its therapeutic alternatives. The second highest is Farxiga with \$29.8 million. Notably, Jardiance has the **most utilization among the drugs, at 164,419 claims**, as compared to the second highest utilization of Farxiga, at 37,843 claims. Invokana has a **higher payer paid per claim compared to Jardiance, which are \$954 and \$858 respectively.**

Jardiance also has the highest total enrollee paid at \$12.3 million and Farxiga follows behind with \$2.4 million. Invokana has the highest patient paid per claim of \$95, which is higher than both Jardiance at \$76 and Farxiga at \$64. The drug with the lowest patient paid per claim is Steglatro, which is \$2.

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

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

Drug	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid ³³	Payer paid/claim	Patient paid/claim ³⁴
<i>Subject Drug</i> Jardiance (Data call)³⁵	8,589	27,481	\$22,637,956	\$2,345,386	\$824	\$85
<i>Subject Drug</i> Jardiance (APAC)	33,438	164,419	\$141,128,924	\$12,437,255	\$858	\$76
Brenzavvy³⁶						
Farxiga	7,387	37,843	\$29,820,729	\$2,437,904	\$788	\$64
Invokana	376	1,873	\$1,787,166	\$178,575	\$954	\$95
Steglatro	2,541	25,425	\$8,092,496	\$38,847	\$318	\$2

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

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 cost includes all lines of business.

³⁴ Ibid.

³⁵ Information from the data call with the cost information after price concessions.

³⁶ Information is unavailable due to the NDC of Brenzavvy yielding no results in APAC database.

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 Jardiance 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 **164,419 total claims for Jardiance among 35,580 total enrollees**, corresponding to a **total payer expenditure of \$141,128,924**.

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 **96,639** claims from **21,475** enrollees and a total spend of **\$89.6 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **\$37.5 million** and **\$14.1 million**, respectively.

Table 10 Estimated 2023 APAC total annual gross payers expenditure for total enrollees and total claims³⁷

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	9,765	44,606	\$37,486,136	\$3,839	\$840
Medicaid	4,340	23,174	\$14,060,699	\$3,240	\$607
Medicare	21,475	96,639	\$89,582,089	\$4,171	\$927
Totals	35,580³⁸	164,419	\$141,128,924		

Table 11 provides utilization for the healthcare system for Jardiance and its therapeutic alternatives, distinguished by lines of business. **Jardiance has the most utilization** among the drugs, with **164,419 claims**. In all lines of business, Jardiance is the most utilized. **Farxiga is the second most utilized with 37,843 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.

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
Jardiance	44,606	23,174	96,639	164,419
Brenzavvy ⁴¹				
Farxiga	10,405	8,498	18,940	37,843
Invokana	428	374	1,071	1,873
Steglatro	8,717	16,220	488	25,425

Table 12 shows the overall payer expenditure of Jardiance and its therapeutic alternatives, distinguished by lines of business. Jardiance has a **total expenditure of \$141.1 million** with **Medicare being the biggest portion at \$89.9 million**. The therapeutic alternative with the **least expenditure is Invokana, at \$1.8 million**.

Table 12 Estimated APAC payer 2023 annual gross expenditure of the review drug and its therapeutic alternatives from all lines of business⁴²

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total ⁴³
Jardiance	\$37,486,136	\$14,060,699	\$89,582,089	\$141,128,924
Brenzavvy ⁴⁴				
Farxiga	\$8,191,489	\$4,863,562	\$16,765,678	\$29,820,729
Invokana	\$323,596	\$206,315	\$1,257,255	\$1,787,166
Steglatro	\$2,441,964	\$5,442,491	\$208,041	\$8,092,496

Table 13 compares the overall payer cost per enrollee of Jardiance and its therapeutic alternatives, distinguished by lines of business. **Invokana has the highest total cost per enrollee at \$4,753**. Farxiga has the **highest cost per enrollee in commercial at \$3,923**, though the cost per enrollee of the commercial line of business is comparable to both Jardiance and Invokana.

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 Information is unavailable due to the NDC of Brenzavvy yielding no results in APAC database.

⁴² 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.

⁴³ Total is the sum of all expenditure for the drug across all lines of business.

⁴⁴ Information is unavailable due to the NDC of Brenzavvy yielding no results in APAC database.

The median cost per enrollee for Jardiance is \$624, which is less than the median cost per enrollee of Invokana.

Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives⁴⁵

Proprietary name	Commercial cost/enrollee	Medicaid cost/enrollee	Medicare cost/enrollee	Total ⁴⁶ cost per enrollee	Cost per enrollee, median	IQR	Cost per enrollee, 75 th percentile	Cost per enrollee, 95 th percentile
Jardiance	\$3,839	\$3,240	\$4,171	\$4,221	\$624	\$1,101	\$1,601	\$1,901
Brenzavvy ⁴⁷								
Farxiga	\$3,923	\$3,313	\$3,828	\$4,037	\$589	\$1,023	\$1,526	\$1,811
Invokana	\$3,852	\$3,079	\$4,854	\$4,753	\$1,237	\$1,189	\$1,761	\$1,958
Steglatro	\$1,930	\$2,242	\$1,387	\$3,185	\$330	\$7	\$333	\$791

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the large group represented the majority of commercial spending (67% of total), followed by individual and small group markets. The collected **total net cost to the healthcare system was around \$25.0 million**, with payer paying **\$22.6 million**, and enrollees out-of-pocket estimating to be **\$2.3 million**. Table 14 includes the average plan cost per enrollee in the commercial market, ranging from **\$2,785 (small group)** to **\$2,573 (large group)** annually.

Table 14 Estimated 2023 data call annual total net costs to the healthcare system, payers and OOP/enrollee⁴⁸

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of-pocket cost
Individual	4,109	1,314	\$4,224,592	\$3,641,910	\$582,682
Large Group	19,081	5,972	\$16,736,979	\$15,367,153	\$1,369,826
Small Group	4,291	1,303	\$4,021,770	\$3,628,892	\$392,878
Total	27,481	8,589	\$24,983,342	\$22,637,956	\$2,345,386

⁴⁵ 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.

⁴⁶ Total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

⁴⁷ Information is unavailable due to the NDC of Brenzavvy yielding no results in APAC database.

⁴⁸ Cost information from the data call is the cost of the drug after price concessions.

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	\$1,028	\$886	\$142	\$3,215	\$2,772	\$443
Large Group	\$877	\$805	\$72	\$2,803	\$2,573	\$229
Small Group	\$937	\$846	\$92	\$3,087	\$2,785	\$302

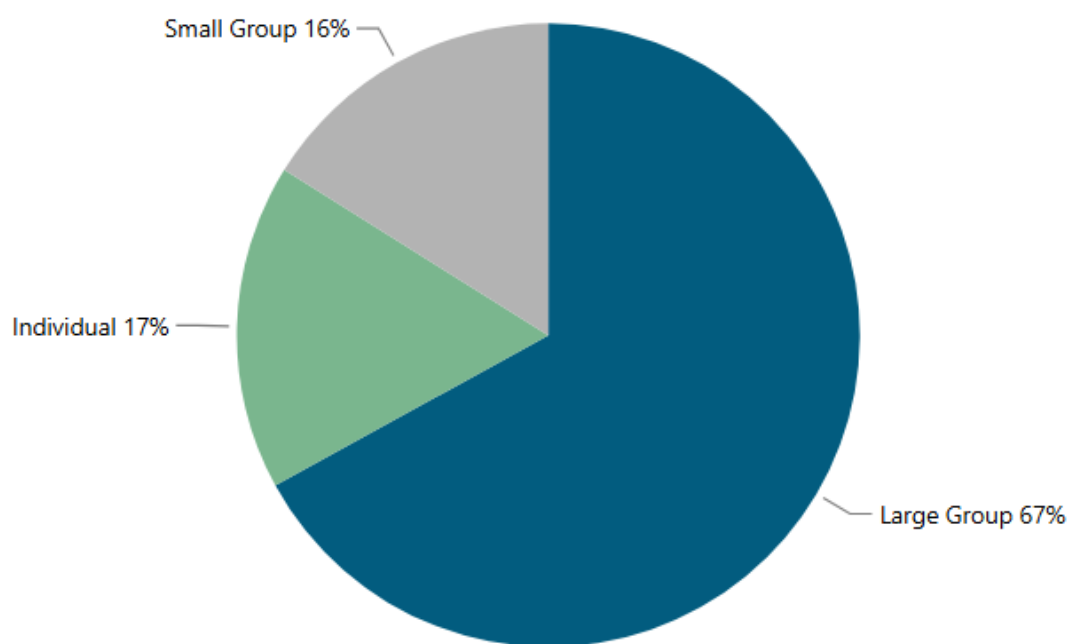


Figure 5 Data call total annual percent spend (payer paid) by market

Table 15 indicates CCOs reported Jardiance as having an annual greatest increase from 2022-2023 (rebates not included) with a **\$5.2 million year-over-year increased cost growth**.

Table 15 Medicaid CCOs greatest increase in share to total cost from 2022-2023 (rebates not included)⁴⁹

Medicaid CCOs			
2022	2023	YoY change in spending	Percent of total CCO cost 2023
\$7,828,996	\$12,979,111	\$5,150,115	0.4%

Impact on patient 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 Jardiance, 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 Jardiance. In 2023, approximately **36 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **1.1 percent of plans required step therapy** before approving its use.

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

Table 16 Plan design analysis from 2023 data call

Percentage of Plans	
Required Prior Authorization	36.0%
Required Step Therapy	1.1%
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

⁴⁹ CCO Pharmacy spend provided by Oregon State University drug use research and management program. 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>.

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 Jardiance 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 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 [drug] 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.

Table 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.

Table 17 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee⁵⁰

Proprietary name	Annual Medicare OOP Cost/Enrollee	Annual Commercial OOP Cost/Enrollee	Total ⁵¹	Median	IQR	75 th percentile	95 th percentile
Jardiance	\$420	\$350	\$409	\$47	\$148	\$148	\$606
Brenzavvy ⁵²							
Farxiga	\$383	\$365	\$383	\$45	\$151	\$151	\$550
Invokana	\$428	\$805	\$524	\$30	\$158	\$158	\$1,066
Steglatro	\$170	\$11	\$28	\$0	\$0	\$0	\$70

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 ⁵³	Median	IQR	75 th percentile	95 th percentile
Jardiance	\$93	\$77	\$88	\$30	\$92	\$92	\$417
Brenzavvy ⁵⁴							
Farxiga	\$88	\$73	\$83	\$30	\$90	\$90	\$419
Invokana	\$104	\$158	\$119	\$10	\$100	\$100	\$600
Steglatro	\$52	\$2	\$4	\$0	\$0	\$0	\$0

Information from manufacturers⁵⁵

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:
 - To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure

⁵⁰ 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.

⁵¹ The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

⁵² Information is unavailable due to the NDC of Brenzavvy yielding no results in APAC database.

⁵³ The total is the overall cost per claim across commercial insurers, Medicaid, and Medicare.

⁵⁴ Information is unavailable due to the NDC of Brenzavvy yielding no results in APAC database.

⁵⁵ U.S. Food & Drug Administration. Jardiance (empagliflozin) Prescribing Information. Teva Pharms., Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf.

- To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression
- To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease
- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
- Limitations of Use:
 - Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
 - Not recommended for use to improve glycemic control in patients with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m².
 - Not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of intravenous immunosuppressive therapy or greater than 45 mg of prednisone or equivalent for kidney disease. JARDIANCE is not expected to be effective in these populations.
- Off Label Uses:
 - Glycemic control for patients with Type 1 diabetes mellitus^{56, 57}

Clinical efficacy

Jardiance (*empagliflozin*) is an oral sodium-glucose co-transporter 2 (SGLT2) inhibitor that improves glycemic control in type-2 diabetes mellitus by promoting urinary glucose excretion, leading to reduction in hemoglobin A1c (HbA1c), fasting plasma glucose, body weight, and blood pressure. Initial approval was based on 6 placebo controlled studies demonstrating a reduction in HgA1c with empagliflozin 10 mg daily and 25 mg daily of 0.6% to 1.27% as monotherapy and adjunctive therapy in adults with T2DM. Beyond glucose lowering, empagliflozin demonstrated significant cardiovascular benefit in the EMPA-REG OUTCOME trial, where it reduced the risk of a composite outcome of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke (HR 0.86; 95% CI 0.74 to 0.99) and heart failure hospitalization (HR 0.65; 95% CI, 0.50 to 0.85) in adults with type-2 diabetes and established cardiovascular disease.

⁵⁶ 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>.

⁵⁷ Edwards, K., Uruska, A., Duda-Sobczak, A., Zozulinska-Ziolkiewicz, D., & Lingvay, I. (2023). Patient-perceived benefits and risks of off-label use of SGLT2 inhibitors and GLP-1 receptor agonists in type 1 diabetes: a structured qualitative assessment. *Therapeutic advances in endocrinology and metabolism*, 14, 20420188231180987. <https://doi.org/10.1177/20420188231180987>.

It later demonstrated efficacy in reducing the risk of CV death or hospitalization for heart failure in patients with heart failure, regardless of whether or not they had T2DM (EMPEROR-Reduced and EMPEROR-Preserved). In 2023, empagliflozin resulted in a reduction in kidney disease progression or death from CV causes (HR 0.72; 95% CI 0.64 to 0.82) in patients with chronic kidney disease (EMPA-KIDNEY). Empagliflozin is recommended by guidelines for use in heart failure with reduced ejection fraction, heart failure with preserved ejection fraction, T2DM, and chronic kidney disease.

Clinical safety

- FDA safety warnings and precautions:
 - Ketoacidosis
 - Volume Depletion
 - Urosepsis and Pyelonephritis
 - Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues
 - Necrotizing Fasciitis of the Perineum (Fournier's Gangrene)
 - Genital Mycotic Infections
 - Hypersensitivity Reactions
 - Lower limb amputation
- Contraindications:
 - Hypersensitivity to empagliflozin
- Common side effects:
 - Dyslipidemia (4%), increased thirst (2%), nausea (2%), genitourinary fungal infection (2-6%), urinary tract infection (8-9%)

Therapeutic alternatives:

FDA approved indications

Indication	Empagliflozin (Jardiance)	Dapagliflozin (Farxiga)	Canagliflozin (Invokana)	Ertugliflozin (Steglatro)
Adults with Type 2 Diabetes Mellitus				
Glucose Lowering	Yes	Yes	Yes	Yes
Heart Failure	Yes	Yes	Yes	
Kidney disease	Yes	Yes	Yes	
Children with Type 2 Diabetes Mellitus (10 years and older)				
Glucose Lowering	Yes	Yes	Yes	
Adults without Diabetes Mellitus				
Heart Failure	Yes	Yes		
Kidney Disease	Yes	Yes		

Comparative clinical efficacy

Drug	~A1C Decrease	Cardiovascular Benefits	Heart Failure Risk Reduction (CV death or HF hospitalization)	Reduction in CKD progression or CV death
Jardiance (empagliflozin)	0.5 %	3-point MACE: HR 0.86; 95% CI 0.74 – 0.99	HFrEF: HR 0.75; 95% CI 0.65–0.86 HFpEF: HR 0.79; 95% CI 0.69–0.90	HR 0.72 (0.64–0.82)
Farxiga (dapagliflozin)	0.5%	3-point MACE: HR 0.93; 95% CI 0.84 -103	HFrEF: HR 0.74 95% CI 0.65–0.85 HFpEF: HR 0.82; 95% CI 0.73–0.92	HR 0.61 (0.51–0.72)
Invokana (canagliflozin)	0.6%	3-point MACE: HR 0.86; 95% CI 0.75 – 0.97	_____	HR 0.70 (0.59–0.82)
Steglatro (ertugliflozin)	0.5%	_____	_____	_____
Abbreviations: CI = confidence interval; CKD = chronic kidney disease; CV = cardiovascular; HF = heart failure; HR = hazard ratio; MACE = major cardiovascular adverse events; T2D= type 2 diabetes.				

Safety & therapeutic considerations

- Lower limb amputations:
 - There are conflicting data involving the risk of lower limb amputations with SGLT2 inhibitors. Although a class effect cannot be ruled out, this rare risk has been seen specifically with canagliflozin. There was a higher risk observed in the Canvas trials (pooled HR 2.12; 5.9 vs 2.8 and 7.5 vs 4.2 events/1000 pt-yrs).
- All SGLT 2 inhibitors include the following warnings and precautions. There is no evidence that one is safer than the other regarding these risks:
 - Diabetic ketoacidosis (DKA): In patients with type 1 DM, SGLT2 inhibitors significantly increase the risk of DKA compared to placebo. The risk of ketoacidosis and/or glucosuria have been reported and can continue from 6 days to 2 weeks after discontinuing SGLT2 inhibitors. It is recommended to hold therapy ≥3 days prior to any major surgery.
 - Volume depletion
 - Serious urinary tract infections
 - Fournier’s gangrene
 - Genital yeast infections
 - Lower limb amputations:

Strengths, dosing, and route

Drug	Strengths	Usual adult dosing (per indication)	Route / admin notes
Jardiance	Tabs: 10 mg, 25 mg	10 mg PO once daily in AM; for additional glycemic control may ↑ to 25 mg if tolerated. (Renal/CKD/HF indications use 10 mg once daily per label.) Hold ≥3 days pre-major surgery. Not recommended for glycemic control if eGFR <30.	Oral; with or without food.
Farxiga	Tabs: 5 mg, 10 mg	For HF/CKD & HHF-risk: 10 mg once daily. For glycemic control: start 5 mg; may ↑ to 10 mg. eGFR 25–<45: 10 mg daily; initiation not recommended if eGFR <25 (may continue 10 mg for CKD risk-reduction). Hold ≥3 days pre-surgery.	Oral; with or without food.
Invokana	Tabs: 100 mg, 300 mg	Start 100 mg once daily before first meal; may ↑ to 300 mg if eGFR ≥60 and additional glycemic control needed. For diabetic nephropathy CV/renal risk reduction: 100 mg once daily. Hold ≥3 days pre-surgery. Not recommended to improve glycemic control if eGFR <30.	Oral; take before first meal.
Steglatro	Tabs: 5 mg, 15 mg	Start 5 mg once daily; may ↑ to 15 mg for extra glycemic control. Not recommended if eGFR <45. Hold ≥4 days pre-surgery.	Oral; with or without food.

Input from specified stakeholders

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

See appendix 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 24 individuals taking or having an association with Jardiance. According to the survey results, 92 percent of respondents had coverage for Jardiance.

Three patients were on Medicaid, with one being on a patient assistance program. The patient out of pocket cost ranged from \$0-49 and \$100-\$399. Medicare covered 13 patients with two having cost coverage from PAPs, however did not report what the cost contribution was. Eight responses indicated paying monthly out of pocket costs over \$100 with one indicating an OOP ranging from \$800-\$999. Seven patients with private health insurance had coverage with one respondent indicating there was no coverage for the drug and they were not on a PAP, resulting in them spending a monthly OOP cost of \$600-\$799. Four reported paying \$0-\$49 as their monthly OOP cost. One response showed above \$1000 OOP costs.

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

}} **Jardiance** }}

- ✚ “The first year Jardiance cost me \$649 for the year. Now it’s \$2,139 per year after insurance.”
- ✚ “My diabetes would be far more serious without the medication.”
- ✚ “Before insulin’s price was dropped, there were three drugs that fell in the \$750 range for a 90-day supply, which is what prompted us to look into the Canadian pharmacy because the costs were so high we were having difficulty affording them.”
- ✚ “It’s a tier 2 drug and I first had to meet my deductible.”

Below is a written answer from the Drug Price Transparency program’s legislative report in 2023. The comment has been edited for readability, length and to protect patient privacy.

- ✚ My husband is on Medicare and a private insurance plan and he pays out of pocket \$460 every 3 months for Jardiance and \$400 for Eliquis. These are required to keep him alive per our primary doctor and not due to the ridiculous advertising we’re subjected to non-stop while watching TV. We are both on a fixed income and cannot afford this. One step we should take as a nation is to ban prescription advertising to the public as is done in most countries except for the US and New Zealand. Only doctors should be made aware of their fabulous drugs. These ads must be very costly as they air in prime time and include elaborate casts of actors with dancing and singing. Tell the drug companies to pass the cash savings on to those who really need these drugs. The Jardiance "little pill with the big story to tell" is particularly heinous given its cost to us.

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 Jardiance 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 Jardiance, 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, **11 clinics indicated that Jardiance 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 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 Jardiance 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 19 Safety net provider survey responses

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

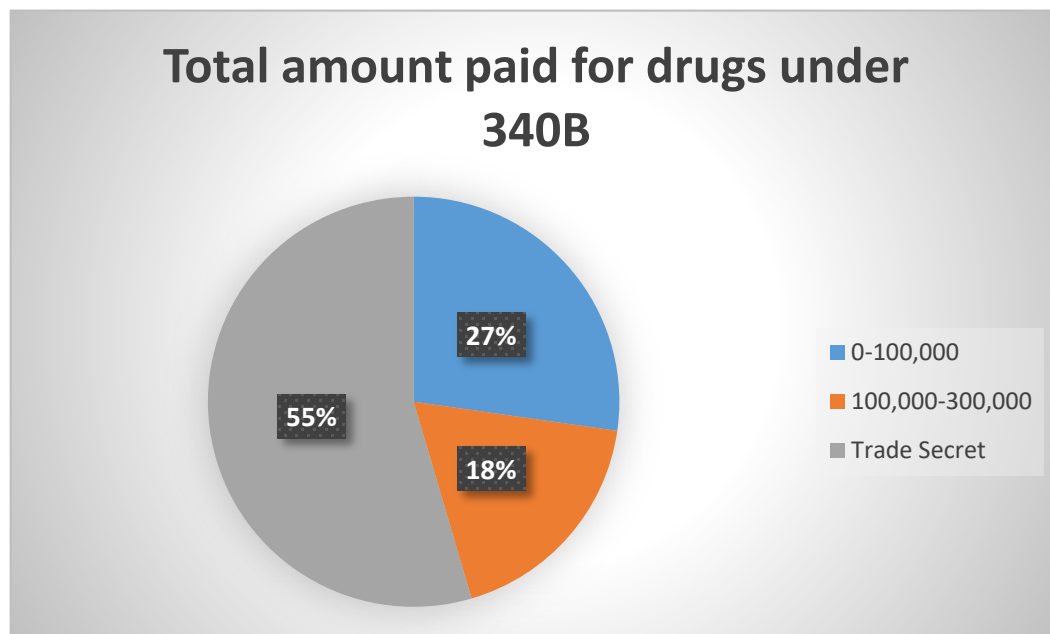


Figure 6 Amounts paid for drug under 340B discount program

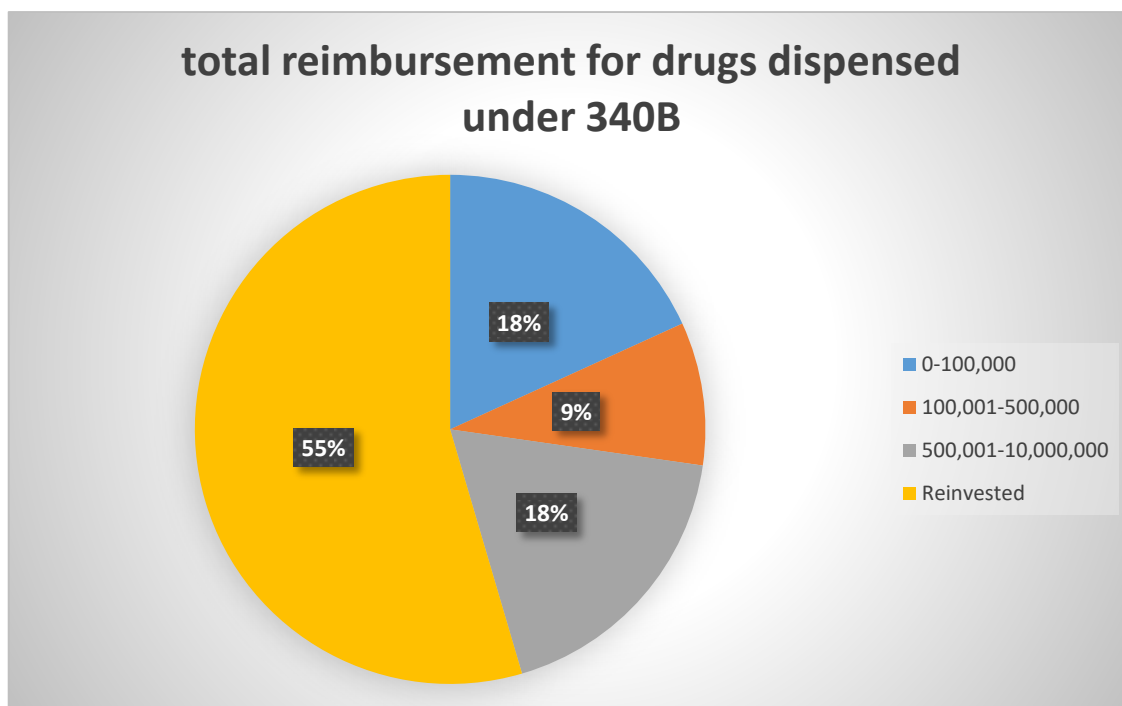


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

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
Stacie Phan	Boehringer Ingelheim	Jardiance	Letter	5/21/2025	Exhibit A



Mounjaro[®]

*(tirzepatide)*¹

Version 1.0



¹Image source: <https://mylocalsurgery.co.uk/conditions/weight-loss-treatments/treatments/mounjaro/28>

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Review summary

Therapeutic alternatives^{2,3,4}

Mounjaro (*tirzepatide*) has the following therapeutic alternatives:

Proprietary name	Non-proprietary name	Manufacturer	Approved year	Number of patents	Patent date range	Exclusivity expiration	On the CMA drug price negotiation list (effective date)
Mounjaro	<i>tirzepatide</i>	Eli Lilly and Co.	2022	4	2036-2041	2027	No
Ozempic	<i>semaglutide</i>	Novo Nordisk Inc.	2017	19	2025-2028	2028	Yes (2027)
Rybelsus⁵	<i>semaglutide</i>	Novo Nordisk Inc.	217	13	2026-2039		Yes (2027)
Trulicity⁶	<i>dulaglutide</i>	Eli Lilly and Co.	2014				No
Victoza⁷	<i>liraglutide</i>	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 No exclusivity was listed for Rybelsus. 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 No patent or exclusivity information was listed for Trulicity. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration, Aug. 27, 2025. <https://purplebooksearch.fda.gov/>.

⁷ No exclusivity was listed for Victoza. 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>.

Price history^{8,9}

Mounjaro rose at an **average annual rate of 4.7 percent** from 2022-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
 - Ozempic: 4.8 percent
 - Rybelsus: 4.4 percent
 - Trulicity: 5.0 percent
 - Victoza: -2.3 percent

Additionally, the average annual rate of Mounjaro exceeded inflation in **2023 and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 5.4 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions¹⁰

Based on data received from healthcare carriers, Mounjaro in 2023 had the **gross spend of \$1,143 per claim**, while the **spend net of discount was \$608 per claim**. Price concession per claim was reported to be **\$535**.

Cost to the payers¹¹

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

Drug	Total expenditure	Utilization	Cost per enrollee	Cost per enrollee, median
Mounjaro	\$24,384,519	22,658	\$5,672	\$974
Ozempic	\$81,017,647	78,032	\$4,427	\$902
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

⁸ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

⁹ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

¹⁰ 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.

¹¹ 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 enrollees¹²

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

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Mounjaro	\$520	\$35	\$100	\$30
Ozempic	\$360	\$40	\$89	\$30
Rybelsus	\$530	\$47	\$121	\$40
Trulicity	\$499	\$25	\$76	\$10
Victoza	\$367	\$10	\$78	\$4

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.

¹² 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>.

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 information¹³

Drug proprietary name(s)	Mounjaro®
Non-proprietary name	<i>tirzepatide</i>
Manufacturer	Eli Lilly and Company
Treatment: Mounjaro is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated for:	<ul style="list-style-type: none">• As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
Dosage and strengths	<ul style="list-style-type: none">• 2.5 mg
	<ul style="list-style-type: none">• 5 mg
	<ul style="list-style-type: none">• 7.5 mg.
	<ul style="list-style-type: none">• 10 mg
	<ul style="list-style-type: none">• 12.5 mg
	<ul style="list-style-type: none">• 15 mg per 0.5 mL in single-dose pen or single-dose vial
Form/route	Subcutaneous Injection

FDA approval

Mounjaro was first approved by the FDA on **May 13, 2022**.¹⁴

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.

Glucagon-like peptide-1 or GLP-1 continues to expand, but data shows lower initiation and higher discontinuation among Black and Hispanic patients and those with lower income

¹³ U.S. Food & Drug Administration. *Mounjaro (tirzepatide)* Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf.

¹⁴ 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.

patterns linked to affordability, insurance hurdles, and care fragmentation.^{15, 16} The U.S. Food and Drug Administration (FDA) confirmed tirzepatide injection shortages were resolved in December 2024. However, utilization management and cost remain key access barriers that may differentially burden low-income and the Medicaid and Medicare populations.^{17,18} Coverage for weight management indications remain limited in many programs. While this does not control diabetes indications directly, plan level policies and demand spillovers can indirectly affect access and continuity for people with type-2 diabetes.¹⁹

Residents prescribed

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

Based on APAC claims, **22,658** Oregonians filled a prescription for Mounjaro in 2023.²⁰

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.

Price history

This section examines the pricing dynamics of Mounjaro, 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 Mounjaro's list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts costs.

¹⁵ 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>.

¹⁶ Rodriguez, P. J., Zhang, V., Gratzl, S., Do, D., Goodwin Cartwright, B., Baker, C., Gluckman, T. J., Stucky, N., & Emanuel, E. J. (2025). Discontinuation and Reinitiation of Dual-Labeled GLP-1 Receptor Agonists Among US Adults With Overweight or Obesity. *JAMA network open*, 8(1), e2457349. <https://doi.org/10.1001/jamanetworkopen.2024.57349>.

¹⁷ Letter to Patty Donnelly, Eli Lilly and Company, from Dr. Patrizia Cavazzoni, Center for Drug Evaluation and Research. U.S. Food & Drug Administration, Dec. 19, 2024. https://www.cfpr.org/files/2024.12.19_tirzepatide_declaratory_order.pdf.

¹⁸ 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>.

¹⁹ Medicare Coverage of GLP-1 Drugs, H.R. 4818, S. 2407, P.L. 108-173, P.L. 117-169, Sept. 9, 2024. <https://www.congress.gov/crs-product/IF12758>

²⁰ 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>.

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

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

Table 4 Drug vs therapeutic alternatives and 2018-2024 WAC per 30-day supply²¹

Year	Mounjaro	Ozempic	Rybelsus	Trulicity	Victoza
2018		\$729		\$730	\$870
2019		\$772		\$759	\$922
2020		\$811		\$797	\$968
2021		\$852	\$852	\$844	\$1,016
2022	\$974	\$892	\$892	\$887	\$1,065
2023	\$1,023	\$936	\$936	\$931	\$1,117
2024	\$1,069	\$969	\$969	\$977	\$677
Avg. Annual % Change	4.7%	4.8%	4.4%	5.0%	-2.3%
% change 2018 between 2024		32.8%		33.9%	-22.2%

The WAC of Mounjaro, averaged across six NDCs reported, was approximately **\$534.54 per unit** at the end of 2024.²² Between 2022-2024, the unit WAC increased at an average annual rate of **4.7 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2022-2023 and 2023-2024** (see Figures 1 and 2).²³

²¹ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

²² Ibid.

²³ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

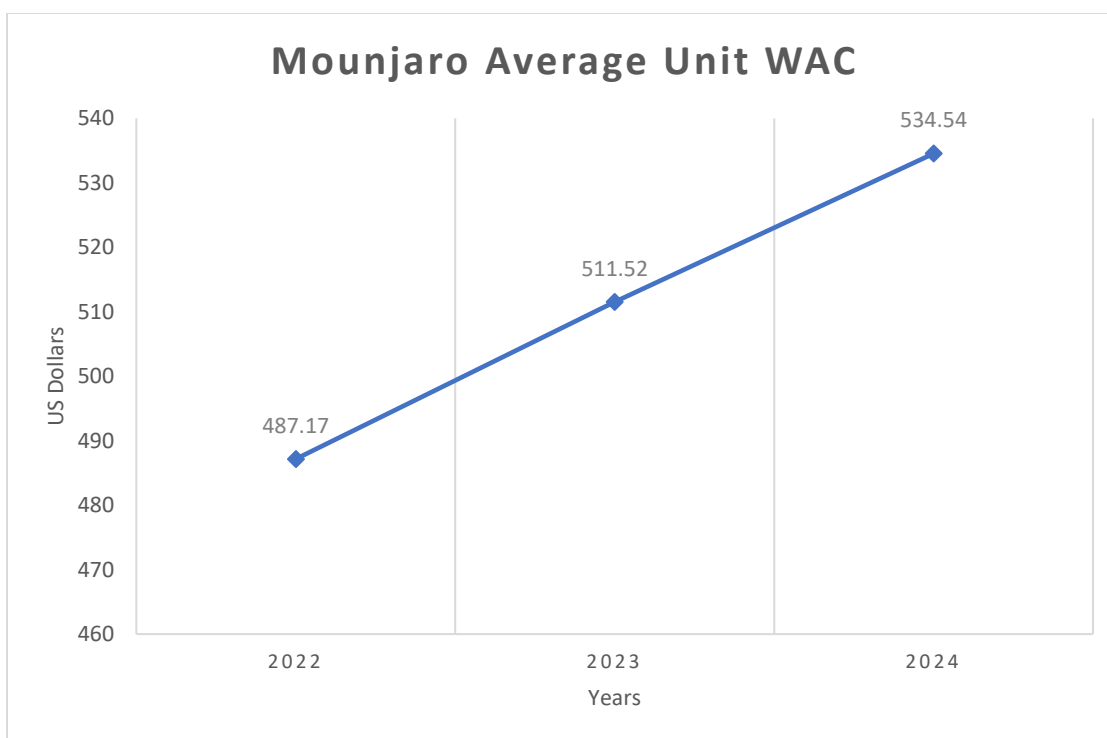


Figure 1 Mounjaro average unit WAC from 2018-2024

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison²⁴

Year	Mounjaro	Byetta	Ozempic	Trulicity	Rybelsus	Victoza	CPI-U
2018-2019			5.9%	4.0%		5.9%	1.7%
2019-2020		3.0%	5.0%	5.0%		5.0%	0.7%
2020-2021		3.5%	-21.3%	5.9%		5.0%	5.3%
2021-2022		3.0%	4.8%	5.0%	4.8%	4.8%	9.0%
2022-2023	5.0%	3.0%	4.9%	5.0%	4.9%	4.9%	3.1%
2023-2024	4.5%	3.0%	3.5%	5.0%	3.5%	-34.1%	3.0%

²⁴ Percentages might differ from Table 4 as Table 5 percentages are based on unit WAC only.

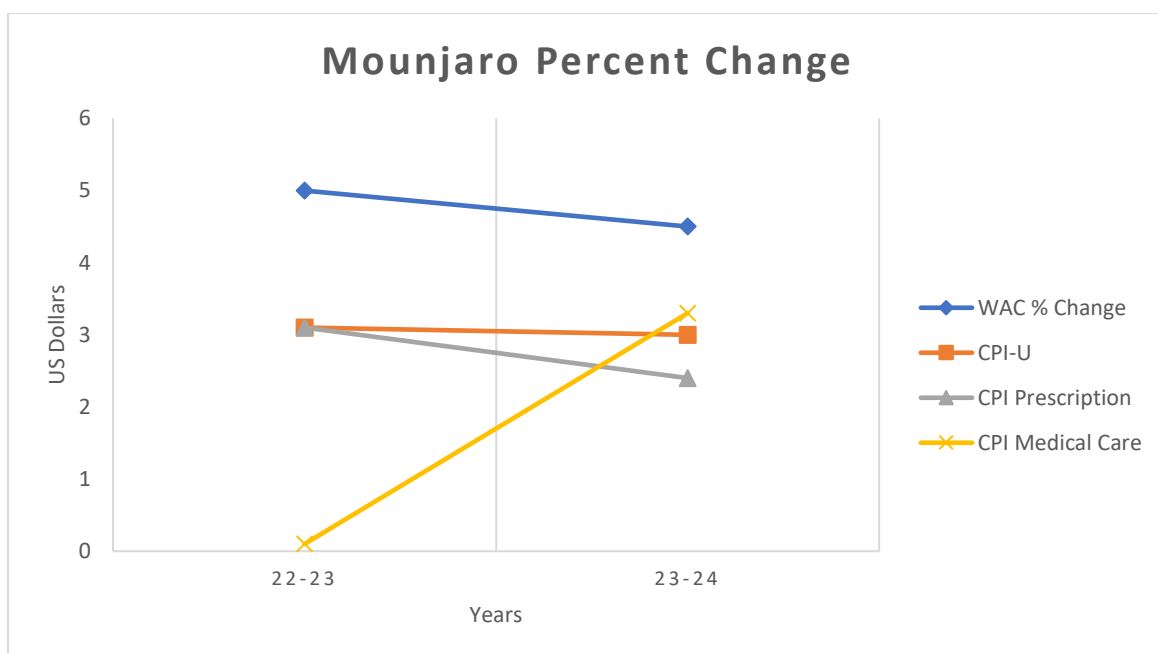


Figure 2 Year over year change in WAC compared to inflation rates²⁵

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **\$492.42 per unit in Quarter 1 of 2023 to \$513.80 per unit in Quarter 4 of 2024**, an approximate **5.4 percent increase** over the period (see Figure 3).²⁶ Relative to the \$534.54 WAC in end-of-year 2024, an **AAAC discount of 4.0 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 Mounjaro's price trajectory relative to inflation and affordability for public and private payers.

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

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC average	Average unit WAC
2023	\$492	\$492	\$493	\$495	\$493.33	\$511.51
2024	\$517	\$516	\$515	\$514	\$515.37	\$534.54

²⁵ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

²⁶ 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/>.

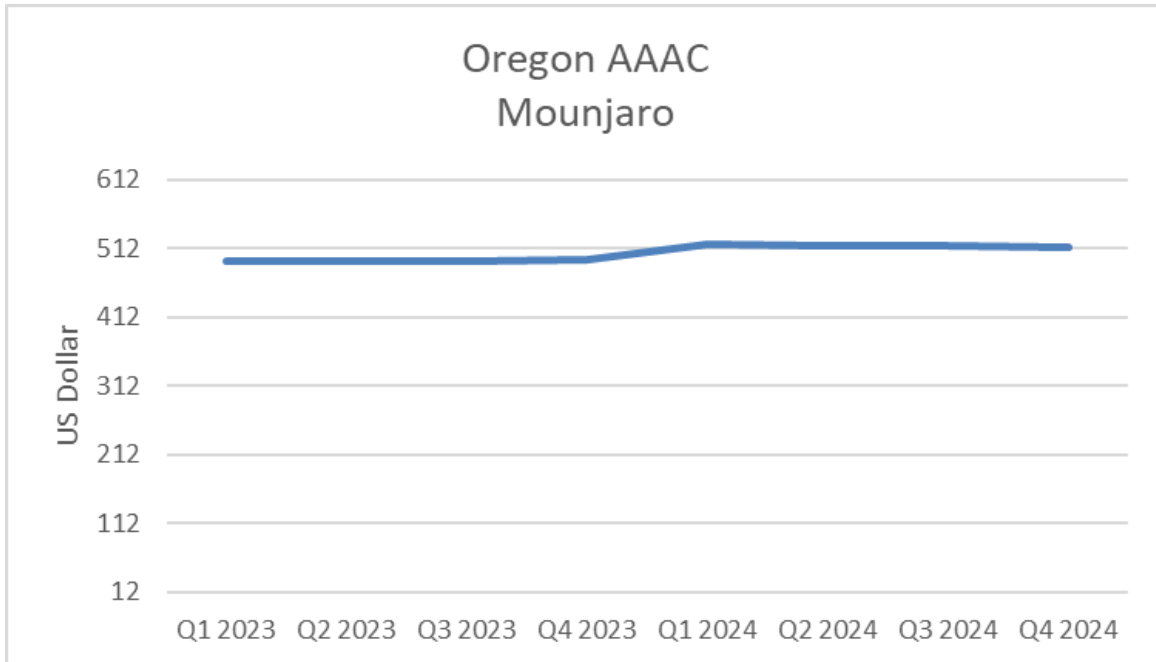


Figure 3 AAAC For Mounjaro from Q1 2023 to Q4 2024

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 Mounjaro 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 Mounjaro per enrollee in the commercial market was approximately \$2,480**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately \$1,319**, reflecting an **estimated mean discount of 46.8 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Mounjaro before concessions was \$9,166,321**, with total reported **price concessions amounting to approximately \$4,290,646**, as detailed in Table 7. Notably, **82.8 percent of claims benefited from some form of price concession**, leaving **17.2 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	3,696
Total number of claims	8,019
Total number of claims with price concessions applied	6,879

Percentage of claims with price concessions applied	85.8%
Percentage of cost remaining after concessions	53.2%
Percentage of discount	46.8%

Manufacturer price concessions for all market types	\$2,545,742
PBM price concessions for all market types	\$1,743,743
Other price reductions for all market types	\$1,161

Cost before price concessions across all market types	\$9,166,321
Total price concessions across all market types	\$4,290,646
Cost of after price concessions across all market types	\$4,875,675

Avg. payer spend per enrollee without price concessions	\$2,480
Avg. payer spend per enrollee with price concessions	\$1,319

Including all market segments, the **gross spend of Mounjaro per claim for commercial carriers was \$1,143** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **\$608**, meaning that insurers reported a price concession of **\$535** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types

	Average	Individual Market	Large Market	Small Market
Spend per Claim, gross	\$1,143	\$1,165	\$1,133	\$1,167
Spend per Claim, net	\$608	\$604	\$612	\$596
Price Concessions per Claim	\$535	\$561	\$521	\$571

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

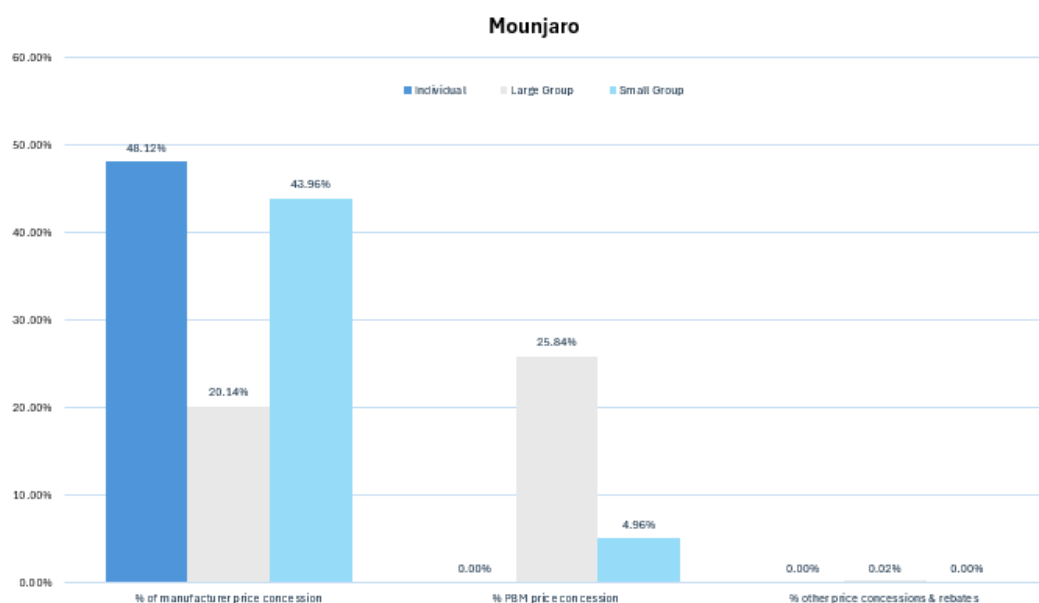


Figure 4 Percent of price concession in each market type^{27, 28}

²⁷ 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.fda.gov/oc/2024/04/24/cfr-2024-title42-vol3-sec423-100.pdf).

²⁸ 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 Mounjaro 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 alternatives²⁹

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 [drug] 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.

Mounjaro' gross total payer paid, based on APAC data, **was \$24.4 million**, while total net payer paid received from the **carriers indicated a cost of \$7.8 million. Trulicity has the highest gross total pay in consideration** with its therapeutic alternatives. 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 third highest utilization of Mounjaro, at 22,658 claims. Rybelsus has a **higher payer paid per claim compared to Mounjaro, which are \$1,351 and \$1,076 respectively**.

Ozempic also has the highest total enrollee paid at \$6.2 million and Trulicity follows behind with \$6.0 million. Rybelsus has the highest patient paid per claim of \$111 and **Mounjaro is the second highest patient paid per claim of \$93**. The drug with the lowest patient paid per claim is Trulicity, which is \$57.

²⁹ 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) PDAB 1-2023: Prescription Drug Affordability Review (oregon.gov). Accessed 01/09/2024.

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 Mounjaro vs therapeutic alternatives³⁰

Drug	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid ³¹	Payer paid/claim	Patient paid/claim ³²
<i>Subject Drug</i> Mounjaro (Data call)³³	3,696	8,019	\$7,805,072	\$827,650	\$973	\$103
<i>Subject Drug</i> Mounjaro (APAC)	4,299	22,658	\$24,384,519	\$2,107,423	\$1,076	\$93
Ozempic	18,301	78,032	\$81,017,647	\$6,223,820	\$1,038	\$80
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 Mounjaro, 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.

³⁰ 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.

³¹ The cost includes all lines of business.

³² Ibid.

³³ Information from the data call with the cost information after price concessions.

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 Mounjaro 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 **22,658 total claims for Mounjaro among 4,393 total enrollees**, corresponding to a **total payer expenditure of \$24,384,519**.

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 **10,614** claims from **1,978** enrollees and a total spend of **\$12,456,155 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **\$10.5 million** and **\$1.5 million**, respectively.

Table 10 Estimated 2023 APAC total annual gross payers expenditure for total enrollees and total claims³⁴

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	2,111	10,464	\$10,473,836	\$4,962	\$1,001
Medicaid	304	1,580	\$1,454,528	\$4,785	\$921
Medicare	1,978	10,614	\$12,456,155	\$6,297	\$1,174
Totals	4,393³⁵	22,658	\$24,384,519		

Table 11 provides utilization for the healthcare system for Mounjaro and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the most utilization** among the

³⁴ 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.

³⁵ The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

drugs, with **104,682 claims**. In all lines of business, Trulicity is the most utilized, aside from Ozempic in the commercial sector. **Ozempic is the second most utilized at 78,032 claims**.

Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives³⁶

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims ³⁷
Mounjaro	10,464	1,580	10,614	22,658
Ozempic	37,201	8,338	32,493	78,032
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 12 shows the overall payer expenditure of Mounjaro and its therapeutic alternatives, distinguished by lines of business. Mounjaro has a **total expenditure of \$24.4 million** with **Medicare being the biggest portion at \$12.5 million**. The therapeutic alternative with the **least expenditure is Rybelsus, at \$15.6 million**.

Table 12 Estimated APAC payer 2023 annual gross expenditure of the review drug and its therapeutic alternatives from all lines of business³⁸

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total ³⁹
Mounjaro	\$10,473,836	\$1,454,528	\$12,456,155	\$24,384,519
Ozempic	\$36,494,230	\$7,438,499	\$37,084,917	\$81,017,647
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 13 compares the overall payer cost per enrollee of Mounjaro 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** The median cost per

³⁶ 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.

³⁷ Total is the sum of all utilization for the drug across all lines of business.

³⁸ 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.

³⁹ Total is the sum of all expenditure for the drug across all lines of business.

enrollee for Mounjaro is \$974, which is the second highest median of cost per enrollee.

Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives⁴⁰

Proprietary name	Commercial cost/enrollee	Medicaid cost/enrollee	Medicare cost/enrollee	Total ⁴¹ cost per enrollee	Cost per enrollee, median	IQR	Cost per enrollee 75 th percentile	Cost per enrollee, 95 th percentile
Mounjaro	\$4,962	\$4,785	\$6,297	\$5,672	\$974	\$239	\$1,085	\$2,932
Ozempic	\$4,117	\$3,736	\$4,288	\$4,427	\$902	\$952	\$1,719	\$2,782
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 submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the large group represented the majority of commercial spending (69% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around \$8.6 million**, with payer paying \$7.8 million, and enrollees out-of-pocket estimating to be **\$827,650**. Table 14 includes the average plan costs per enrollee in the commercial market, ranging from **\$2,360 (large group)** to **\$2,223 (individual)** annually.

Table 14 Estimated 2023 data call annual total net costs to the healthcare system, payers and OOP/enrollee⁴²

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of-pocket cost
Individual	750	393	\$873,750	\$623,139	\$250,611
Large Group	5,631	2,518	\$5,942,646	\$5,559,522	\$383,124
Small Group	1,638	785	\$1,816,327	\$1,622,412	\$193,915
Total	8,019	3,696	\$8,632,723	\$7,805,072	\$827,650

⁴⁰ 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.

⁴¹ The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

⁴² Cost information from the data call is the cost of the drug after price concessions.

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	\$1,165	\$831	\$334	\$2,223	\$1,586	\$638
Large Group	\$1,055	\$987	\$68	\$2,360	\$2,208	\$152
Small Group	\$1,109	\$990	\$118	\$2,314	\$2,067	\$247

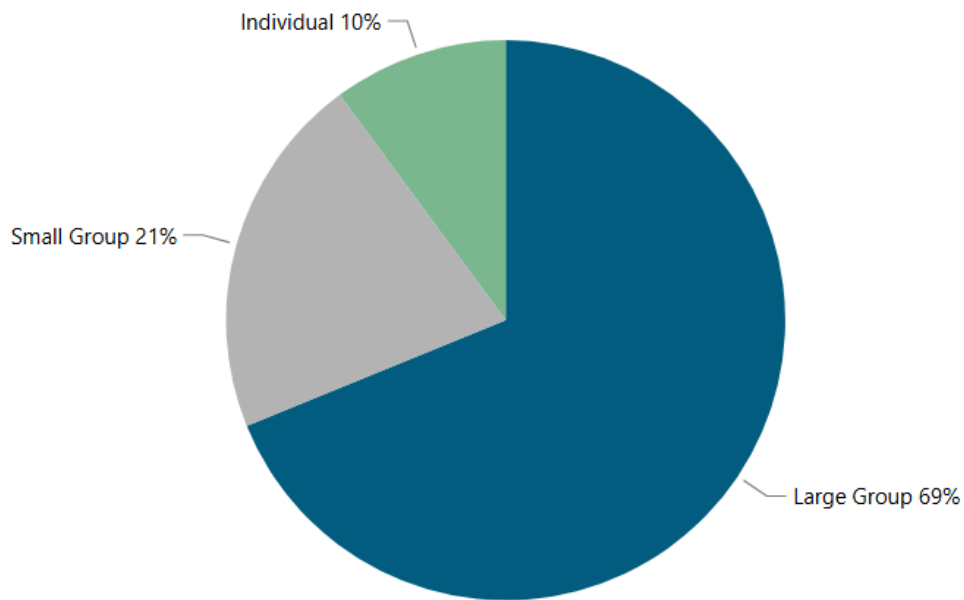


Figure 5 Data call total annual percent spend (payer paid) by market

Table 15 indicates CCOs reported Mounjaro as having an annual greatest increase from 2022-2023 (rebates not included) with a **\$1.3 million year-over-year increased cost growth**.

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

Medicaid CCOs			
2022	2023	YoY change in spending	Percent of total CCO cost 2023
\$52,441	\$1,336,276	\$1,283,835	0.1%

Impact on patient 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 Mounjaro, 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 Mounjaro. In 2023, approximately **64.2 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **35.4 percent of plans required step therapy** before approving its use.

For formulary placement, **61.7 percent of plans categorized Mounjaro as a non-preferred drug**, and **1.5 percent of plans excluded it entirely from the formulary**.

Table 16 Plan design analysis from 2023 data call

Percentage of plans	
Required Prior Authorization	64.2%
Required Step Therapy	35.4%
On a non-preferred formulary	61.7%
Not covered	1.5%

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 Mounjaro 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 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 Mounjaro 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.

Table 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.

Table 17 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee⁴³

Proprietary name	Annual Medicare OOP cost/enrollee	Annual Commercial OOP cost/enrollee	Total ⁴⁴	Median	IQR	75 th percentile	95 th percentile
Mounjaro	\$453	\$573	\$520	\$35	\$114	\$114	\$940
Ozempic	\$399	\$313	\$360	\$40	\$115	\$115	\$673
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 ⁴⁵	Median	IQR	75 th percentile	95 th percentile
Mounjaro	\$85	\$116	\$100	\$30	\$85	\$85	\$496
Ozempic	\$106	\$75	\$89	\$30	\$75	\$75	\$454
Rybelsus	\$135	\$103	\$121	\$40	\$101	\$105	\$606
Trulicity	\$88	\$60	\$76	\$10	\$50	\$50	\$396
Victoza	\$93	\$56	\$78	\$4	\$60	\$60	\$400

Information from manufacturers

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:
 - Tirzepatide MOUNJARO® is a glucose-dependent insulintropic polypeptide (GIP) receptor and 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:
 - Has not been studied in patients with a history of pancreatitis
 - Is not indicated for use in patients with type 1 diabetes mellitus
- Off Label Uses:
 - Chronic weight management.

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

Clinical efficacy

Approval of tirzepatide was based on five phase 3 trials (SURPASS trials). Tirzepatide was compared to placebo in 2 trials and active treatment in 3 trials, including insulin glargine, insulin degludec and semaglutide 1 mg. Tirzepatide was studied with background therapy of insulin glargine (with or without metformin), metformin alone, or combination treatment with metformin, sulfonylurea and SGLT2inhibitors. Once-weekly tirzepatide demonstrated improved efficacy overall comparators, with HbA1c changes from baseline ranging from -1.87% to -2.58%. Patients receiving tirzepatide achieved HbA1c less than 7% more than comparators ranging from 75.1% to 89.6% of the population studied (P<0.05 for all comparisons). Weight loss was more significant in the tirzepatide groups versus comparators, including semaglutide, with losses of -5.3 kg to -11.3 kg. Additional details are included in the trial information below.

Trial: SURPASS-1 (Monotherapy vs placebo) – Week 40

Endpoint	Placebo	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	0.04	-1.87	-1.89	-2.07
Diff vs placebo (95% CI)	—	-1.9 (-2.2, -1.4)	-1.6 (-1.9, -1.3)	-1.6 (-1.9, -1.3)
A1C < 7% (% pts)	23%	82%	85%	78%
OR (95% CI)	—	49.0 (21.1, 113.7)	80.4 (31.8, 203.2)	52.9 (22.3, 125.7)
Weight change (kg)	-1.0	-7.0	-7.8	-9.5
Diff vs. placebo (95% CI)	—	-6.3 (-7.8 to -4.7)	-7.1 (-8.6 to -5.5)	-8.8 (-10.3 to -7.2)

Term: BL=baseline; CI: confidence interval; kg: kilogram; OR: odds ratio; A1c: hemoglobin A1c

Trial: SURPASS-2 (Add-on to metformin; vs semaglutide 1 mg) – Week 40

Endpoint	semaglutide	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	-1.9	-2.0	-2.2	-2.3
Diff vs sema (95% CI)	—	-0.2 (-0.3, -0.0)	-0.4 (-0.5, -0.3)	-0.5 (-0.6, -0.3)
A1C < 7% (% pts)	79%	82%	86%	86%
Weight change (kg)	-5.7	-7.6	-9.3	-11.2
Diff vs. sema (95% CI)	—	-1.9 (-0.28, -1.0)	-3.6 (-4.5, -2.7)	-5.5 (-6.4, -4.6);

Term: BL=baseline; CI: confidence interval; kg: kilogram; A1c: hemoglobin A1c; sema: semaglutide

Trial: SURPASS-3 (Add-on to metformin ± SGLT2i; vs insulin degludec) – Week 52

Endpoint	Insulin degludec	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	-1.3	-1.9	-2.0	-2.4
Diff vs insulin (95% CI)	—	-0.6 (-0.7, -0.5)	-0.9 (-1.0, -0.7)	-1.0 (-1.2, -0.9)
A1C < 7% (% pts)	61%	82%	90%	93%
OR (95% CI)	—	3.45 (2.38, 5.01)	7.02 (4.55, 10.84)	10.79 (6.65, 17.48)

Endpoint	Insulin degludec	Tirzepatide		
Weight change (kg)	2.3	-7.5	-10.7	-12.9
Diff vs. insulin (95% CI)	—	-9.8 (-10.8, -8.8)	-13.0 (-14.0, -11.9)	-15.2 (-16.2, -14.2)
Term: BL=baseline; CI: confidence interval; kg: kilogram; OR: odds ratio; A1c: hemoglobin A1c; sema: semaglutide				

Trial: SURPASS-4 (Add-on to 1–3 orals; vs insulin glargine) – Week 52

Endpoint	Insulin glargine	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	-1.4	-2.2	-2.4	-2.6
Diff vs insulin (95% CI)	—	-0.8 (-0.9, -0.7)	-1.0(-1.1, -0.9)	-1.1 (-1.3, -1.0)
A1C < 7% (% pts)	51%	81%	88%	91%
OR (95% CI)	—	4.78 (3.47, 6.58)	9.23 (6.31, 13.49)	11.87 (7.88, 17.89)
Weight change (kg)	1.9	-7.1	-9.5	-11.7
Diff vs. insulin (95% CI)	—	-9.0 (-9.8, -8.3)	-11.4(-12.1, -10.6)	-13.5(-14.3, -12.8)
Term: BL=baseline; CI: confidence interval; kg: kilogram; OR: odds ratio; A1c: hemoglobin A1c; sema: semaglutide				

Trial: SURPASS-5 (Add-on to insulin glargine ± metformin; vs placebo) – Week 40

Endpoint	Placebo	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	-0.9	-2.1	-2.4	-2.3
Diff vs placebo (95% CI)	—	-1.2 (-1.5, -1.0)	-1.5 (-1.8, -1.3)	-1.5 (-1.7, -1.2)
A1C < 7% (% pts)	35%	87%	90%	85%
OR (95% CI)	—	14.7 (7.0, 30.6);	19.5 (9.2, 41.3)	11.5 (5.6, 23.3)
Weight change (kg)	1.6	-5.4	-7.5	-8.8
Diff vs. placebo (95% CI)	—	-7.1 (-8.7, -5.4)	-9.1 (-10.7, -7.5)	-10.5 (-12.1, -8.8)
Term: BL=baseline; CI: confidence interval; kg: kilogram; OR: odds ratio; A1c: hemoglobin A1c				

Clinical safety

- FDA safety warnings and precautions:
 - Risk of Thyroid C-Cell Tumors
 - Pancreatitis
 - Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin
 - Hypersensitivity Reactions
 - Acute Kidney Injury
 - Severe Gastrointestinal Reactions

- Diabetic Retinopathy Complications
- 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)
 - Known serious hypersensitivity to tirzepatide
- **Common side effects:**
 - Gastrointestinal: constipation (6-17%), decreased appetite (5-11%), diarrhea (12-23%), nausea (12-29%), vomiting (5-13%)
 - Immunologic: antibody development (51-65%)

Therapeutic alternatives

FDA-approved indications^{46,47,48,49,50}

Drug	Formulation	Dosing Frequency	Indications (per label)		
			T2DM	CV Risk Reduction	CKD
Tirzepatide (Mounjaro)	SubQ	Weekly	Yes		
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		

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

⁴⁶ U.S. Food & Drug Administration. *Mounjaro (tirzepatide)* Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf.

⁴⁷ U.S. Food & Drug Administration. *Ozempic (semaglutide)* Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf

⁴⁸ U.S. Food & Drug Administration. *Rybelsus (semaglutide)* Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf

⁴⁹ U.S. Food & Drug Administration. *Trulicity (dulaglutide)* Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf

⁵⁰ U.S. Food & Drug Administration. *Victoza (liraglutide)* Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf

Comparative clinical efficacy (selected label trials)

Drug	~A1C Decrease	Short term weight loss	Rates of nausea	Cardiovascular Benefits
Tirzepatide (Mounjaro)	1.7%-2.5%	5.0-12.0 kg	12% - 29%	↓ MACE*
Dulaglutide (Trulicity)	1.0% - 1.8 %	2.5 – 4.6 kg	12% - 20%	↓ MACE (NNT 71)
Exenatide (Byetta)	1.0%	2 kg	8% - 11%	_____
Exenatide ER (Bydureon)	1.5%	1.5 - 2.5 kg	8% - 11%	_____
Liraglutide (Victoza)	1.0% - 1.3%	2.5 kg	18% - 20%	↓ MACE (NNT 53)
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)

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 in 2025.

- 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.⁵¹ 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).

⁵¹ 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 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.⁵²
- 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).⁵³

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

Drug	Key Warnings/Precautions	Notable considerations
Mounjaro	Boxed warning: thyroid C-cell tumors; pancreatitis; hypoglycemia with insulin/SU; hypersensitivity; acute kidney injury (often with severe GI AEs); severe GI disease (incl. gastroparesis) — not recommended; retinopathy monitoring if history; acute gallbladder disease.	May reduce efficacy of oral contraceptives around dose-escalation—use non-oral or barrier method for 4 weeks after initiation and each escalation.
Ozempic	Boxed warning; pancreatitis; diabetic retinopathy complications signal from semaglutide injection CVOT; AKI; gallbladder disease; hypoglycemia with insulin/SU.	SC once weekly; counsel patients with pre-existing retinopathy.
Rybelsus	Same class warnings; retinopathy warning references semaglutide injection CVOT; AKI; gallbladder disease; hypoglycemia with insulin/SU.	Oral administration with strict empty-stomach instructions (≥30 min before first food/drink/other meds, with ≤4 oz water).
Trulicity	Boxed warning; pancreatitis; diabetic retinopathy complications observed in REWIND; acute gallbladder disease; severe GI disease caution.	Once-weekly SC; approved in pediatrics ≥10 y.
Victoza	Boxed warning; pancreatitis; acute gallbladder disease; renal impairment/AKI caution; hypoglycemia with insulin/SU.	Once-daily SC dosing (titrate 0.6 to 1.2 to 1.8 mg).

⁵² 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.

⁵³ 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>.

Input from specified stakeholders

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

See appendix 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 18 individuals taking or having an association with Mounjaro. According to the survey results, 39 percent of respondents had insurance covered for Mounjaro.

Zero patients were on Medicaid, 10 patients were on Medicare, and eight patients had private health insurance. Six patients with private health insurance reported their prescription was not covered. Two patients reported being on patient assistance programs.

Below 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, which is included in the appendix.



Mounjaro



✚ 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 per month. 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 every day. 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 to collect information were posted on the PDAB website to collect drug information from individuals with scientific and medical training. There were no reports for Mounjaro 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 Mounjaro, 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, **10 clinics indicated that Mounjaro 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 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 Mounjaro 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 19 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	8
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%

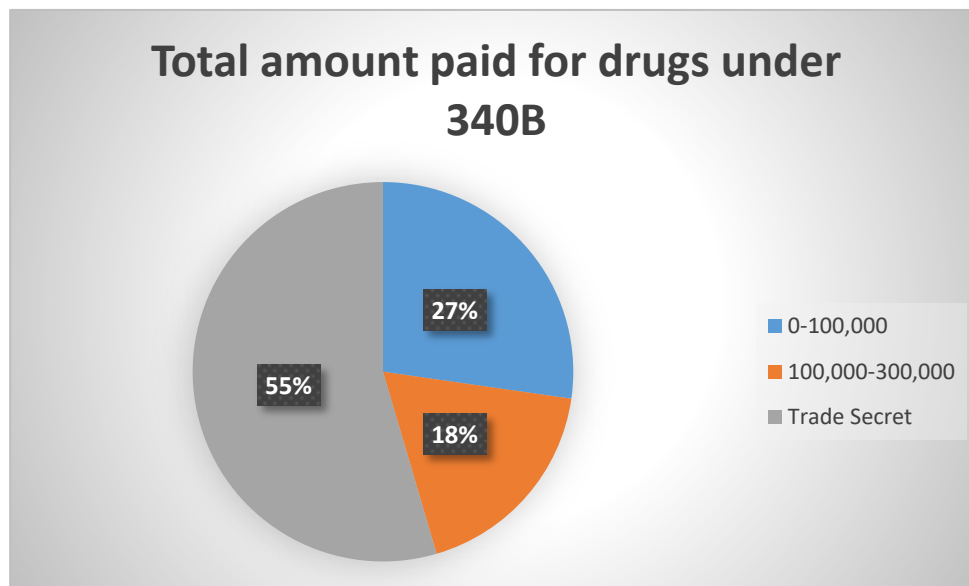


Figure 6 Amounts paid for drug under 340B discount program

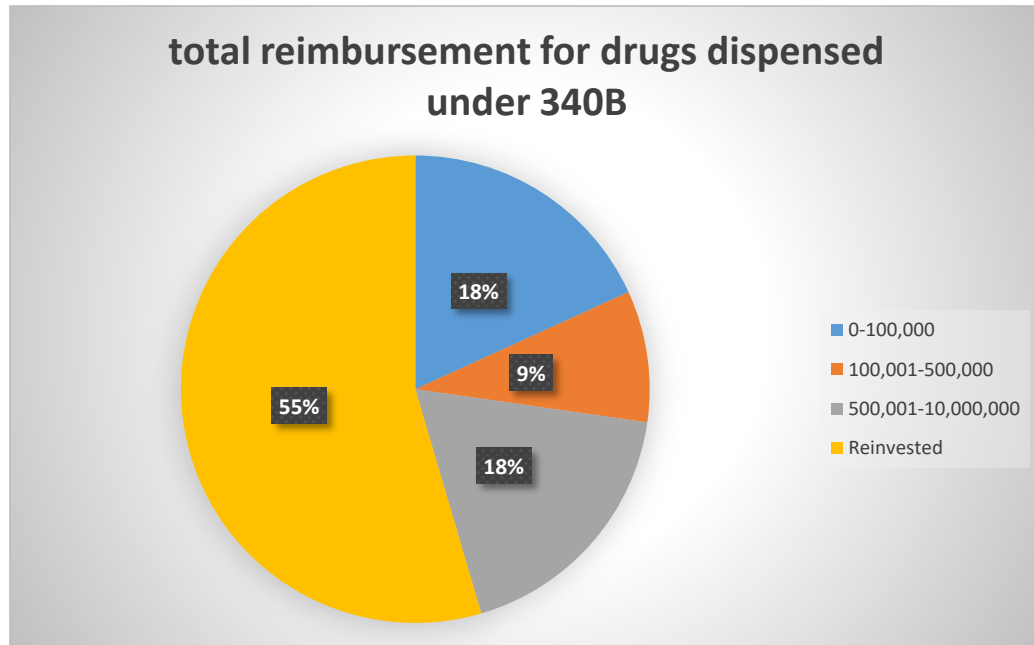


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

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	Mounjaro	Letter	5/21/2025	Exhibit A
Cynthia Ransom	Eli Lilly	Mounjaro	Letter	5/21/2025	Exhibit B
Carol Elkins	Retired, patient	Mounjaro	Letter	6/18/25	Exhibit C



Ozempic[®] (*semaglutide*)¹

Version 1.0



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

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Review summary

Therapeutic alternatives^{2,3,4}

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

Proprietary name	Non-proprietary name	Manufacturer	Year approved	Number of patents	Patent Date Range	Exclusivity expiration	On the CMA drug price negotiation list (effect date)
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%20and%20exclusivity)

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 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, and 2023**. 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

Drug	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 APAC annual enrollee out-of-pocket (OOP) cost

Drug	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

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,

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>.

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	<i>semaglutide</i>
Manufacturer	Novo Nordisk
Treatment: Ozempic is a glucagon-like peptide 1 (GLP-1) receptor agonist indicated:	<ul style="list-style-type: none">• as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.• to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus 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).
Dosage and strength	<ul style="list-style-type: none">• 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

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 [drug]'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 syringe of 3ml)	1 package (1 pen of 2.4ml)	30 units (30 pills)	1 package (4 pens of 0.5ml)	1 package (3 pens of 9ml)

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 **\$290.56 per unit** at the end of 2024.²³ Between 2018-2024, the unit WAC increased at an average annual rate of **-1.9 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2018-2019, 2019-2020, and 2022-2023** (see Figures 1 and 2).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/>.

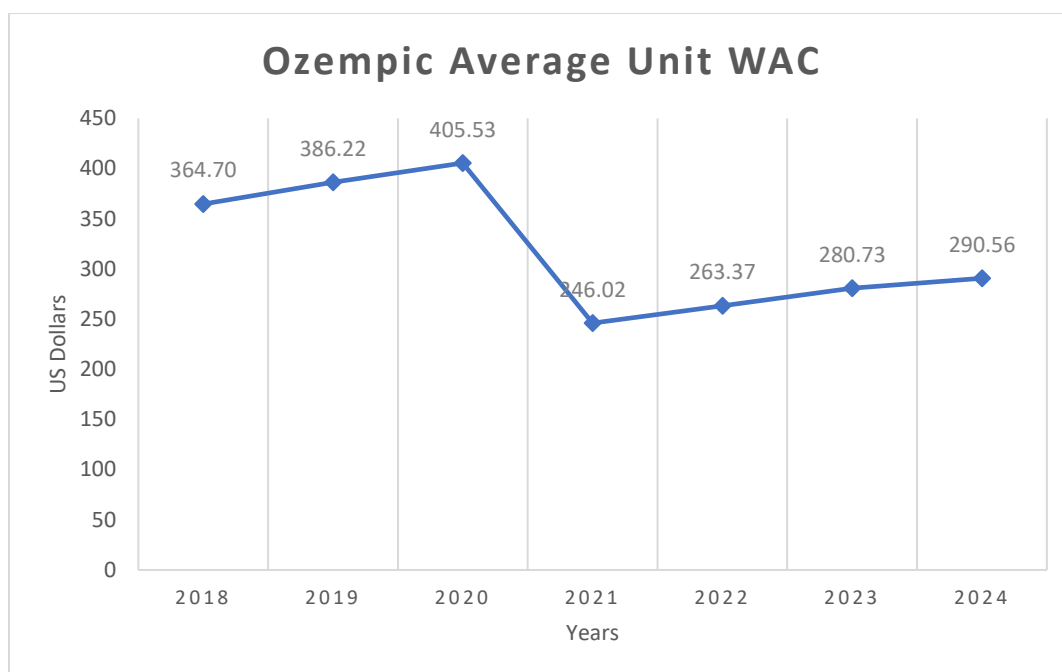


Figure 1 Ozempic average unit WAC from 2018-2024

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	-39.3%	3.5%		5.9%	5.0%	5.3%
2021-2022	7.1%	3.0%	4.8%	5.0%	4.8%	9.0%
2022-2023	6.6%	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.

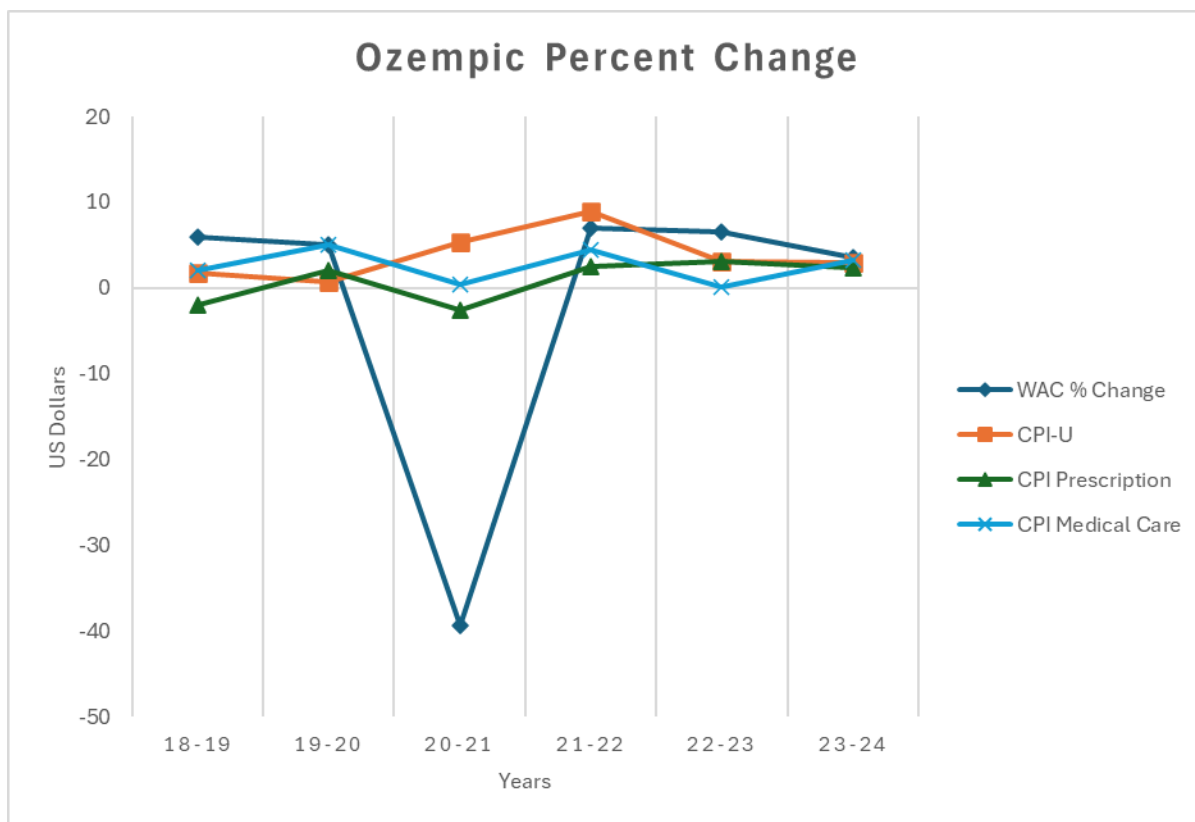


Figure 2 Year over year change in WAC compared to inflation rates²⁶

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 Figure 3).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	\$388.55	\$405.53
2021	\$404	\$408	\$380	\$363	\$388.81	\$246.02
2022	\$379	\$381	\$377	\$357	\$373.65	\$263.37
2023	\$370	\$371	\$367	\$357	\$366.49	\$280.73
2024	\$372	\$379	\$388	\$388	\$381.77	\$290.56

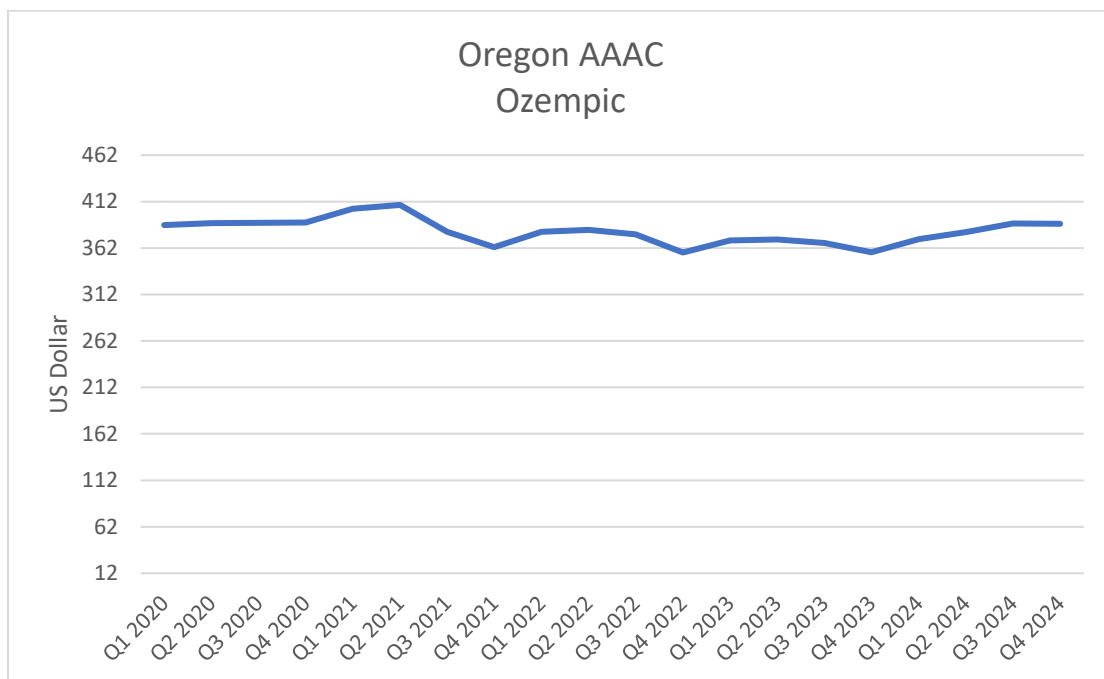


Figure 3 AAAC For Ozempic from Q1 2020 to Q4 2024

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

	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.

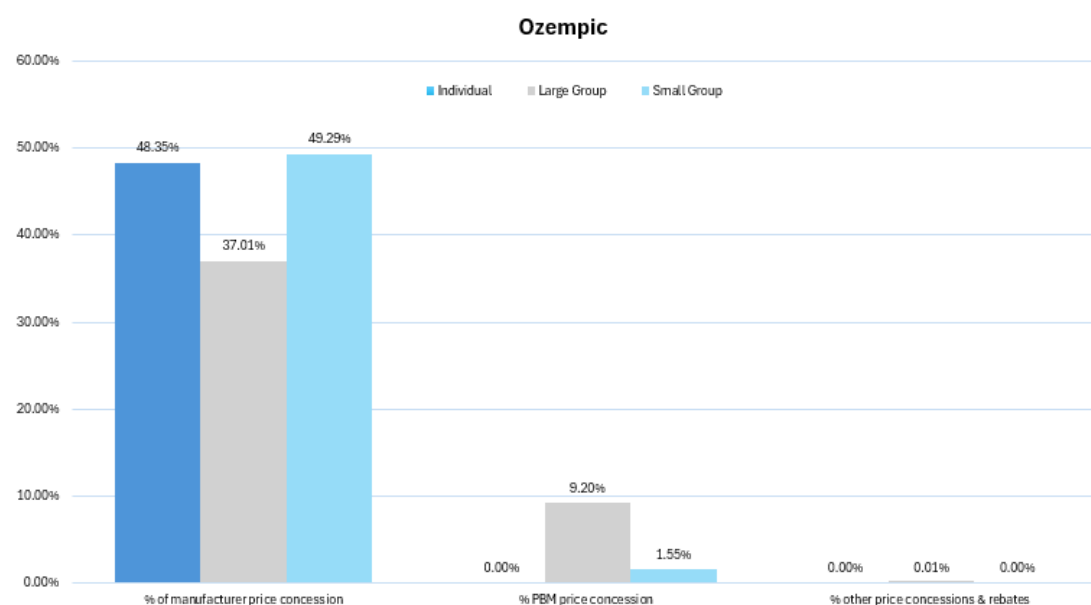


Figure 4 Percent of price concession in each market type^{28, 29}

²⁸ 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).

²⁹ 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 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 alternatives³⁰

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

- The estimated net price is not included due to lack of information on discounts, rebates, and other price adjustments. Pharmaceutical companies negotiate prices with pharmacies, insurance companies and other stakeholders, but the price negotiations of drugs are not disclosed to the public. The lack of transparency and regulation in pricing of prescription drugs makes it difficult to know the true cost and value of the drug.
- Cost and availability:
 - Data regarding costs, expenditures, and utilization are listed below and shown in Tables 3 and 4.
 - According to the FDA, there is no shortage status for Ozempic.³¹

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>.

³⁰ 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). <https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0020.pdf>. Accessed Jan. 9, 2024.

³¹ FDA Drug Shortages: Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Federal Drug Administration, Dec. 15, 2023. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Dulaglutide%20Injection&st=c.

Comparative effectiveness to therapeutic alternatives:

Table 9 Alternative glucagon-like peptide-1 receptor agonist

Drug	FDA approved indications	~A1C decrease	Short term weight loss	Rates of nausea	Formulation	Dosing frequency
<i>Subject drug</i> Semaglutide (Ozempic)	<ul style="list-style-type: none"> T2DM CV risk reduction 	1.5%	4.0 – 6.0 kg	15% - 20%	SubQ	Weekly
Dulaglutide (Trulicity)	<ul style="list-style-type: none"> T2DM CV risk reduction 	1.5% - 1.8 %	2.5 – 4.6 kg	12% - 20%	SubQ	Weekly
Exenatide (Byetta)	<ul style="list-style-type: none"> T2DM 	1.0%	2 kg	8% - 11%	SubQ	Twice Daily
Exenatide ER (Bydureon)	<ul style="list-style-type: none"> T2DM 	1.5%	1.5 - 2.5 kg	8% - 11%	SubQ	Weekly
Liraglutide (Victoza)	<ul style="list-style-type: none"> T2DM CV risk reduction 	1.5%	2.5 kg	18% - 20%	SubQ	Daily
Semaglutide (Rybelsus)	<ul style="list-style-type: none"> T2DM 	1.0%	2.5 kg	11% - 20%	Oral	Daily

Abbreviations: CV: cardiovascular; ER: extended release; kg: kilogram; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus

- 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.³² Agents with proven CV benefits are recommended, including dulaglutide (Trulicity), liraglutide (Victoza), and subcutaneous semaglutide (Ozempic).
- Dulaglutide (Trulicity), liraglutide (Victoza), and injectable semaglutide (Ozempic) are therefore FDA approved to reduce CV risk in patients with T2DM, while the other GLP-1 receptor agonists are approved for glycemic control only. Currently, semaglutide oral (Rybelsus) does not have the same indication for CV disease reduction in adults with T2D as the injectable formulation (Ozempic).
- There are no studies directly comparing GLP-1 agonists on CV outcomes.
- 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.

³² 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.

- 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.³³
- 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).³⁴ For a more complete cost comparison, these medications will also be compared. Metformin has proven to be safe and effective in the management of T2DM, is inexpensive and widely available, and may reduce CV events. SGLT2 inhibitors, including empagliflozin, are recommended first line in patients with T2DM and CVD, heart failure, and or chronic kidney disease. As newer classes of diabetes medications are available, costs have increased dramatically, including for the GLP-1 agonists. Providers and patients often must choose alternative drug classes based on insurance coverage, cost of therapy, and access to newer medications.

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.

³³ Pratley R, et al. Oral semaglutide versus subcutaneous liraglutide and placebo in type 2 diabetes (PIONEER 4): a randomized, double-blind, phase 3a trial. *Lancet*. 2019 Jul 6;394(10192):39-50. [Oral semaglutide versus subcutaneous liraglutide and placebo in type 2 diabetes \(PIONEER 4\): a randomised, double-blind, phase 3a trial - PubMed](#).

³⁴ 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.

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 10 Average healthcare and average patient OOP costs for Ozempic vs therapeutic alternatives³⁵

Drug	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid ³⁶	Payer paid/claim	Patient paid/claim ³⁷
<i>Subject Drug</i> Ozempic (Data call)³⁸	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.

³⁵ 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>.

³⁶ The cost includes all lines of business.

³⁷ Ibid.

³⁸ Information from the data call with the cost information after price concessions.

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 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 \$173,091,290**.

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 **\$78.0 million** and **\$16.9 million**, respectively.

Table 11 Estimated 2023 APAC total annual gross payer expenditure for total enrollees and total claims ³⁹

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
Totals	30,305⁴⁰	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

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

drugs, with **170,729 claims**. Trulicity has a higher utilization in Medicaid, with 25,337 claims, while Ozempic has higher utilization in other lines of business. **Trulicity is the second most utilized at 104,682 claims.**

Table 12 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives⁴¹

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims ⁴²
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 13 Estimated 2023 APAC payer annual gross expenditures of the review drug and its therapeutic alternatives from all lines of business⁴³

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total ⁴⁴
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**

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 utilization for the drug across all lines of business.

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

have a higher median cost per enrollee as compared to Ozempic, at \$973 and \$1,089 respectively.

Table 14 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives⁴⁵

Proprietary name	Commercial Cost/ Enrollee	Medicaid Cost/ Enrollee	Medicare Cost/ Enrollee	Total ⁴⁶ 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 submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the large group represented the majority of commercial spending (66% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around \$52.5 million**, with payer 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 15 Estimated 2023 data call annual total net costs to the healthcare system, payers and OOP/enrollee⁴⁷

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

⁴⁵ 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.

⁴⁶ The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

⁴⁷ Cost information from the data call is the cost of the drug after price concessions.

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

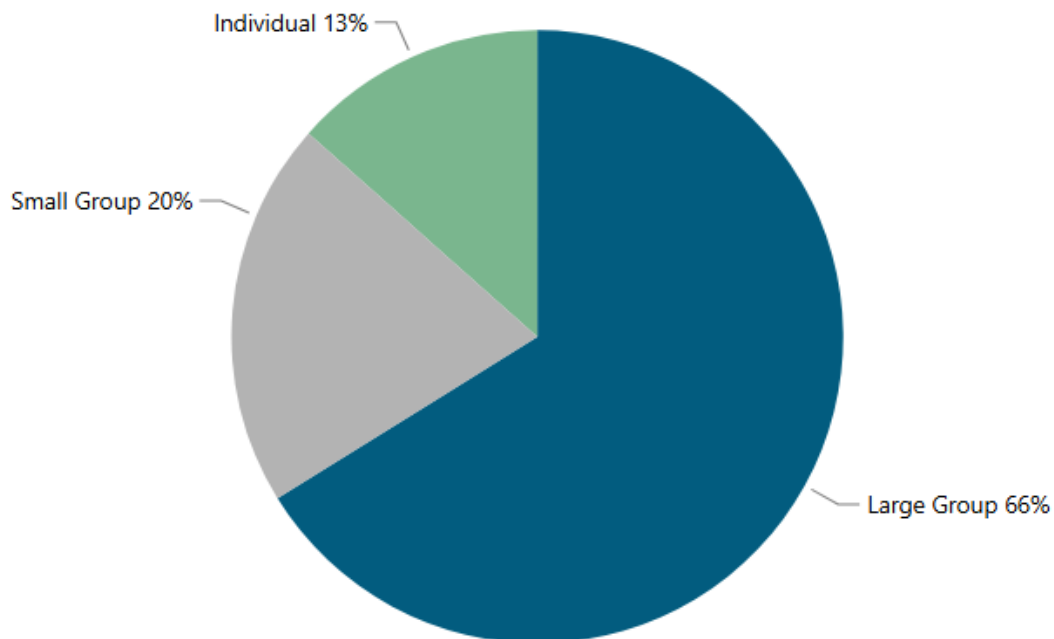


Figure 5 Data call total annual percent spend (payer paid) by market

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

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 patient 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 Ozempic, 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 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 17 Plan design analysis from 2023 data call

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 incredibly 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.⁴⁸

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.⁴⁹ The cost of 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.⁵⁰ 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.⁵¹ Copayments for Ozempic can vary, with patients typically paying a percentage of the drug's total cost, often ranging from \$30 to \$100.⁵² 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). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Table 18 and 19 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.

⁴⁸ 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/>.

⁴⁹ Ozempic Costs: Pricing, Coverage, and Affordability. Concierge MD 2024. <https://conciernemdla.com/blog/ozempic-costs-pricing-coverage-affordability/#:~:text=In%20the%20USA%2C%20Ozempic's%20price,involves%20evaluating%20its%20cost%2Deffectiveness.>

⁵⁰ 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/>.

⁵¹ Ozempic Costs: Pricing, Coverage, and Affordability. Concierge MD 2024. <https://conciernemdla.com/blog/ozempic-costs-pricing-coverage-affordability/#:~:text=In%20the%20USA%2C%20Ozempic's%20price,involves%20evaluating%20its%20cost%2Deffectiveness.>

⁵² Ibid.

Table 18 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 19 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.

Information from manufacturers

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^{56,57}

- 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-1's has been used off label for both pediatric and adult Type 1 diabetes mellitus patients to manage their diseases. GLP-1's is 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.^{58, 59}
 - Semaglutide is a glucose-dependent insulinotropic polypeptide (CIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist. GLP-1

⁵⁶ Ozempic Prescribing Information. Novo Nordisk. Plainsboro, NJ 09/2023. <https://www.novo-pi.com/ozempic.pdf>.

⁵⁷ Rybelsus Prescribing Information. Novo Nordisk. Plainsboro, NJ 01/2024. <https://www.rybelsus.com/prescribing-information.html>.

⁵⁸ 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>.

⁵⁹Gallagher, 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 use of weight loss.^{60, 61, 62}

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 52.⁶³
- 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.⁶⁴ Semaglutide SC resulted in a dose-dependent weight loss of 3.5 to 6.5 kg in clinical trials.⁶⁵
- In January 2020, the FDA labeling of semaglutide SC (Ozempic) was expanded to include the reduction of risk of major adverse CV events.⁶⁶ 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.⁶⁷ 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

⁶⁰ 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>.

⁶¹ 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>.

⁶² 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.literatunonline.com/doi/10.1111/dom.12932>.

⁶³ FDA Center for Drug Evaluation and Research. Semaglutide Clinical Review. Application Number: 209637Prog1s000: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000MedR.pdf.

⁶⁴ 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/>.

⁶⁵ Ibid.

⁶⁶ Ozempic Prescribing Information. Novo Nordisk. Plainsboro, NJ 09/2023. <https://www.novo-pi.com/ozempic.pdf>.

⁶⁷ 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).⁶⁸ 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).⁶⁹

- 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^{70,71}

- 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

⁶⁸ FDA Center for Drug Evaluation and Research. Semaglutide Clinical Review. Application Number: 209637Prog1s000. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000MedR.pdf.

⁶⁹ Ibid.

⁷⁰ Ozempic Prescribing Information. Novo Nordisk. Plainsboro, NJ 09/2023. <https://www.novo-pi.com/ozempic.pdf>.

⁷¹ Rybelsus Prescribing Information. Novo Nordisk. Plainsboro, NJ 01/2024. <https://www.rybelsus.com/prescribing-information.html>.

no evidence that one GLP-1 is associated with higher rates of GI symptoms than 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).⁷² 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.⁷³ Despite, an increased risk compared to placebo, the absolute risk remains small (additional 27 cases per 10,000 persons treated per year).⁷⁴

Therapeutic alternatives

FDA-approved indications^{75,76,77,78,79}

Drug	Formulation	Dosing Frequency	Indications (per label)		
			T2DM	CV Risk Reduction	CKD
semaglutide (Ozempic)	SubQ	Weekly	Yes	Yes	Yes

⁷² 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/>.

⁷³ 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/>.

⁷⁴ Ibid.

⁷⁵ 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

⁷⁶ U.S. Food & Drug Administration. *Byetta (exenatide) Prescribing Information*. Teva Pharms., Action year 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf

⁷⁷ 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

⁷⁸ 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

⁷⁹ 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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf)

Drug	Formulation	Dosing Frequency	Indications (per label)		
			T2DM	CV Risk Reduction	CKD
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		
<u>Abbreviations:</u> CKD: chronic kidney disease; CV: cardiovascular; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus					

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%	_____
Exenatide ER (Bydureon)	1.5%	1.5 - 2.5 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*

Drug	~A1C Decrease	Short term weight loss	Rates of nausea	Cardiovascular Benefits
<p><u>Abbreviations:</u> CV: cardiovascular; ER: extended release; kg: kilogram; MACE: major adverse cardiovascular events; NNT: number needed to treat; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus</p> <p>*Unpublished data. Pending publication of CV outcomes trial.</p>				

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.⁸⁰ 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 reduction in body weight (-4.4 kg vs. -3.1 kg; p=0.003), with no known effects on CV outcomes.⁸¹
- 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

⁸⁰ 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>.

⁸¹ 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.

metformin, sodium-glucose cotransporter 2 inhibitors (SGLT2i), and inhibitors of dipeptidyl peptidase 4 (DPP-4).⁸²

Safety & therapeutic considerations

Drug	Boxed warning	Notable warnings/precautions (selected)
Ozempic	Thyroid C-cell tumors	Pancreatitis; diabetic retinopathy complications; AKI/dehydration; gallbladder disease; hypoglycemia with SU/insulin; delayed gastric emptying affecting oral meds.
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.
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.
Victoza	Thyroid C-cell tumors	Pancreatitis; renal impairment cautions; hypersensitivity; gallbladder disease; daily injection/titration requirements.
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.

Strengths, dosing & route

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
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).
Rybelsus	Oral, once daily (empty stomach)	R1: 3 mg to 7 mg to 14 mg; R2: 1.5 mg to 4 mg to 9 mg	Tablets: R1 3/7/14 mg; R2 1.5/4/9 mg.

⁸² 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>.

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
	with ≤4 oz water; wait ≥30 min)	(formulations not mg-for-mg substitutable).	
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.
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.
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 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.

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: 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 20 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%
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%

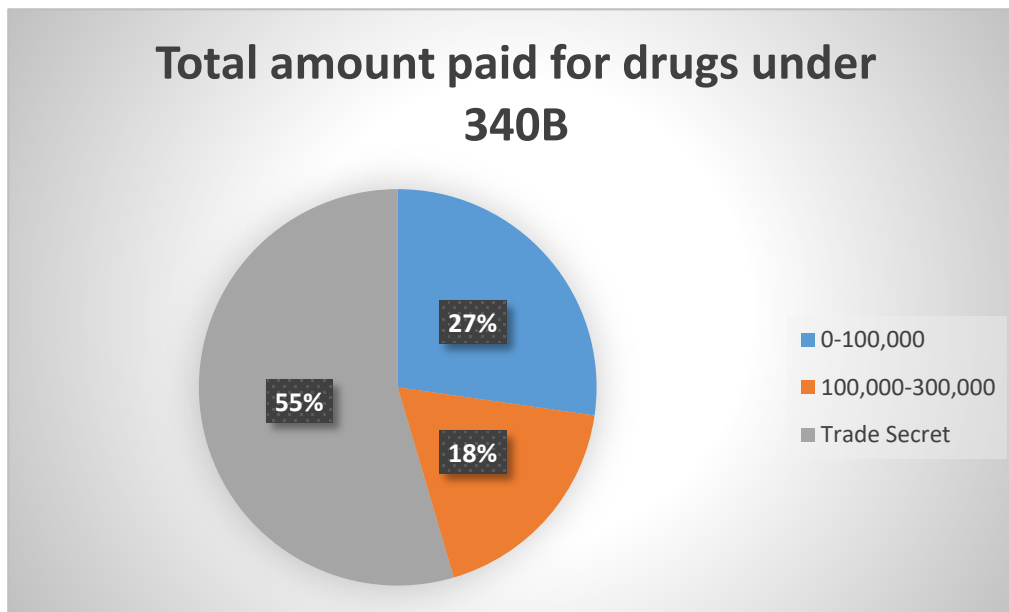


Figure 6 Amounts paid for drug under 340B discount program

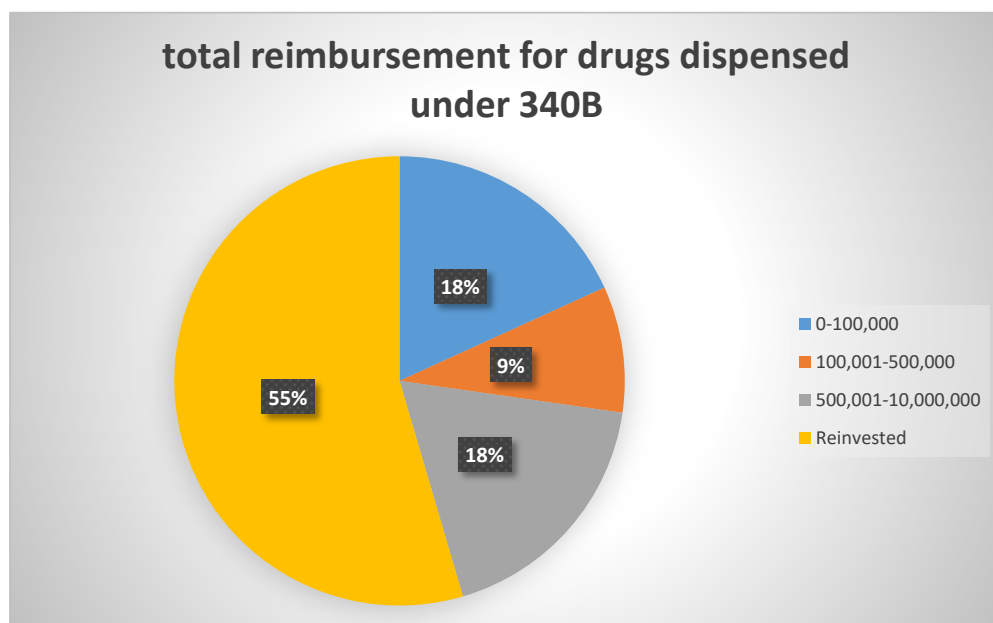


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

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



Rybelsus[®] (*semaglutide*)¹

Version 1.0



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

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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 CMA drug price negotiation list (effective year)
Rybelsus⁵	<i>semaglutide</i>	Novo Nordisk Inc.	2017	13	2026-2039		Yes (2027)
Byetta⁶	<i>Exenatide synthetic</i>	Astrazeneca Ab	2005				No
Ozempic	<i>semaglutide</i>	Novo Nordisk Inc.	2017	19	2025-2028	2028	Yes (2027)
Trulicity⁷	<i>dulaglutide</i>	Eli Lilly and Co.	2014				No
Victoza⁸	<i>liraglutide</i>	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 No exclusivity was listed for Rybelsus in the U.S. Food & Drug Administration Orange Book Database. 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 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>.

⁷ No patent or exclusivity information was listed for Trulicity in the U.S. Food & Drug Administration Purple Book Database. <https://purplebooksearch.fda.gov/>.

⁸ 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^{9,10}

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 concessions¹¹

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 payers¹²

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

Drug	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

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 APAC annual enrollee out-of-pocket (OOP) cost

Drug	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 (example)

Domain	Consideration
Impact & equity	Minor disparities; may affect underserved populations
Access	61% plans have Rx as non-preferred; 67% require prior-auth
Utilization	15,787
Price evaluation	change in WAC between 0% to 3.99% for four 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
Therapeutic alternative	Rx has 2-6 TA/TE/Biosim
Stakeholder input	No concerns raised; positive feedback or minimal stakeholder input
Patent expirations	Patent is expiring in 18 months but manufacturer is actively seeking exclusivity extensions ¹⁴
Maximum Fair Price	Drug on MFP, but no negotiated price set.

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>.

¹⁴ Novo Nordisk vs. Apotex – A GLP-1 Clash. Habib & Mason, Oct. 25, 2024. [Novo Nordisk vs. Apotex – A GLP-1 Clash — H&M Law](#). See also Soni, Aruni. “Novo Nordisk Sues Apotex to Block Generic Version of Rybelsus.” Bloomberg Law, Oct. 14, 2024. <https://news.bloomberglaw.com/ip-law/novo-nordisk-sues-apotex-to-block-generic-version-of-rybelsus>. See also Buntz, Brian. “Lilly, Novo Nordisk battle surge in copycat weight-loss drugs amid safety concerns.” Drug Discovery & Development, Oct. 22, 2024. <https://www.drugdiscoverytrends.com/lilly-novo-nordisk-battle-surge-in-copycat-weight-loss-drugs-amid-safety-concerns/>.

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 information¹⁵

Drug proprietary name(s)	Rybelsus®
Non-proprietary name	<i>semaglutide</i>
Manufacturer	Novo Nordisk
Treatment: Rybelsus is a glucagon-like peptide 1 (GLP-1) receptor agonist	<ul style="list-style-type: none">Used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
Dosage and strength	3mg, 7mg, and 14mg
Form/Route	Tablet/Oral

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

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 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

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>.

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>.

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 syringe of 3ml)	1 package (4 pens of 0.5ml)	1 package (3 pens of 9ml)

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

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

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

²³ Idib.

of **4.6 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2019-2020, 2022-2023, and 2023-2024** (see Figures 1 and 2).²⁴

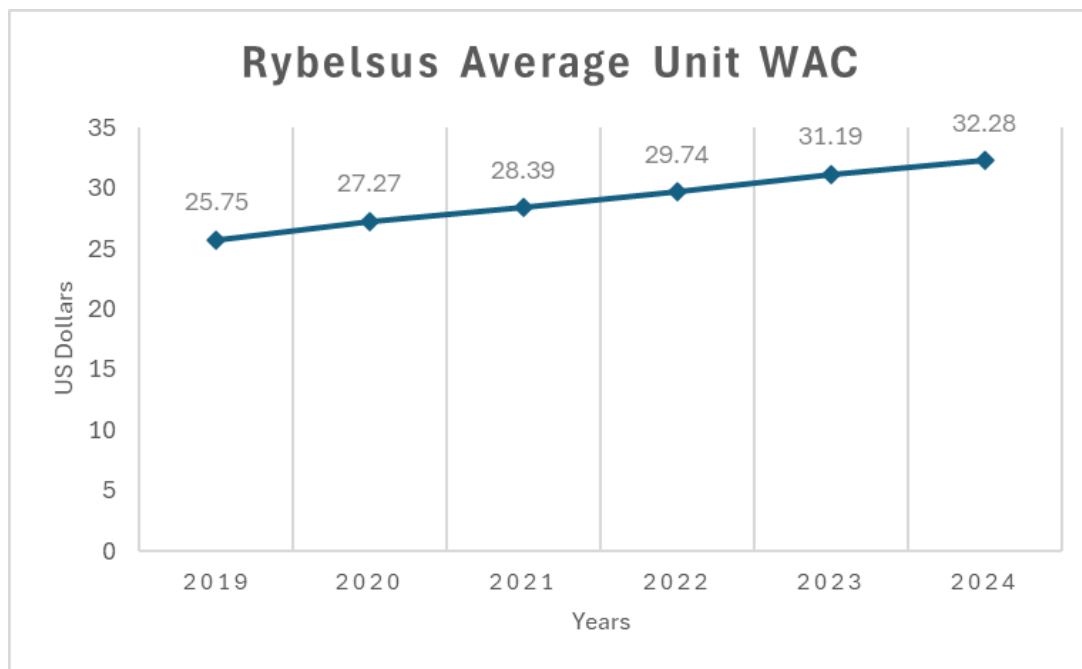


Figure 1 Rybelsus average unit WAC from 2018-2024

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

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%

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

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

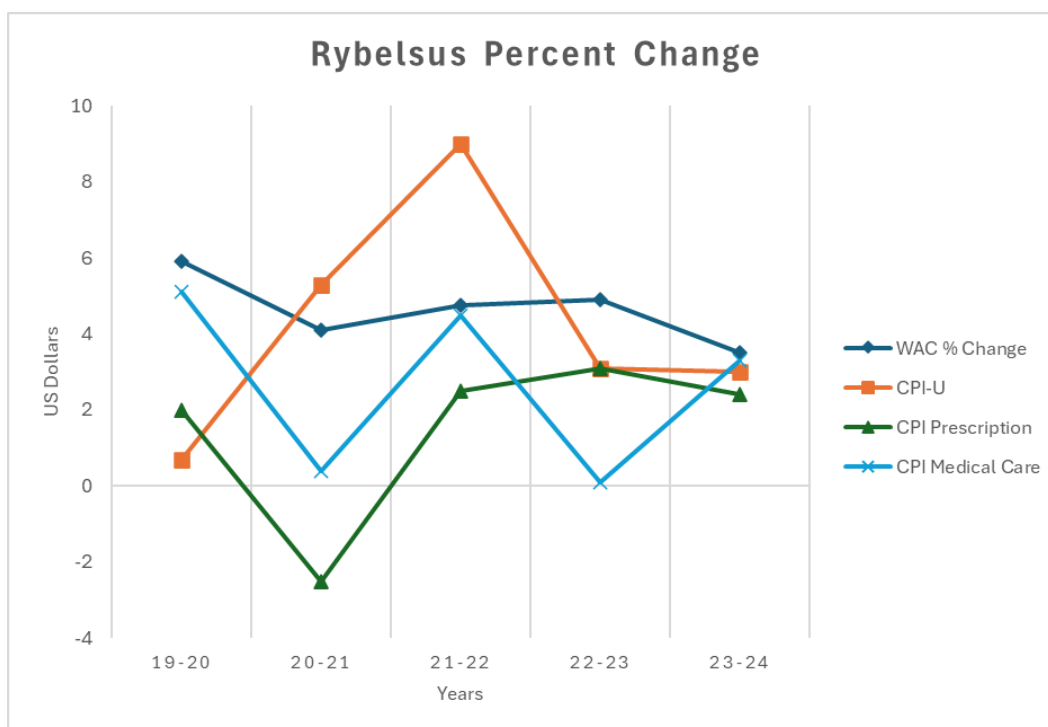


Figure 2 Year over year change in WAC compared to inflation rates²⁶

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **\$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 Figure 3).²⁷ Relative to the **\$32.28 WAC** in end-of-year 2024, an **AAAC discount of 3.9 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 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	\$26.82	\$28.39
2022	\$29	\$29	\$29	\$29	\$28.59	\$29.74

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/>.

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC Average	Average unit WAC
2023	\$30	\$30	\$30	\$30	\$30.02	\$31.19
2024	\$31	\$31	\$31	\$31	\$31.08	\$32.28

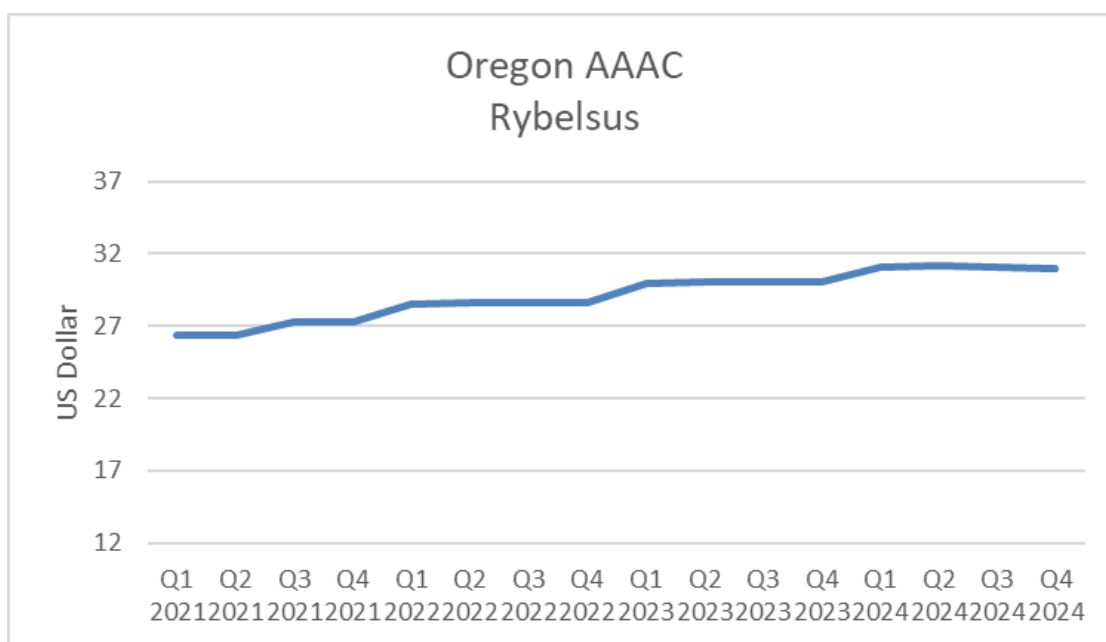


Figure 3 AAAC For Rybelsus from Q1 2021 to Q4 2024

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

	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.

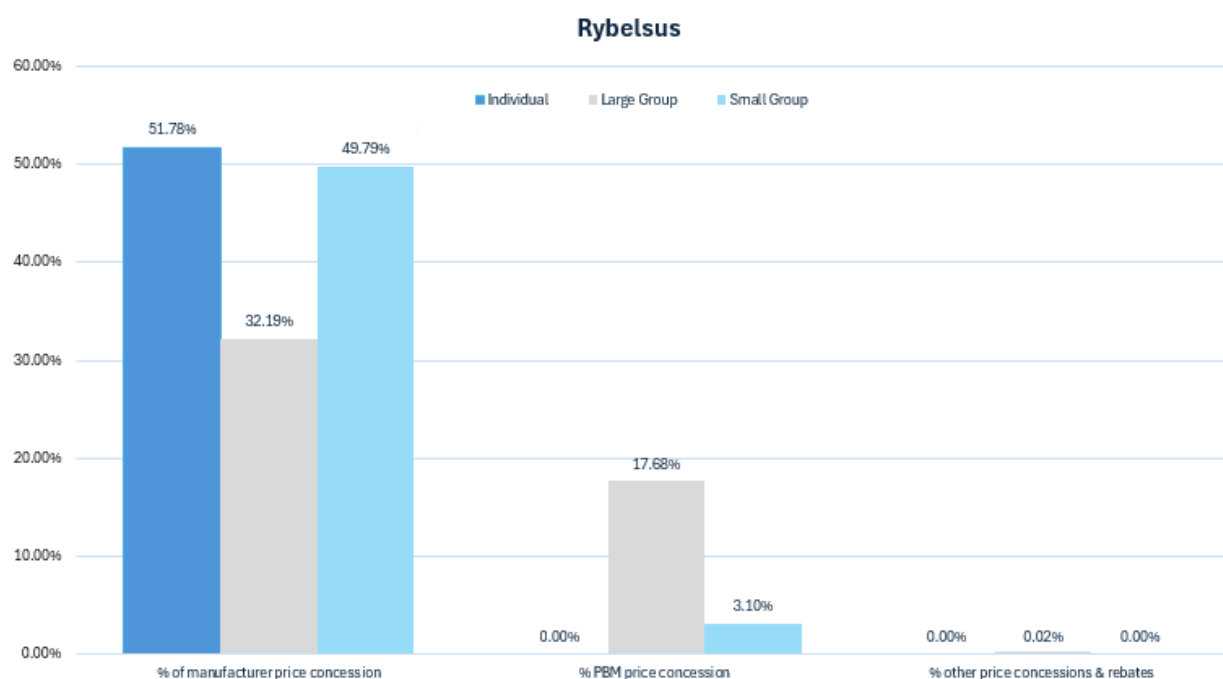


Figure 4 Percent of price concession in each market type^{28, 29}

²⁸ 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.fda.gov/oc/2024/04/24/cfr-2024-title42-vol3-sec423-100.pdf).

²⁹ 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 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 alternatives³⁰

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.

³⁰ 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) PDAB 1-2023: Prescription Drug Affordability Review (oregon.gov).

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 alternatives³¹

Drug	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid ³²	Payer paid/claim	Patient paid/claim ³³
<i>Subject Drug</i> Rybelsus (Data call)³⁴	1,424	3,724	\$4,722,455	\$331,150	\$1,268	\$89
<i>Subject Drug</i> 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 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.

³¹ 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.

³² The cost includes all lines of business.

³³ Ibid.

³⁴ Information from the data call with the cost information after price concessions.

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 \$20,042,008**.

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 ³⁵

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	3,612³⁶	15,787	\$20,042,008		

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.

³⁵ 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.

³⁶ 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 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives³⁷

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims ³⁸
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 business³⁹

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total ⁴⁰
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 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.**

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

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 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 alternatives⁴¹

Proprietary name	Commercial Cost/ Enrollee	Medicaid Cost/ Enrollee	Medicare Cost/ Enrollee	Total ⁴² Cost per Enrollee	Cost per Enrollee, Median	IQR	Cost per enrollee, 75 th percentile	Cost per enrollee, 95 th 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 submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the **large group** represented the majority of commercial spending (64% of total), followed by small group and individual markets. The **total net cost to the healthcare system was around \$5.1 million**, with payer 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 Estimated 2023 data call total net costs to the healthcare system, payers and OOP/enrollee⁴³

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

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

⁴³ Cost information from the data call is the cost of the drug after price concessions.

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

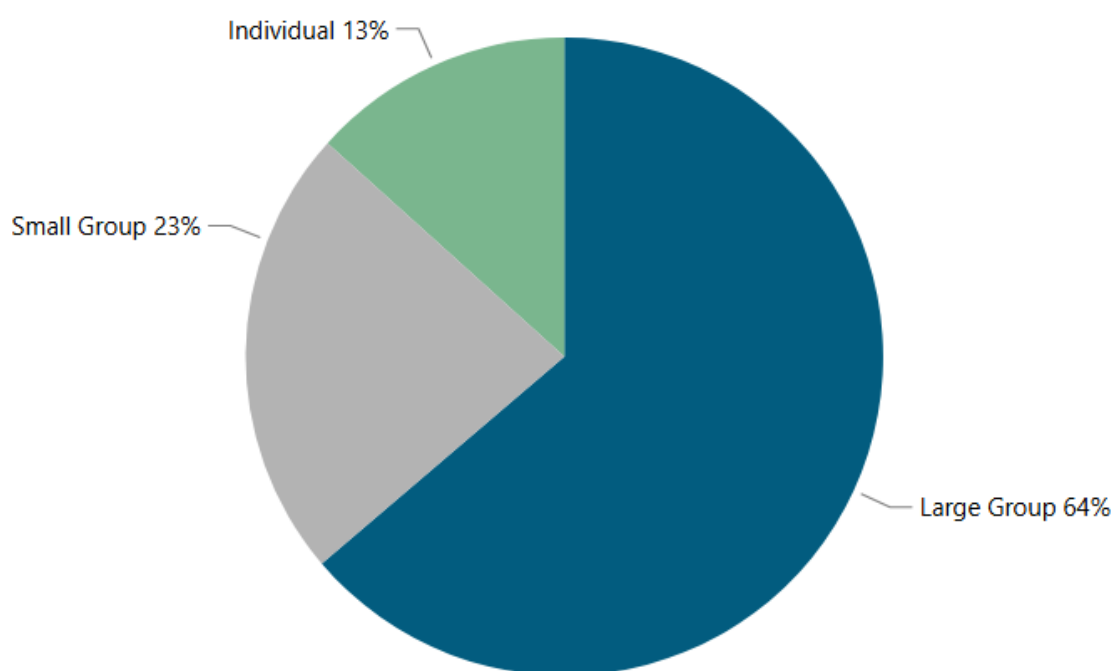


Figure 5 Data call total annual percent spend (payer paid) by market

Impact on patient 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 data call

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 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 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.

Table 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 enrollee⁴⁴

Proprietary name	Annual Medicare OOP cost/enrollee	Annual commercial OOP Cost/enrollee	Total ⁴⁵	Median	IQR	75 th percentile	95 th 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

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 ⁴⁶	Median	IQR	75 th percentile	95 th 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

⁴⁴ 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.

⁴⁵ The total is the overall cost per enrollee across commercial insurers and Medicare.

⁴⁶ The total is the overall cost per claim across commercial insurers and Medicare.

Proprietary name	Medicare OOP cost/claim	Commercial OOP cost/claim	Total ⁴⁶	Median	IQR	75 th percentile	95 th percentile
Victoza	\$93	\$56	\$78	\$4	\$60	\$60	\$400

Information from manufacturers

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 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

FDA-approved indications^{47,48,49,50,51}

Drug	Formulation	Dosing Frequency	Indications (per label)		
			T2DM	CV Risk Reduction	CKD
semaglutide (Ozempic)	SubQ	Weekly	YES	YES	YES
semaglutide (Rybelsus)	Oral	Daily	YES		

⁴⁷ 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.

⁴⁸ U.S. Food & Drug Administration. *Byetta (exenatide) Prescribing Information*. Teva Pharms., Action year 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf.

⁴⁹ 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.

⁵⁰ 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.

⁵¹ 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	Formulation	Dosing Frequency	Indications (per label)		
			T2DM	CV Risk Reduction	CKD
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					

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%	_____
Exenatide ER (Bydureon)	1.5%	1.5 - 2.5 kg	8% - 11%	_____
Liraglutide (Victoza)	1.0% - 1.3%	2.5 kg	18% - 20%	↓ MACE (NNT 53)
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.⁵² 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 reduction in body weight (-4.4 kg vs. -3.1 kg; p=0.003), with no known effects on CV outcomes.⁵³
- 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).⁵⁴

⁵² 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.

⁵³ 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.

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.

Safety & therapeutic considerations

Drug	Boxed warning	Notable warnings/precautions (selected)
Ozempic	Thyroid C-cell tumors	Pancreatitis; diabetic retinopathy complications; AKI/dehydration; gallbladder disease; hypoglycemia with SU/insulin; delayed gastric emptying affecting oral meds.
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.
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.
Victoza	Thyroid C-cell tumors	Pancreatitis; renal impairment cautions; hypersensitivity; gallbladder disease; daily injection/titration requirements.
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.

Strengths, dosing & route

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
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).
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.
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.

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
Victoza	SC, once daily	Start 0.6 mg daily $\times \geq 1$ 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.
Byetta	SC, twice daily (≤ 60 min before morning & evening meals)	Start 5 mcg BID $\times 1$ 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 18 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%

Survey information	Response
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%

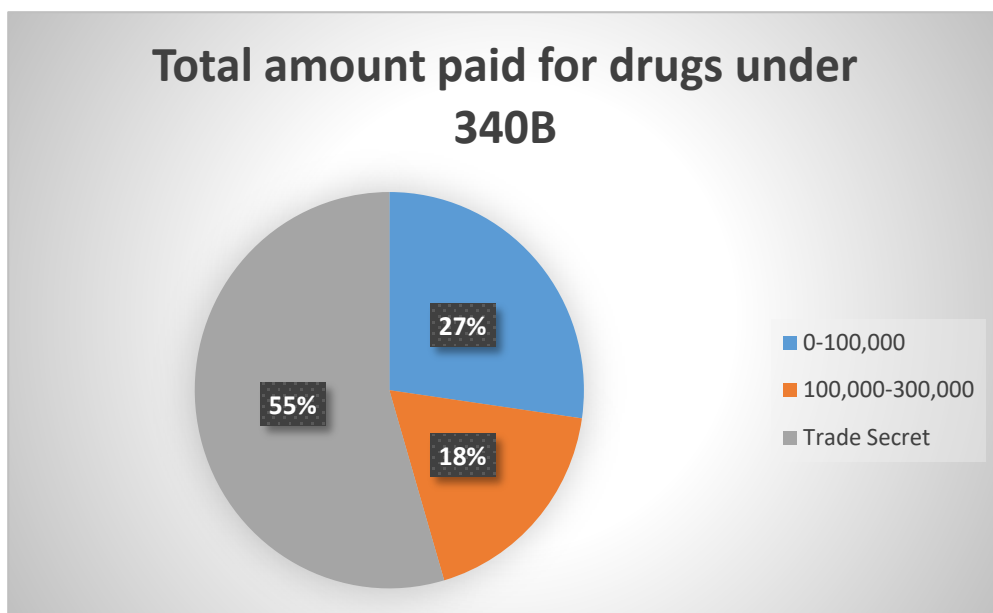


Figure 6 Amounts paid for drug under 340B discount program

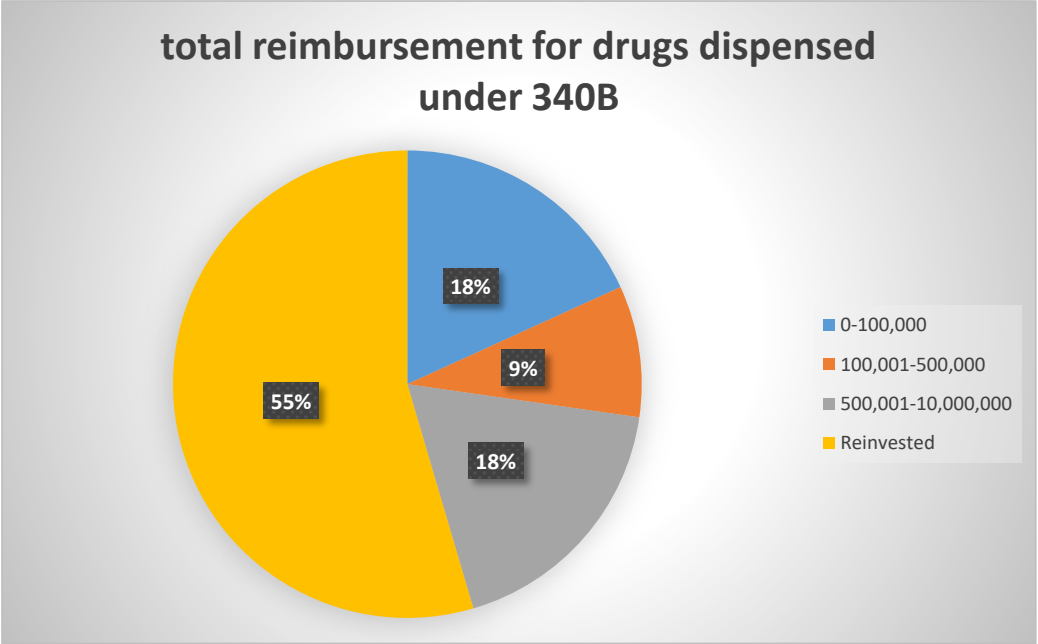


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

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



Trulicity[®] (*dulaglutide*)¹

Version 1.0



¹ Image source: <https://www.adces.org/education/danatech/insulin-medicine-delivery/find-compare-delivery-devices/product-detail/trulicity>

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Review summary

Therapeutic alternatives^{2,3,4}

Trulicity (*dulaglutide*) has the following therapeutic alternatives:

Proprietary name	Non-proprietary name	Manufacturer	Year approved	Number of patents	Patent Date range	Exclusivity expiration	On the CMA drug price negotiation list
Trulicity⁵	<i>dulaglutide</i>	Eli Lilly and Co.	2014				No
Byetta⁶	<i>Exenatide synthetic</i>	Astrazeneca Ab	2005				No
Ozempic	<i>semaglutide</i>	Novo Nordisk Inc.	2017	19	2025-2028	2028	Yes (2027)
Rybelsus⁷	<i>semaglutide</i>	Novo Nordisk Inc.	2017	13	2026-2039		Yes (2027)
Victoza⁸	<i>liraglutide</i>	Novo Nordisk Inc.	2010	4	2025-2037		No

Price history^{9,10}

Trulicity rose at an **average annual rate of 0.6 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
 - Byetta: 3.1 percent

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](https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What%20is%20the%20difference%20between%20patents%20a).

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

⁶ 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>.

⁷ No exclusivity was listed for Rybelsus in the U.S. Food & Drug Administration Orange Book Database.

⁸ No exclusivity was listed for Victoza in the U.S. Food & Drug Administration Orange Book Database.

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/>.

- Ozempic: 4.8 percent
- Rybelsus: 4.4 percent
- Victoza: -2.3 percent

Additionally, the average annual rate of Trulicity exceeded inflation in **2019, 2021, 2023, and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 25.6 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions¹¹

Based on data received from healthcare carriers, Trulicity in 2023 had a **gross spend of \$1,236 per claim**, while the **spend net of discount was \$689 per claim**. Price concession per claim was reported to be **\$547**.

Cost to the payers¹²

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

Drug	Total expenditure	Utilization	Cost per enrollee	Cost per enrollee, median
Trulicity	\$152,767,272	142,338	\$8,187	\$908
Byetta	\$418,695	375	\$5,234	\$826
Ozempic	\$81,017,647	78,032	\$4,427	\$902
Rybelsus	\$15,574,551	11,524	\$6,023	\$973
Victoza	\$26,835,206	20,794	\$6,963	\$1,089

Cost to enrollees¹³

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

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Trulicity	\$528	\$30	\$79	\$10
Byetta	\$297	\$35	\$76	\$4
Ozempic	\$360	\$40	\$89	\$30
Rybelsus	\$530	\$47	\$121	\$40

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>.

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>.

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Victoza	\$367	\$10	\$78	\$4

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)	Trulicity®
Non-proprietary name	<i>dulaglutide</i>
Manufacturer	Eli Lilly and Co.
Treatment: Trulicity is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:	<ul style="list-style-type: none"> • As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus (T2DM). • To reduce the risk of major adverse cardiovascular events in adults with T2DM have established cardiovascular disease or multiple cardiovascular risk factors.
Dosage and strength	<ul style="list-style-type: none"> • 0.75 mg/0.5 mL solution in a single-dose pen • 1.5 mg/0.5 mL solution in a single-dose pen • 3 mg/0.5 mL solution in a single-dose pen • 4.5 mg/0.5 mL solution in a single-dose pen
Form/Route	Injection

FDA approval

Trulicity was first approved by the FDA on **Sept. 18, 2014**.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. Trulicity (*dulaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.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.

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.

Weekly autoinjector simplifies dosing frequency, but device handling and cold-chain storage needs can be harder for patients with visual impairment, neuropathy and dexterity limitations, or limited refrigeration access.^{16,17} Intermittent U.S. supply constraints have persisted into 2025, which can exacerbate inequities when substitution isn't feasible or formularies restrict alternatives.^{18,19} Disparities in GLP-1 use across different ethnic groups and income remain documented.^{20,21}

Residents prescribed

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

Based on APAC claims, **142,338** Oregonians filled a prescription for Trulicity in 2023.²²

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.

Price history

This section examines the pricing dynamics of Trulicity, 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

¹⁶ U.S. Food & Drug Administration. Trulicity (*dulaglutide*) Prescribing information, May 2022.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.

¹⁷ National Diabetes Statistics Report. U.S. Centers for Disease Control and Prevention, May 15, 2024.

<https://www.cdc.gov/diabetes/php/data-research/index.html>.

¹⁸ Current drug shortages: Dulaglutide injection. American Society of Health-System Pharmacists (ASHP), July 17,

2025. [https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-](https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=862&loginreturnUrl=SSOCheckOnly)

[detail.aspx?id=862&loginreturnUrl=SSOCheckOnly](https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=862&loginreturnUrl=SSOCheckOnly).

¹⁹ Rozner, Lisa. "Diabetes patients frustrated as popularity of Ozempic and Trulicity limits supply." CBS News, Jan.

23, 2024. [https://www.cbsnews.com/newyork/news/diabetes-patients-frustrated-as-popularity-of-ozempic-and-](https://www.cbsnews.com/newyork/news/diabetes-patients-frustrated-as-popularity-of-ozempic-and-trulicity-limits-supply/)

[trulicity-limits-supply/](https://www.cbsnews.com/newyork/news/diabetes-patients-frustrated-as-popularity-of-ozempic-and-trulicity-limits-supply/).

²⁰ Moore, J., Iheme, N., Rebold, N. S., Kusi, H., Mere, C., Nwaogwugwu, U., Ettienne, E., Chaijamorn, W., & Rungkitwattanukul, 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>.

²¹ 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.

²² 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>.

view of Trulicity's list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts costs.

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

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

Table 4 Drug vs therapeutic alternatives for 2018-2024 WAC per 30-day supply²³

Year	Trulicity	Byetta	Ozempic	Rybelsus	Victoza
2018	\$730	\$708	\$729		\$870
2019	\$759	\$730	\$772		\$922
2020	\$598	\$752	\$811		\$968
2021	\$633	\$778	\$852	\$852	\$1,016
2022	\$665	\$801	\$892	\$892	\$1,065
2023	\$698	\$825	\$936	\$936	\$1,117
2024	\$733	\$850	\$969	\$969	\$677
Avg. Annual % Change	0.6%	3.1%	4.8%	4.4%	-2.3%
% change 2018 between 2024	0.4%	20.0%	32.8%		-22.2%

The WAC of Trulicity, averaged across six NDCs reported, was approximately **\$489 per unit** at the end of 2024.²⁴ Between 2018-2024, the unit WAC increased at an average annual rate of **5.0 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2018-2019, 2020-2021, 2022-2023, and 2023-2024** (see Figures 1 and 2).²⁵

²³ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

²⁴ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

²⁵ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

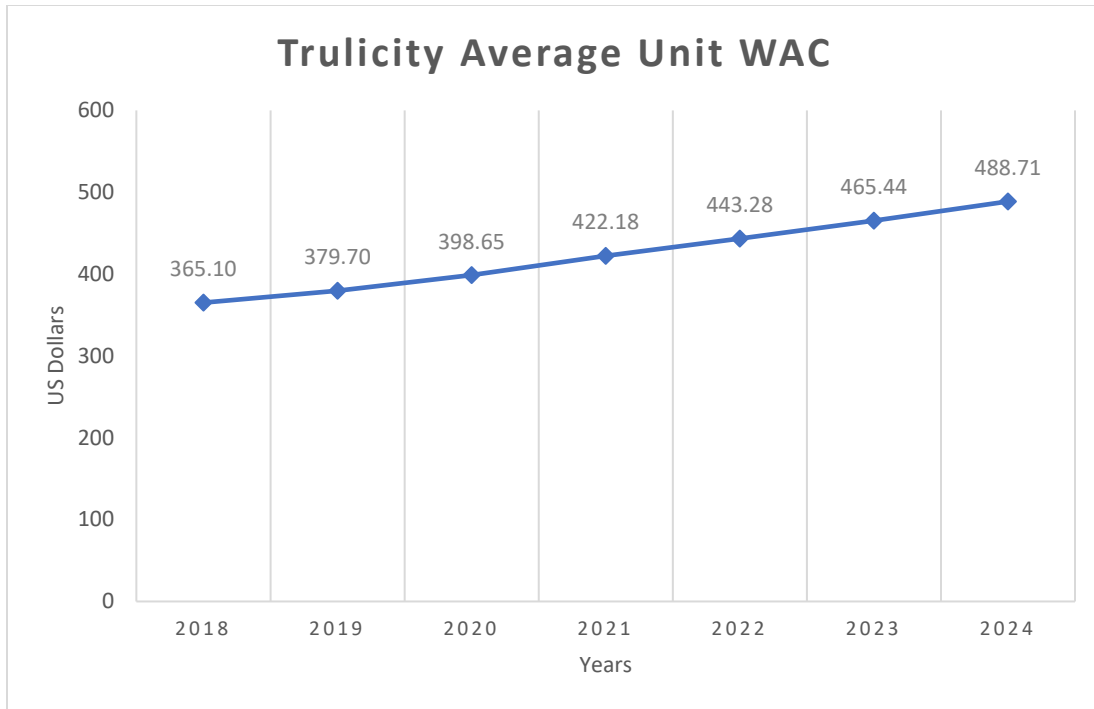


Figure 1 Trulicity average unit WAC from 2018-2024

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison²⁶

Year	Trulicity	Byetta	Ozempic	Rybelsus	Victoza	CPI-U
2018-2019	4.0%		5.9%		5.9%	1.7%
2019-2020	5.0%	3.0%	5.0%		5.0%	0.7%
2020-2021	5.9%	3.5%	-21.3%		5.0%	5.3%
2021-2022	5.0%	3.0%	4.8%	4.8%	4.8%	9.0%
2022-2023	5.0%	3.0%	4.9%	4.9%	4.9%	3.1%
2023-2024	5.0%	3.0%	3.5%	3.5%	-34.1%	3.0%

²⁶ Percentages might differ from Table 4 as Table 5 percentages are based on unit WAC only.

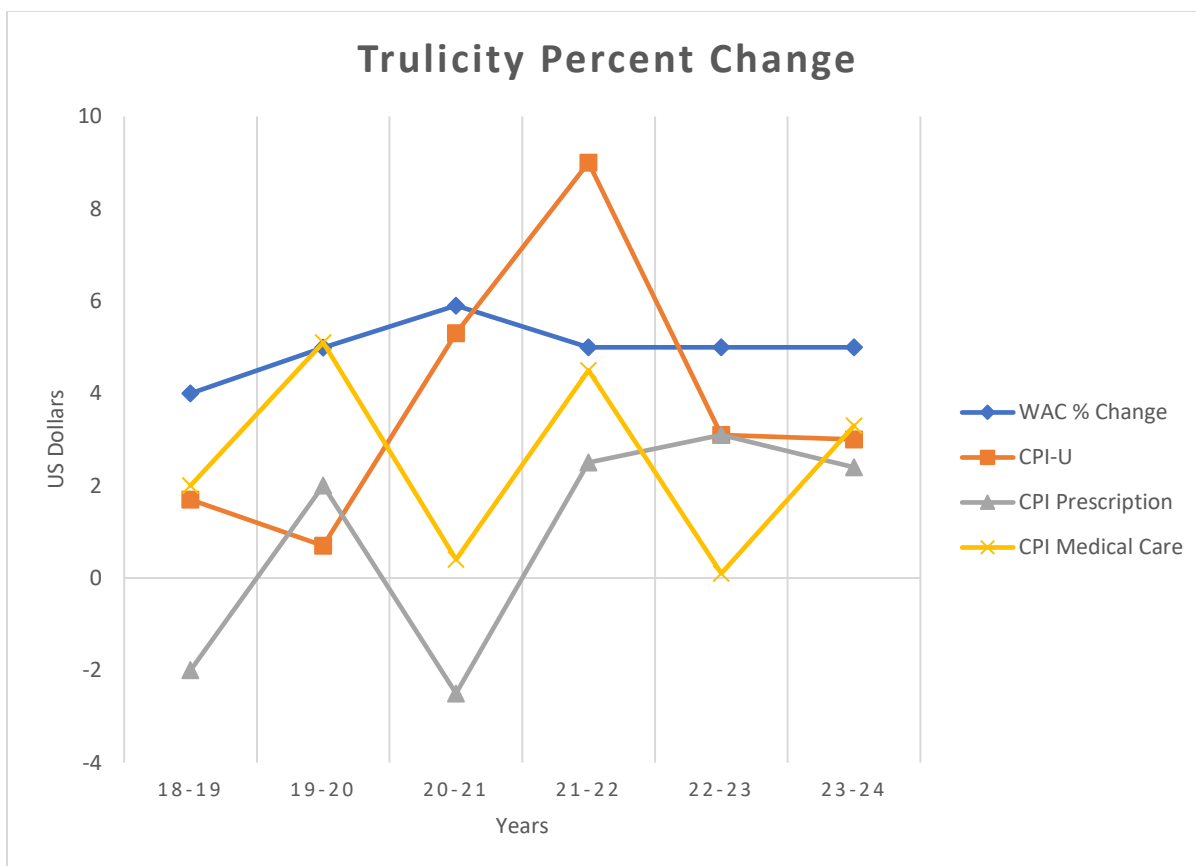


Figure 2 Year over year change in WAC compared to inflation rates²⁷

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **\$374.76 per unit in Quarter 1 of 2020 to \$470.88 per unit in Quarter 4 of 2024**, an approximate **25.6 percent increase** over the period (see Figure 3).²⁸ Relative to the **\$488.71 WAC** in end-of-year 2024 an **AAAC discount of 3.6 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 Trulicity's price trajectory relative to inflation and affordability for public and private payers.

²⁷ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

²⁸ 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 Trulicity

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC Average	Average Unit WAC
2020	\$375	\$382	\$382	\$382	\$380.18	\$398.65
2021	\$403	\$405	\$405	\$405	\$404.63	\$422.18
2022	\$424	\$427	\$427	\$426	\$425.94	\$443.28
2023	\$446	\$447	\$447	\$449	\$447.40	\$465.44
2024	\$471	\$470	\$471	\$471	\$470.74	\$488.71

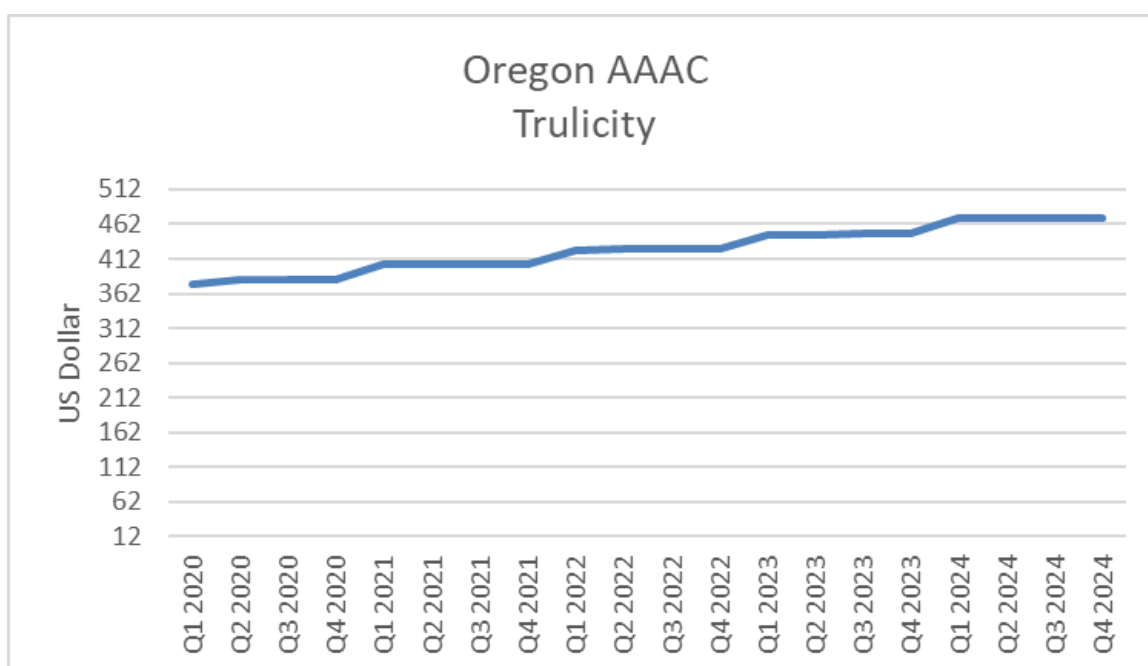


Figure 3 AAAC For Trulicity from Q1 2020 to Q4 2024

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 Trulicity 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 Trulicity per enrollee in the commercial market was approximately \$4,384**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately \$2,445**, reflecting an **estimated mean discount of 44.2 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Trulicity before concessions was \$26,245,521**, with total reported **price concessions amounting to approximately \$11,612,175**, as detailed in Table 7. Notably, **91.7 percent of claims benefited from some form of price concession**, leaving **8.2 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	5,986
Total number of claims	21,238
Total number of claims with price concessions applied	19,465

Percentage of claims with price concessions applied	91.7%
Percentage of cost remaining after concessions	55.8%
Percentage of discount	44.2%

Manufacturer price concessions for all market types	\$9,829,548
PBM price concessions for all market types	\$1,782,049
Other price reductions for all market types	\$578

Cost before price concessions across all market types	\$26,245,521
Total price concessions across all market types	\$11,612,175
Cost of after price concessions across all market types	\$14,633,347

Avg. payer spend per enrollee without price concessions	\$4,384
Avg. payer spend per enrollee with price concessions	\$2,445

Including all market segments, the **gross spend of Trulicity per claim for commercial carriers was \$1,236** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **\$689**, meaning that insurers reported a price concession of **\$547** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types

	Average	Individual Market	Large Market	Small Market
Spend per Claim, gross	\$1,236	\$1,192	\$1,248	\$1,232
Spend per Claim, net	\$689	\$627	\$717	\$637
Price Concessions per Claim	\$547	\$565	\$530	\$594

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

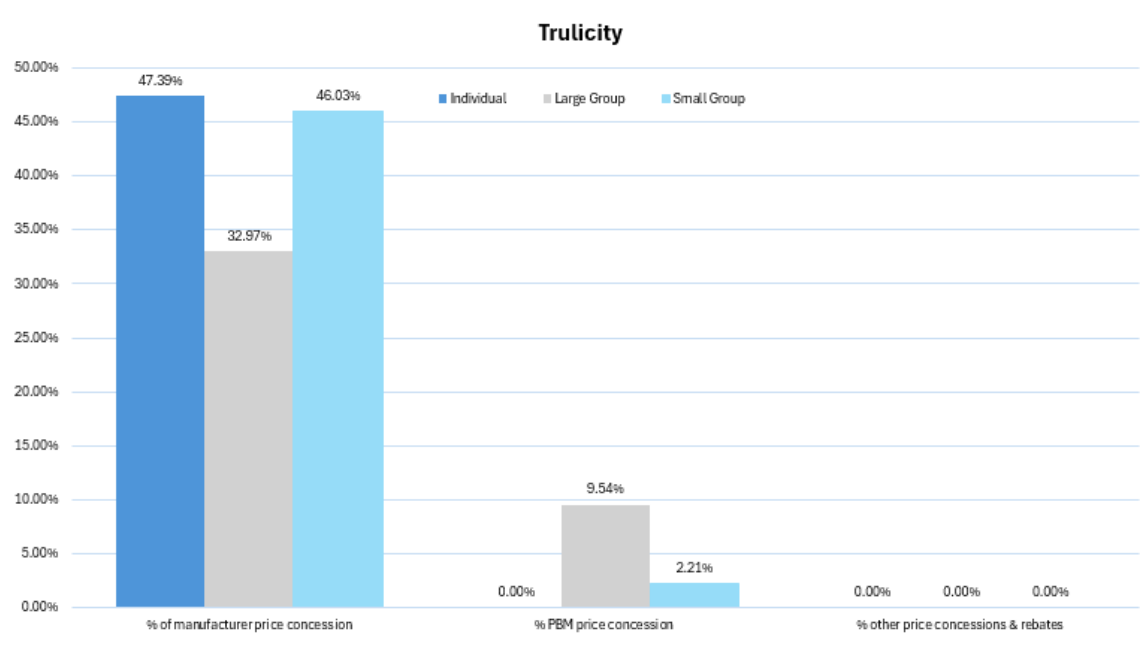


Figure 4 Percent of price concession in each market type^{29, 30}

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

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 Trulicity 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 Trulicity 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.

Trulicity's gross total payer paid, based on APAC data, **was \$152.8 million**, while total net payer paid received from the **carriers indicated a cost of \$23.1 million**. **Trulicity has the highest gross total pay** in consideration with its therapeutic alternatives. The second highest is Ozempic with **\$81.0 million**. Notably, Trulicity has the **most utilization among the drugs, at 142,338 claims**, as compared to the second highest utilization of Ozempic, at 78,032 claims. Only Ozempic has a lower payer paid per claim than Trulicity, which are \$1,038 and \$1,073 respectively.

Trulicity also has the highest total enrollee paid at \$8.3 million and Ozempic follows behind with \$6.2 million. Rybelsus has the highest patient paid per claim of \$111, which is higher than both Trulicity at \$60 and Ozempic at \$80. The drug with the lowest patient paid per claim is Byetta, which is \$49.

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) PDAB 1-2023: Prescription Drug Affordability Review (oregon.gov). Accessed 01/09/2024.

Ozempic and Rybelsus have been designated by the FDA as being in a 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 Trulicity vs therapeutic alternatives³²

Drug	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid ³³	Payer paid/claim	Patient paid/claim ³⁴
<i>Subject Drug</i> Trulicity (Data call)³⁵	5,986	21,238	\$23,128,584	\$2,186,726	\$1,089	\$103
<i>Subject Drug</i> Trulicity (APAC)	18,659	142,338	\$152,767,272	\$8,337,684	\$1,073	\$60
Byetta	80	675	\$418,695	\$18,421	\$1,117	\$49
Ozempic	18,301	78,032	\$81,017,647	\$6,223,820	\$1,038	\$80
Rybelsus	2,586	11,524	\$15,574,551	\$1,282,285	\$1,351	\$111
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 Trulicity, 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.

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 cost includes all lines of business.

³⁴ Ibid.

³⁵ Information from the data call with the cost information after price concessions.

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 Trulicity 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 **142,338 total claims for Trulicity among 21,058 total enrollees**, corresponding to a **total payer expenditure of \$152,767,272**.

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 **61,023** claims from **9,623** enrollees and a total spend of **\$75.6 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **\$46.9 million** and **\$30.3 million**, respectively.

Table 10 Estimated 2023 APAC total annual gross payers expenditure for total enrollees and total claims ³⁶

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	6,837	47,256	\$46,916,082	\$6,862	\$993
Medicaid	4,598	34,059	\$30,280,945	\$6,586	\$889
Medicare	9,623	61,023	\$75,570,255	\$7,853	\$1,238
Totals	21,058³⁷	142,338	\$152,767,272		

Table 11 provides utilization for the healthcare system for Trulicity and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the most utilization** among the

³⁶ 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.

³⁷ The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

drugs, with **142,338 claims**. In all lines of business, Trulicity is the most utilized. **Ozempic is the second most utilized at 78,032 claims**.

Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives³⁸

Proprietary name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total claims ³⁹
Trulicity	47,256	34,059	61,023	142,338
Byetta	56	132	187	375
Ozempic	37,201	8,338	32,493	78,032
Rybelsus	4,571	962	5,991	11,524
Victoza	6,379	5,180	9,235	20,794

Table 12 shows the overall payer expenditure of Trulicity and its therapeutic alternatives, distinguished by lines of business. Trulicity has a **total expenditure of \$161.1 million** with **Medicare being the biggest portion at \$80.8 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 business⁴⁰

Proprietary name	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total ⁴¹
Trulicity	\$46,916,082	\$30,280,945	\$75,570,255	\$152,767,272
Byetta	\$61,211	\$105,425	\$252,059	\$418,695
Ozempic	\$36,494,230	\$7,438,499	\$37,084,917	\$81,017,647
Rybelsus	\$5,975,209	\$1,099,301	\$8,500,041	\$15,574,551
Victoza	\$7,708,332	\$5,519,972	\$13,606,902	\$26,835,206

Table 13 compares the overall payer cost per enrollee of Trulicity and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the highest total cost per enrollee at \$8,187**. Trulicity has **highest cost per enrollee in all lines of business**. The median cost per enrollee for Trulicity is \$908, which is comparable to the median cost per enrollee for Ozempic

³⁸ 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.

³⁹ Total is the sum of all utilization for the drug across all lines of business.

⁴⁰ 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.

⁴¹ Total is the sum of all expenditure for the drug across all lines of business.

at \$902. **Rybelsus and Victoza have higher median costs per enrollee as compared to Trulicity,** at \$973 and \$1,089 respectively.

Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives⁴²

Proprietary name	Commercial Cost/ Enrollee	Medicaid Cost/ Enrollee	Medicare Cost/ Enrollee	Total ⁴³ Cost per Enrollee	Cost per Enrollee, Median	IQR	Cost per Enrollee, 75 th percentile	Cost per Enrollee, 95 th percentile
Trulicity	\$6,862	\$6,586	\$7,853	\$8,187	\$908	\$1,359	\$2,200	\$2,910
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
Rybelsus	\$6,036	\$5,336	\$5,870	\$6,023	\$973	\$1,650	\$2,502	\$2,925
Victoza	\$5,542	\$5,349	\$6,876	\$6,963	\$1,089	\$1,209	\$2,182	\$3,514

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the large group represented the majority of commercial spending (68% of total), followed by individual and small group markets. The collected **total net cost to the healthcare system was around \$25.3 million**, with payer paying **\$23.1 million**, and enrollees out-of-pocket estimating to be **\$2.2 million**. Table 14 includes the average plan costs per enrollee in the commercial market, ranging from **\$4,305 (individual)** to **\$3,929 (small group)** annually.

Table 14 Estimated 2023 data call annual total net costs to the healthcare system, payers and OOP/enrollee⁴⁴

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of-pocket cost
Individual	3,567	988	\$4,252,909	\$3,599,306	\$653,602
Large Group	14,172	4,003	\$17,152,829	\$15,975,770	\$1,177,059
Small Group	3,499	995	\$3,909,573	\$3,553,508	\$356,065
Total	5,986	21,238	\$25,315,310	\$23,128,584	\$2,186,726

⁴² 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.

⁴³ The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

⁴⁴ Cost information from the data call is the cost of the drug after price concessions.

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	\$1,192	\$1,009	\$183	\$4,305	\$3,643	\$662
Large Group	\$1,210	\$1,127	\$83	\$4,285	\$3,991	\$294
Small Group	\$1,117	\$1,016	\$102	\$3,929	\$3,571	\$358

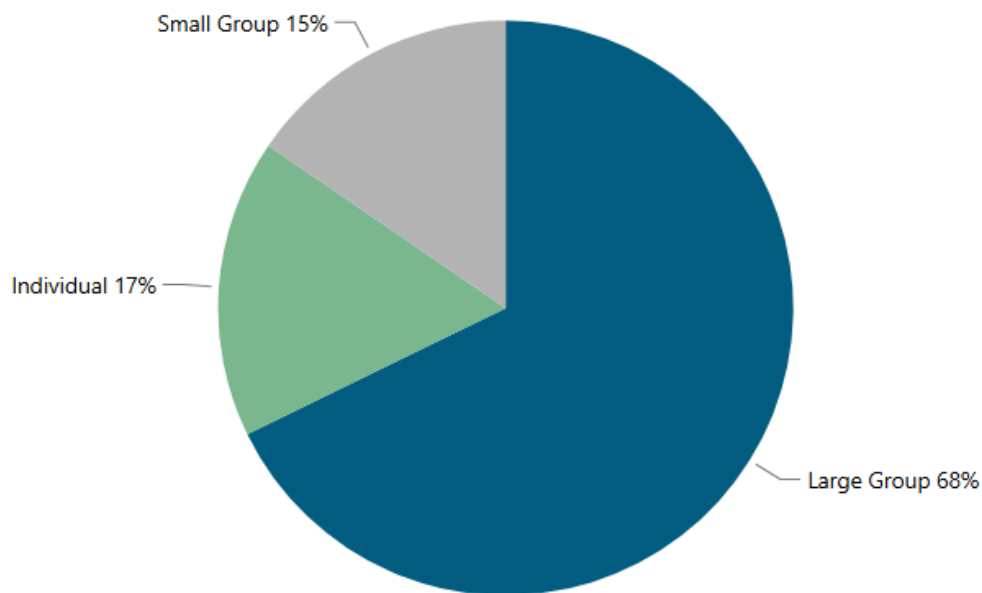


Figure 5 Data call total annual percent spend (payer paid) by market

Table 15 indicates CCOs reported Trulicity as having an annual greatest increase from 2022-2023 (rebates not included) with a **\$5.3 million year-over-year increased cost growth**.

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

Medicaid CCOs ⁴⁵			
2022	2023	YoY change in spending	Percent of total CCO cost 2023
\$22,160,030	\$27,421,046	\$5,261,016	0.4%

Impact on patient 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 Trulicity, 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 Trulicity. In 2023, approximately **76.5 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **11.9 percent of plans required step therapy** before approving its use.

For formulary placement, **34.7 percent of plans categorized Trulicity as a non-preferred drug**, and **no plans excluded it entirely from the formulary**.

Table 16 Plan design analysis from 2023 data call

Percentage of Plans	
Required Prior Authorization	76.5%
Required Step Therapy	11.9%
On a non-preferred formulary	34.7%
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.

⁴⁵ 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>.

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 Trulicity 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 becomes available.

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 Trulicity 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 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.

Table 17 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee⁴⁶

Proprietary name	Annual Medicare OOP cost/enrollee	Annual Commercial OOP cost/enrollee	Total ⁴⁷	Median	IQR	75 th percentile	95 th percentile
Trulicity	\$569	\$451	\$528	\$30	\$125	\$125	\$843
Byetta	\$362	\$75	\$297	\$35	\$146	\$146	\$455
Ozempic	\$399	\$313	\$360	\$40	\$115	\$115	\$673
Rybelsus	\$560	\$476	\$530	\$47	\$161	\$165	\$828
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 ⁴⁸	Median	IQR	75 th percentile	95 th percentile
Trulicity	\$90	\$65	\$79	\$10	\$50	\$50	\$446
Byetta	\$93	\$19	\$76	\$4	\$89	\$89	\$441
Ozempic	\$106	\$75	\$89	\$30	\$75	\$75	\$454
Rybelsus	\$135	\$103	\$121	\$40	\$101	\$105	\$606
Victoza	\$93	\$56	\$78	\$4	\$60	\$60	\$400

Information from manufacturers

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:
 - Trulicity is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:
 - As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with T2DM.
 - To reduce the risk of major adverse cardiovascular events in adults with T2DM who have established cardiovascular disease or multiple cardiovascular risk factors.
- Limitations of Use:
 - Includes warnings of pancreatitis and gallbladder events.

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.

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

- 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

Clinical efficacy⁴⁹

- Dulaglutide was FDA approved based on three, phase 3, double-blind, randomized controlled trials (RCTs) in patients with T2DM both as monotherapy and as add-on therapy to background metformin with or without additional oral agents. These studies compared dulaglutide to placebo and active comparators including metformin, sitagliptin, and exenatide. The primary outcome in all trials was change in hemoglobin A1c (HbA1C) from baseline to week 26 or 52.⁵⁰
- These initial studies concluded that dulaglutide 0.75 mg and 1.5 mg weekly reduces short term HbA1c from baseline, ranging from -0.71% to -1.51% as monotherapy or as add-on therapy.⁵¹ Dulaglutide resulted in a dose-dependent weight loss of 1 to 3 kg in clinical trials.⁵²
- In February 2020, the FDA labeling of dulaglutide was expanded to include the reduction of risk of major adverse CV events.⁵³ This indication was added based on data from the REWIND study, a double-blind, randomized placebo-controlled trial comparing dulaglutide to placebo in 9,901 adults with T2DM and CV disease on background therapy for glycemic control.⁵⁴ Over a median follow-up of 5.4 years, there was a reduction in the primary composite CV outcome (nonfatal myocardial infarction, nonfatal stroke, CV death) of 1.4% (12% in the dulaglutide group and 13.5% in the placebo group; hazard ratio [HR] 0.99; 95% CI 0.79 to 0.99; p=0.26; number needed to

⁴⁹ U.S. Food & Drug Administration. Trulicity (*dulaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.

⁵⁰ FDA Center for Drug Evaluation and Research. Dulaglutide Summary Review. Application Number: 125469Orig1s000. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000MedRedt.pdf.

⁵¹ Pasqua, MR., Tsoukas, M.A., Kobayati, A. et al. Subcutaneous weekly semaglutide with automated insulin delivery in type 1 diabetes: a double blind, randomized, crossover trial. *Nat Med* 31, 123901245 (2025). <http://doi.org/10.1038/s41591-024-03463-z>.

⁵² Ibid.

⁵³ U.S. Food & Drug Administration. Trulicity (*dulaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.

⁵⁴ Gerstein HC, Colhoun HM, Dagenais GR, et al. Dulaglutide and cardiovascular outcomes in type 2 diabetes (REWIND): a double-blind, randomised placebo-controlled trial. *Lancet*. 2019 Jul 13;394(10193):121-130. doi: 10.1016/S0140-6736(19)31149-3. Epub 2019 Jun 9. PMID: 31189511.

treat [NNT] 71) and an absolute difference of 0.9% in the risk of stroke (HR 0.76; 0.62 to 0.94).

- In September 2020, FDA approved additional, higher doses of dulaglutide (3.0 and 4.5 mg once weekly) based on a randomized, double-blind, parallel-arm study over 52 weeks comparing these higher doses to 1.5 mg weekly in adults with T2DM, BMI \geq 25 kg/m², and on metformin therapy.⁵⁵ There was a significant difference in HbA1C between the 4.5 mg dose compared to 1.5 mg dose (-0.24%; 95% CI -0.36 to -0.11; $p < 0.001$) but not with the 3.0 mg dose (treatment difference -0.10%; 95% CI -.23 to 0.02). The mean change from baseline in HgA1C in each group was -1.54% with 1.5 mg, -1.64% with 3 mg and -1.77% for 4.5 mg. The higher doses also resulted in more weight loss (3 kg in 1.5 mg group, 3.8 kg in 3 mg group, and 4.6 kg in 4.5 mg group).⁵⁶

Clinical safety⁵⁷

- FDA safety warnings and precautions:
 - Risk of Thyroid C-cell Tumors
 - Pancreatitis
 - Hypoglycemia with concomitant use of insulin secretagogues or insulin
 - Hypersensitivity reactions
 - Acute kidney injury
 - Severe gastrointestinal disease
 - Diabetic Retinopathy complications
 - Acute gallbladder disease
- Contraindications:
 - Patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2.
 - Patients with a serious hypersensitivity reaction to dulaglutide or any of the product components.
- Common side effects:
 - Gastrointestinal effects, including diarrhea (9 to 13%), nausea (12-21%), and vomiting (6 to 13%), abdominal pain (6 to 9%), decreased appetite (5 to 9%), and dyspepsia (4 to 6%).
 - 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

⁵⁵ Frias JP, Bonora E, Nevarez Ruiz L, Li YG, Yu Z, Milicevic Z, Malik R, Bethel MA, Cox DA. Efficacy and Safety of Dulaglutide 3.0 mg and 4.5 mg Versus Dulaglutide 1.5 mg in Metformin-Treated Patients With Type 2 Diabetes in a Randomized Controlled Trial (AWARD-11). *Diabetes Care*. 2021 Mar;44(3):765-773. doi: 10.2337/dc20-1473. Epub 2021 Jan 4. PMID: 33397768; PMCID: PMC7896253.

⁵⁶ Ibid.

⁵⁷ Ibid.

no evidence that one GLP-1 is associated with higher rates of GI symptoms than others.

Therapeutic alternatives

FDA-approved indications^{58,59,60,61,62}

Drug	Formulation	Dosing Frequency	Indications (per label)		
			T2DM	CV Risk Reduction	CKD
Dulaglutide (Trulicity)	SubQ	Weekly	Yes	Yes	
semaglutide (Ozempic)	SubQ	Weekly	Yes	Yes	Yes
semaglutide (Rybelsus)	Oral	Daily	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					

⁵⁸ Ozempic https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.

⁵⁹ Byetta https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf.

⁶⁰ Rybelsus https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.

⁶¹ Trulicity https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf.

⁶² Victoza https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf.

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%	_____
Exenatide ER (Bydureon)	1.5%	1.5 - 2.5 kg	8% - 11%	_____
Liraglutide (Victoza)	1.0% - 1.3%	2.5 kg	18% - 20%	↓ MACE (NNT 53)
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*
<p><u>Abbreviations:</u> CV: cardiovascular; ER: extended release; kg: kilogram; MACE: major adverse cardiovascular events; NNT: number needed to treat; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus</p> <p>*Unpublished data. Pending publication of CV outcomes trial.</p>				

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.⁶³ 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

⁶³ 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.

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 reduction in body weight (-4.4 kg vs. -3.1 kg; p=0.003), with no known effects on CV outcomes.⁶⁴
- 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).⁶⁵

Safety & therapeutic considerations

Drug	Boxed warning	Notable warnings/precautions (selected)
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.
Ozempic	Thyroid C-cell tumors	Pancreatitis; diabetic retinopathy complications; AKI/dehydration; gallbladder disease; hypoglycemia with SU/insulin; delayed gastric emptying affecting oral meds.
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.
Victoza	Thyroid C-cell tumors	Pancreatitis; renal impairment cautions; hypersensitivity; gallbladder disease; daily injection/titration requirements.

⁶⁴ 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.

⁶⁵ 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.

Drug	Boxed warning	Notable warnings/precautions (selected)
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.

Strengths, dosing & route

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
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.
Ozempic	SC, once weekly	Start 0.25 mg weekly $\times 4$ 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).
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.
Victoza	SC, once daily	Start 0.6 mg daily $\times \geq 1$ 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.
Byetta	SC, twice daily (≤ 60 min before morning & evening meals)	Start 5 mcg BID $\times 1$ 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 received from three individuals taking or having an association with Trulicity. According to the survey results, 67 percent of respondents had Trulicity covered under the insurance, regardless of the type of insurance used.

Zero patients were on Medicaid, two patients were on Medicare, and one patient had private health insurance. One patient reported that their prescription was not covered, although they were under private health insurance. Two patients reported being on patient assistance programs.

Individuals with scientific or medical training

Surveys to collect information were posted on the PDAB website to collect drug information from individuals with scientific and medical training. There were no reports for Trulicity 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 Trulicity, 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 Trulicity 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 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 Trulicity 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 19 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%

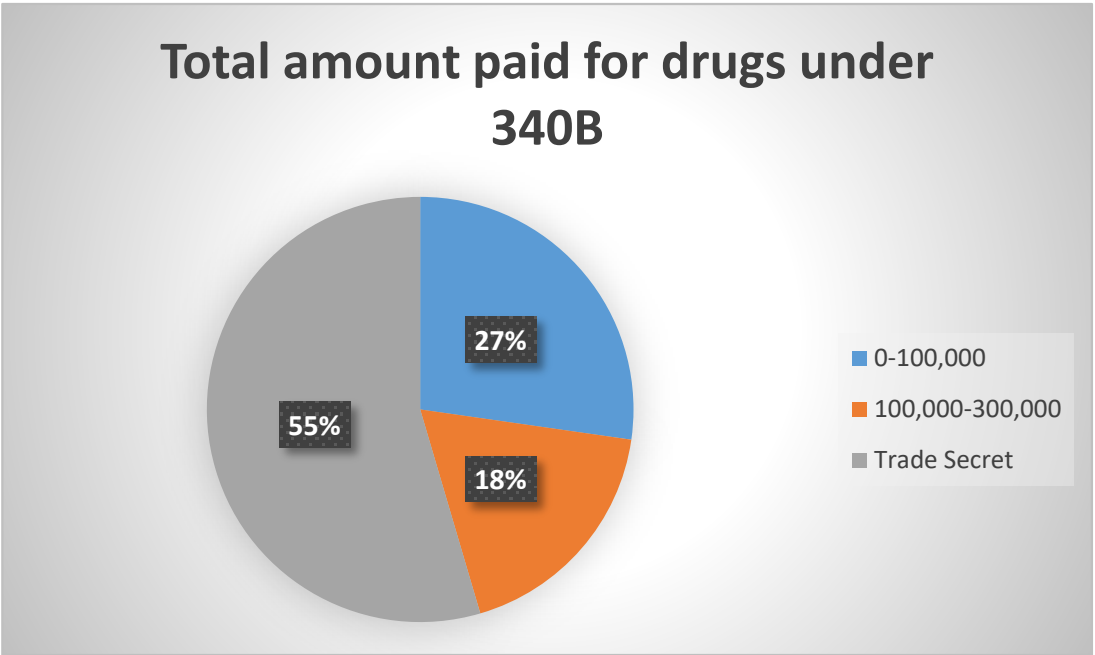


Figure 6 Amounts paid for drug under 340B discount program

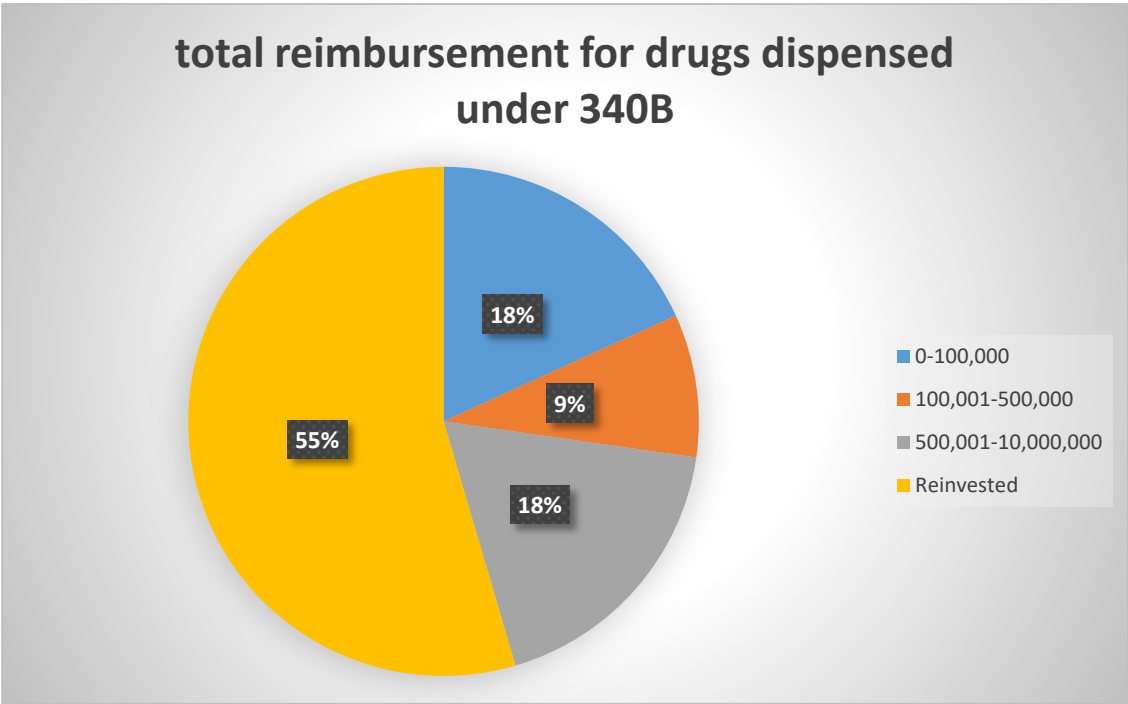


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

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	Trulicity	Letter	5/21/2025	Exhibit A
Cynthia Ransom	Eli Lilly	Trulicity	Letter	5/21/2025	Exhibit B