Oregon Prescription Drug Affordability Board

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Agenda

This is a regular meeting. *Date*: **May 15, 2024** | *Time*: **9:30 a.m.**

This is a draft agenda and subject to change.

Meeting name	**Prescription Drug Affordability Board**
Meeting location	Virtual
Zoom link	Register for the meeting

Board Members: Chair Shelley Bailey; Vice Chair Amy Burns; Daniel Hartung; Robert Judge; Christopher Laman; John Murray; Akil Patterson

Staff: Ralph Magrish, executive director; Cortnee Whitlock, policy analyst; Stephen Kooyman, project manager; Melissa Stiles, administrative specialist; Jake Gill, counsel; Pramela Reddi, counsel

Purpose	Subject	Presenter	Estimated Time Allotted
Informational and vote	Call to order, roll call, approval of **04/17/2024 minutes**	Chair Bailey	5 minutes
Informational	Executive director's program update	Ralph Magrish	5 minutes
Discussion and vote	Board discussion and vote on the OAR 925-200-0010 status of Inflectra and Skyrizi	Chair Bailey	10 minutes
Discussion	**Affordability review: 1) Ozempic**: • Drug-specific public comment • Board discussion	Ralph Magrish and Cortnee Whitlock	30 minutes including 20 minutes of public comment
Discussion	**Affordability review: 2) Trulicity:** • Drug-specific public comment • Board discussion	Ralph Magrish and Cortnee Whitlock	30 minutes including 20 minutes of public comment
	5-minute break	Chair Bailey	5 minutes
Discussion and vote	**Board consideration of and vote on generic drug report prepared for the Oregon Legislature**	Cortnee Whitlock	10 minutes
Discussion	**Senate Bill 192 upper payment planning update**	Ralph Magrish	10 minutes

Informational	Announcements	Chair Bailey, Staff	3 minutes
Informational	General public comment *Comments will be limited to 3 minutes per person or organization. Written comments are reviewed by the board prior to the meeting.*	Chair Bailey	10 minutes
Informational	Adjournment	Chair Bailey	2 minutes

Next meeting

June 19, 2024, at 9:30 a.m.

Accessibility

Anyone needing assistance due to a disability can contact Melissa Stiles at least 48 hours ahead of the meeting at pdab@dcbs.oregon.gov or 971-374-3724. advance.

How to provide testimony to the board

The Prescription Drug Affordability Board welcomes people to provide testimony. Testimony is when a person sends a letter to the board or signs up to speak during a board meeting. There are two types of testimony: general testimony is about any topic not related to the affordability review; affordability review testimony is about the drugs the board will consider during the affordability review process taking place between May and November 2024. There are two ways to provide testimony: oral or written. Oral testimony is speaking to the board during the public comment portion of the agenda. Written testimony is sending comments in writing to the board. Written comments will be posted to the PDAB website.

General testimony

- **Oral:** To speak during a board meeting about any topic not related to the affordability review, please submit the PDAB public comment form no later than 24 hours before the PDAB meeting.
- **Written:** to provide written comments about any topic not related to the affordability review, please submit the PDAB public comment form with attachments no later than 72 hours before the PDAB meeting.

Drug affordability review testimony

- **Oral:** To speak during a board meeting about a drug under reviewed by the board, please submit the PDAB public comment form no later than 24 hours before the PDAB meeting.
- **Written:** to provide written comments about a drug under review by the board, please submit the PDAB public comment form with attachments by the deadlines posted on the affordability review web page. Written comments specific to drugs under review and submitted by the deadlines below will be included in the affordability review drug reports that are posted one week before the meeting. However, written comments specific to drugs under review may be submitted up until 72 hours before the November board meeting.

Open and closed sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed, with the exception of news media and staff. No final actions will be taken in the executive session. When action is necessary, the board will return to an open session.

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting
Wednesday, April 17, 2024
Draft Minutes

Web link to the meeting video: https://www.youtube.com/watch?v=i5blaVYricw
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20240417-PDAB-document-package.pdf

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Call to order and roll call: Chair Shelley Bailey called the meeting to order at 9:34 am and roll was called.
Board members present: Chair Shelley Bailey, Vice Chair Amy Burns, Dan Hartung, Robert Judge, Chris Laman, John Murray, and Akil Patterson
Absent: None

Declaration of potential conflict of interest: John Murray declared a potential conflict of interest as an owner of Murray Drugs, comprised of three independent pharmacies in Eastern Oregon that have pharmacy services contracts with PBMs and insurance companies in the state. He made the announcement at the recommendation of the Oregon Ethics Commission.

Adjournment to executive session: Chair Bailey adjourned the board to executive session pursuant to ORS 192.660(2)(f), to consider information or records that are exempt by law from public inspection. Representatives of the news media and designated staff shall be allowed to attend the executive session. The chair directed members of the news media not to report on or otherwise disclose anything said during the executive session. All other members of the public may not attend.

Return to open session: Chair Bailey announced the board's return to open session after approximately 20 minutes. No decisions were made in executive session. Roll was called to confirm a quorum**.**
Board members present: Chair Shelley Bailey, Vice Chair Amy Burns, Dan Hartung, Robert Judge, Chris Laman, John Murray, and Akil Patterson
Absent: None

Approval of minutes: Chair Bailey asked if board members had any changes to the minutes and there were none. Vice Chair Amy Burns made the motion and Robert Judge provided a second to approve the minutes on Pages 3-5 in the agenda packet. View the approval in the meeting video at minute 00:03:05.

MOTION to approve the minutes
Board Vote:
Yes: Robert Judge, Chris Laman, John Murray, Akil Patterson, Vice Chair Amy Burns, Chair Shelley Bailey
No: None
Abstain: Dan Hartung
Motion passed 6-0

Program update by Executive Director Ralph Magrish. Chair Bailey called on Ralph Magrish to provide an update. View the executive director's report in the meeting video at minute 00:04:35.

Board discussion of new timeline and template for the affordability review: Chair Bailey called on Ralph Magrish, executive director, and Cortnee Whitlock, policy analyst, to discuss the revised timeline and

template shown on Pages 6-28 of the agenda packet. View the video of the board discussion at minute 00:06:10.

Board review of the draft generic drug report: Chair Bailey called on Cortnee Whitlock to discuss the timeline and provide an overview of the draft report shown on Pages 29-42. View the video of the board discussion at minute 00:26:11.

Senate Bill 192 upper payment limit planning update and board discussion: Chair Bailey called on Ralph Magrish to provide an update on the Senate Bill 192 planning efforts shown on Pages 43-53. View the video of the board discussion at minute 00:33:11.

Announcements: Chair Bailey said the next board meeting would be May 15, 2024. Ralph Magrish invited the public to attend in person community forums in Medford April 25 and in Bend April 30 and online May 8 and May 14. View the video of announcements at minute 01:06:30.

Public comment: Chair Bailey called on those who signed up to speak to the board. There were three requests to provide oral testimony and six written comments, which are posted to the PDAB website. View the oral testimony from Tonia Sorrell Neal, PCMA, and Dharia McGrew, PhRMA, in the meeting video at minute 01:07:07. Tiffany Westrich-Robertson signed up to speak but was not present in the Zoom meeting.

Adjournment: Chair Bailey adjourned the meeting at 11:15 am with all board members in agreement. She announced the next board meeting on May 15, 2024, at 9:30 am. View adjournment at minute 01:13:39.

Oregon Prescription Drug
Affordability Board

Email: pdab@dcbs.oregon.gov Phone: 971-374-3724 Website: dfr.oregon.gov/pdab

Ozempic
Affordability Review[1]

[1] Image sources: https://www.ozempic.com/how-to-take/ozempic-dosing.html. Accessed Jan. 23, 2024.

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Review Summary

Price history

Ozempic initially began marketing in December 2017. Over the past five years, Ozempic's wholesale acquisition cost (WAC) has increased by **4.9% YoY**[2] on average. This increase outpaced inflation in 2019, 2020, and 2023.[3]

Therapeutic alternatives

A clinical review found four therapeutic alternatives for Ozempic. The average gross spend per enrollee per year was **$4,439** for Ozempic vs. an average of **$4,436** across this drug and all identified therapeutic alternatives. Average out of pocket cost for patients was **$327**[4] per patient per year for Ozempic, vs. an average of **$328** across this drug and all identified therapeutic alternatives.

Cost to the healthcare system

In 2022, total gross spend for Ozempic in Oregon was **$75 million** across **16,918 enrollees,** with a gross per patient spend of **$4,439**.[5] Net spend for private insurers was estimated to be **$2,098** per enrollee per year.[6]

Cost to patients

On average, the annual patient out-of-pocket cost for Ozempic in 2022 ranged **$278** to **$299**[7] including deductibles, copays, and coinsurance.[8]

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[2] Based on data from Medi-Span.
[3] Consumer Price Index: Archived Consumer Price Index Supplemental Files. U.S. Bureau of Labor Statistics, April 10, 2024. https://www.bls.gov/cpi/tables/supplemental-files/. Accessed Jan. 11, 2024.
[4] APAC total copay, deductible, and coinsurance spend for drug and total enrollees for drug. Averages across commercial, Medicaid, and Medicare plans.
[5] Based on Oregon's 2022 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: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[6] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.
[7] Ibid.
[8] Medicaid and Medicare were excluded from cost information.

Review Background

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.

In accordance with OAR 925-200-0020, PDAB will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010, and identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

This review addresses the affordability review criteria in OAR 925-200-0020, to the extent practicable. Therefore, due to limitations in scope and resources, some criteria will have minimal or no consideration in this review.

In addition to information provided by the Department of Consumer and Business Services (DCBS) pursuant to ORS 646A.694, this review reflects information from various sources, including Oregon's APAC database, state licensed insurance carriers responding to a DCBS data call, Medi-Span, and resources from the U.S. Food and Drug Administration (FDA) such as the Orange Book (small molecule drugs) and the Purple Book (biologics).

Drug Information

Drug proprietary name(s): **Ozempic**

Non-proprietary name: **Semaglutide**

Manufacturer: **Novo Nordisk**

FDA approval

Ozempic was first approved by the FDA on 12/5/2017.[9]

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

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

[9] 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.

Information on the impact of GLP-1 agonists on health inequities has been identified, particularly concerning communities of color and under-resourced communities. An editorial published by Healthline in November 2023 discusses the disparities in access to the anti-obesity and diabetes medication, semaglutide. The article highlights that people belonging to Black and Hispanic communities are the most eligible for this medication due to their higher prevalence of type 2 diabetes.[10] However, white individuals are four times more likely to receive a prescription than other ethnic groups.[11] The article acknowledges the potential role of financial incentives in driving this disparity and it suggests solutions such as spreading awareness GLP-1 medications, making discounted programs more accessible, and addressing insurance coverage issues. The article concludes that access to GLP-1 medications should be equitable and available to those who would benefit from them the most.[12]

It is important to note that, while specific data about Native American and Pacific Islander populations was not found in the search results, these communities also face health disparities. People belonging to Black, Hispanic, Native American, Alaska Native, and Pacific Islander communities have the highest rates of obesity. Research shows that semaglutide can help people with overweight or obesity lower their weight by 9.6% - 17.4%.[13] Unfortunately, access to medications like Ozempic can be a significant issue. Therefore, it is crucial to continue advocating for equitable access to these medications for all populations, especially those most at risk and in need.

Residents prescribed

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

Based on APAC claims, **16,918** Oregonians filled a prescription for Ozempic in 2022.[14]

[10] Cassata, Cathy. Black People Are Facing Greater Challenges Accessing Anti-Obesity Drugs Like Ozempic and Wegovy. Healthline, Nov. 15, 2023. https://www.healthline.com/health-news/ozempic-access-racial-disparities. Accessed May 8, 2024.
[11] Ibid.
[12] Ibid.
[13] Chao AM, Tronieri JS, Amaro A, Wadden TA. Clinical Insight on Semaglutide for Chronic Weight Management in Adults: Patient Selection and Special Considerations. Drug Des Devel Ther. 2022 Dec 29;16:4449-4461. doi: 10.2147/DDDT.S365416. PMID: 36601368; PMCID: PMC9807016.
[14] Number of 2022 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 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

The package wholesale acquisition cost (WAC) for Ozempic (NDC 0169-4132-12, 0.25 mg - 0.5 mg / 1.5 mL Injection Prefilled Injection Pen – 1 Pen) was **$936**, as of 12/31/2023.[15]

The WAC for the drug was evaluated using Medi-Span's price history tables for the package WAC from 2019 to 2023 – see Figure 1. As of January 1, 2024, the WAC price increased another **3.5%** to **$969**.

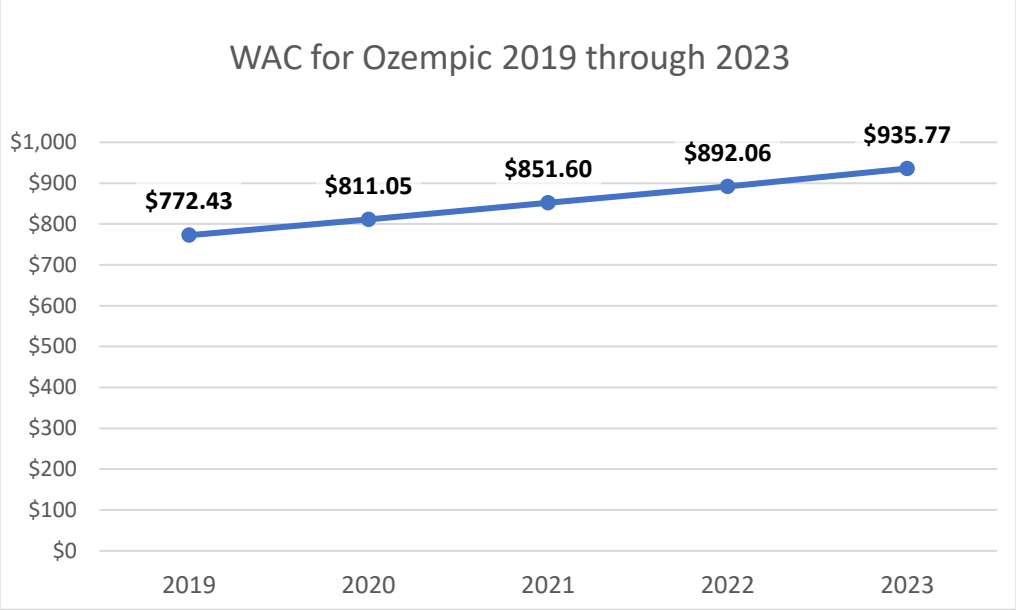

Figure 1 Ozempic WAC from 2019-2023

From 2019 to 2023, the average year-over-year percentage change to the package WAC was calculated to be **5.0%**. The year-over-year percentage change in WAC for Ozempic compared to inflation rates[16] is displayed in Figure 2.

[15] To determine which NDC to use for the WAC price history, the available 2022 utilization data was analyzed and the NDC with the highest volume of claims in 2022 was used.

[16] Consumer Price Index: Archived Consumer Price Index Supplemental Files. U.S. Bureau of Labor Statistics, April 10, 2024. https://www.bls.gov/cpi/tables/supplemental-files/. Accessed Jan. 11, 2024.

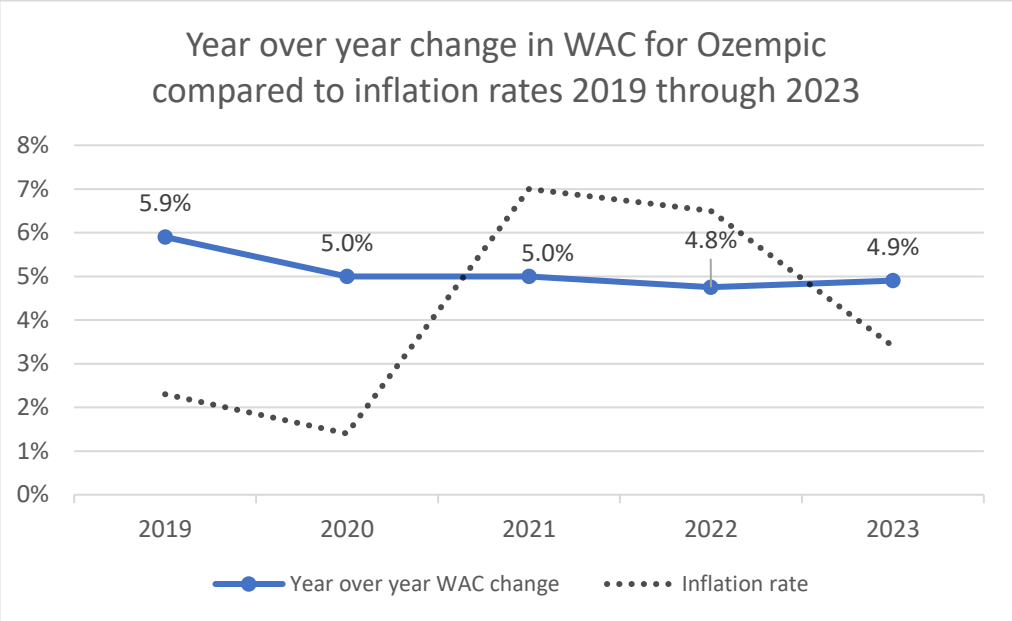

Figure 2 Year over year change in WAC compared to inflation rates[17]

Package WAC 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.

Pharmacy acquisition costs

Figure 3 shows the Oregon actual average acquisition cost (AAAC) for Ozempic (NDC 00169413212, 0.25 mg - 0.5 mg / 1.5 mL Injection Prefilled Injection Pen – 1 Pen) from January 2020 to December 2023. The AAAC for Ozempic rose from **$571** in January 2023, to **$600** in December 2023, an increase of **5%**.[18] Relative to the $936 WAC in December of 2023 a AAAC discount of **44%** is indicated.

AAAC is updated weekly by the Oregon Health Authority (OHA) using pharmacy survey data. The survey reflects the actual cost for pharmacies to purchase a given drug across all Medicaid enrolled pharmacies on a rolling basis. AAAC is used to calculate reimbursement to pharmacies for fee-for-service (or "open card") Medicaid claims.[19]

[17] Consumer Price Index: Archived Consumer Price Index Supplemental Files. U.S. Bureau of Labor Statistics, April 10, 2024. https://www.bls.gov/cpi/tables/supplemental-files/. Accessed Jan. 11, 2024.
[18] This data was compiled using the first weekly AAAC chart of each month from January 2020 to December 2023, available at https://myersandstauffer.com/client-portal/oregon/ as of April 18, 2024.
[19] Average Actual Acquisition Cost (AAAC) Questions and Answers. Oregon Health Authority, Health Systems Division, Medicaid Programs, Jan. 19, 2023. https://www.oregon.gov/oha/HSD/OHP/Tools/aaac-qa.pdf. Accessed April 18 2024.

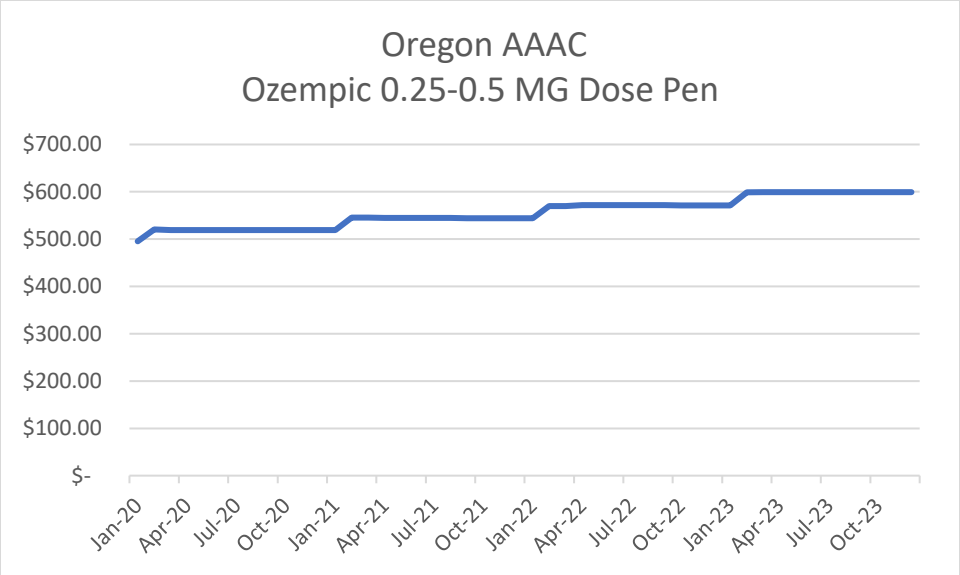

Figure 3 AAAC for Ozempic from Jan. 2020 to Oct. 2023

Effect of price on consumers' access to the drug

The Oregon Prescription Drug Price Transparency (DPT) Program asks consumers to submit stories about their personal experience with the impact of high prescription drug prices in advance of its annual public hearing. In one 2023 submission, a consumer described the following experience with Ozempic:

> "I'm afraid all of my momentum to create positive health gains will cease in 2024, because my insurance company will no longer cover Ozempic for me. After learning about this, I felt like I was set adrift in a small dingy taking on water. I began frantically bailing water to come up with a solution to this problem. I could not afford the $13,000 out-of-pocket for a 30-day supply."[20]

In 2021, two consumers submitted testimony to DPT related to the cost of Ozempic. One stated: "I need to be on Ozempic for my diabetes. I can't afford it due to the cost of $895 per syringe. I'm on Social Security only." The other stated: "I've had to give Ozempic up so that I could eat and pay rent."[21]

[20] Exhibit: stories from consumers received by DCBS through Dec. 13, 2023. Oregon Drug Price Transparency Program. https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/2023-dpt-report-exhibit-1-stories.pdf. Accessed April 18, 2024.

[21] Exhibit 2: stories from consumers received by DCBS through Dec. 7, 2021. Oregon Drug Price Transparency Program. https://dfr.oregon.gov/drugtransparency/Documents/2021-dpt-report-exhibit-2-stories.pdf. Accessed April 18, 2024.

Numerous news stories describe challenges with the cost of Ozempic and other therapies in the GLP-1 agonist class.[22]

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.

Based on the information received from the carrier data call, the average gross cost of the drug per enrollee in 2022 for commercial carriers was **$4,062** before any discounts, rebates, or other price concessions. The average net cost per enrollee after discounts, rebates, and other price concessions was **$2,098**, meaning that insurers reported an average **48%** discount on the initial drug cost.

Table 1 Net cost estimate based on carrier submitted 2022 data

Payer line of business	Total enrollees	Average spend per enrollee pre-discount	Average spend per enrollee post discount
Commercial	7,314	$4,062	$2,098

The carrier data call[23] submissions were analyzed to determine the total gross annual spend, total number of claims and enrollees, the average amount paid for claim and per enrollee, and out-of-pocket (OoP) costs for enrollees.

The total gross drug cost reported from the carrier data call prior to price concessions for Ozempic in 2022 was **$19,293,812**.

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.

No information was provided by the manufacturer or found in data review for price concession, discount or rebate the manufacturer provided to pharmacy benefit managers in this state for Ozempic.

[22] Examples include: Karen Weintraub, "Weight-loss drugs cost $1,000 a month but less than $25 to make. Why do we pay so much?," *USA Today*, March 29, 2024; Madison Muller and Robert Langreth, "Bernie Sanders Wants to Meet Novo CEO Next Week on Ozempic Price," *Bloomberg*, March 28, 2024; Tami Luhby, "Ozempic, Mounjaro and hundreds of other drugs become even more expensive in 2024," *CNN*, February 15, 2024.

[23] Cost information from the data call is the cost of the drug after price concessions.

Estimated price for therapeutic alternatives[24]

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.[25]

Comparative effectiveness to therapeutic alternatives:

Table 2 Alternative glucagon-like peptide-1 receptor agonists

Drug	FDA approved indications	~A1C decrease	Short term weight loss	Rates of nausea	Formulation	Dosing frequency
Subject drug **Semaglutide (Ozempic)**	• T2DM • CV risk reduction	1.5%	4.0 – 6.0 kg	15% - 20%	SubQ	Weekly
Dulaglutide (Trulicity)	• T2DM • CV risk reduction	1.5% - 1.8 %	2.5 – 4.6 kg	12% - 20%	SubQ	Weekly
Exenatide (Byetta)	• T2DM	1.0%	2 kg	8% - 11%	SubQ	Twice Daily
Exenatide ER (Bydureon)	• T2DM	1.5%	1.5 - 2.5 kg	8% - 11%	SubQ	Weekly
Liraglutide (Victoza)	• T2DM • CV risk reduction	1.5%	2.5 kg	18% - 20%	SubQ	Daily
Semaglutide (Rybelsus)	• 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

[24] 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.

[25] FDA Drug Shortages: Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Federal Drug Administration, Dec. 15, 2022. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Dulaglutide%20Injection&st=c. Accessed May 8, 2024.

- 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.[26] 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.
- 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.[27]
- 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).[28] 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.

[26] 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

[27] Pratley R, Amod A, Hoff ST, Kadowaki T, 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.

[28] 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

Table 3 Average healthcare and average patient OoP costs for Ozempic vs therapeutic alternatives

Drug	Average gross healthcare spend per enrollee per year[29]	Average patient out-of-pocket cost per year[30]
Subject drug Ozempic	$4,439	$327
Trulicity	$5,061	$296
Byetta	$4,784	$405
Victoza	$5,645	$299
Rybelsus	$2,252	$315
Average	**$4,436**	**$328**

Table 3 shows the average gross spend per enrollee per year was **$4,439** vs. an average of **$4,436** across this drug and all identified therapeutic alternatives. Average out of pocket costs for patients was **$327** per patient per year, vs. an average of **$328** across this drug and all identified therapeutic alternatives.

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.

No information was provided by manufacturers or found in data review for price concession, discount or rebate manufacturers provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives.

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.

In 2022, Ozempic had **69,214** APAC reported claims across **16,918** enrollees. Total gross cost of the drug was **$75,099,340** or **$4,439** per enrollee per year, and **$1,085** per claim per year.

[29] APAC total gross spend for drug and total enrollees for drug.
[30] APAC total copay, deductible, and coinsurance spend for drug and total enrollees for drug. Averages across commercial, Medicaid, and Medicare plans.

Table 4 2022 Gross cost estimates based on APAC data[31]

Payer line of business	Total enrollees	Total claims	Total spend amount	Average spend amount per enrollee	Average spend amount per claim
Commercial	8,271	34,639	$36,109,496	$4,366	$1,042
Medicaid	1,863	7,727	$6,679,815	$3,586	$864
Medicare	6,784	26,848	$32,310,029	$4,763	$1,203
Total	**16,918**	**69,214**	**$75,099,340**	**$4,439**	**$1,085**

The carrier data call[32] submissions were analyzed to determine the total gross annual spend, total number of claims and enrollees, the average amount paid for claim and per enrollee, and out-of-pocket (OoP) costs for enrollees. Additional OoP information can be found in Table 5 below.

Table 5 2022 data call reported costs to Oregon payers and enrollees

Market	Data call total annual spend (payer paid)	Total unique claims	Total of paid claims	Total unique enrollees	Average paid claim	Average paid per enrollee	Total annual out-of-pocket cost for enrollees	Out-of-pocket cost per enrollee
Individual	$2,588,548	8,619	3,887	964	$666	$2,685	$490,757	$509
Small Group	$2,801,864	11,936	5,872	1,409	$477	$1,989	$369,646	$262
Large Group	$7,651,679	24,691	11,447	2,869	$668	$2,667	$663,856	$231
OEBB	$3,100,519	7,521	3,908	808	$793	$3,837	$304,596	$377
PEBB	$3,151,201	10,444	5,371	1,264	$587	$2,493	$201,873	$160
TOTAL	**$19,293,812**	**63,211**	**30,485**	**7,314**			**$2,030,728**	

Figure 4 represents the percentage of annual spend by market type reported in the carrier data call by commercial carriers. Large Groups represent the largest annual spend of forty percent of the Oregon commercially insured market.

[31] Based on 2022 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[32] Cost information from the data call is the cost of the drug after price concessions.

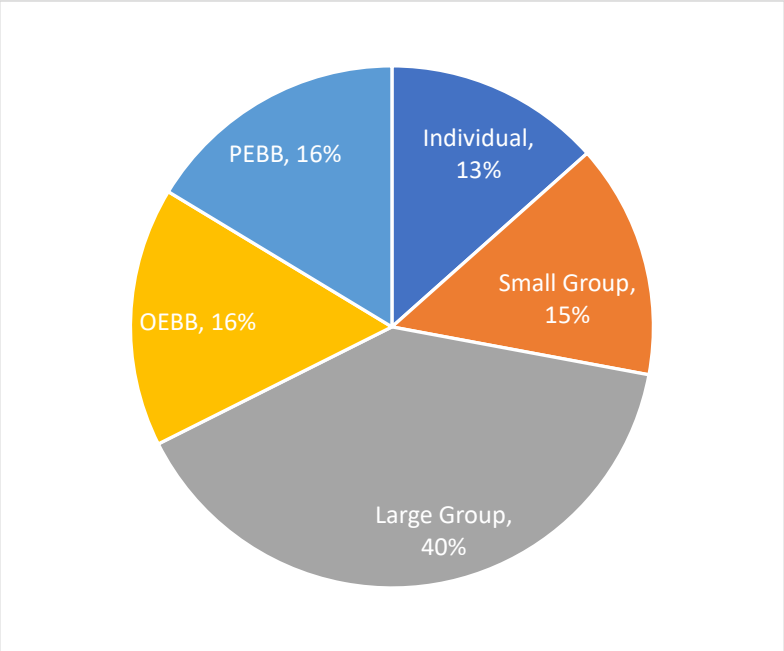

Figure 3 Data call total annual spend (payer paid)

Cost to the state medical assistance fee-for-service program in 2022 had a fourth quarter gross cost of **$50,516** for approximately **114** claims with an average paid claim amount of **$443** in the fourth quarter. The drug was listed as a non-preferred drug and required prior authorization**.** Oregon's coordinated care organizations (CCOs) in 2022 paid **$2,849,188** for **3,224** claims averaging **$884** per paid claim.

Table 6 2022 Gross amount paid for Medicaid/Oregon Health Plan fee-for-service

Fee for Service[33]							
2022 Quarter	**Drug name on report**	**Amount paid**	**% Total fee-for-service costs**	**Claim count**	**Average paid per claim**	**Preferred drug list (PDL)**	**Prior auth**
Q4	OZEMPIC*	$50,516	0.60%	114	$443	Non-preferred	Yes

Drug not indicated in Q1-Q3 of top 40 quarterly reports of the pharmacy utilization summary report provided by the Oregon State University drug use research and management program.

[33] Drug Use and Research Management (DUR) utilization reports 2022. College of Pharmacy, Oregon State University. https://pharmacy.oregonstate.edu/drug-policy/oregon-p-t-committee/dur-reports. Accessed May 8, 2024.

Table 7 2022 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	**Amount paid**	**Claim count**	**Average paid per claim**
Ozempic	$2,849,188	3,224	$884

Label and off-label indications and budget impact

Ozempic has a black box label warning regarding for the possible development of medullary thyroid cancer (MTC) and multiple endocrine neoplasia syndrome type 2 (MEN-2).[34]

Semaglutides, like Ozempic, have been used for the off-label indication for weight loss and for the treatment of Type 1 diabetes mellitus (T1DM). A New England Journal of Medicine study showed nearly 15% loss in individual weight at 68 weeks compared to 2.5% for the placebo.[35] However, even with research showing health improvements of weight loss with semaglutides, most health insurance companies do not cover the drug for the purpose of weight loss. There have been reports of insurers sending letters to health care providers who prescribe the drug for weight loss claiming, "inappropriate or fraudulent activity" and reporting them to the state licensure boards.[36] These threats to health care providers impact patient care and health access to patients who may not have a diabetes diagnosis.

For the 2022 Oregon insurer reported data **100%** of health insurances carriers reported a budget impact with Ozempic identifying it as one of their top 25 most costly and greatest increase for prescription drugs. According to the submitted information provided by the carriers the average costs per prescription was **$631**, with **16,774** prescriptions for **3,657** enrollees. It was estimated that the total annual spend was **$10,581,528** with a total annual spend per enrollee of **$2,893.50**.[37]

Additional label and off label indication information is provided under the Information from manufacturer sections.

[34] Ozempic: highlights of prescribing information, Novo Nordisk. Federal Drug Administration. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209637s003lbl.pdf. Accessed May 8, 2024.
[35] Dr. Wilding, John, et al. Once-weekly Semaglutide in adults with overweight or obesity. New England Journal of Medicine, Feb. 10, 2021. https://www.nejm.org/doi/10.1056/NEJMoa2032183. Accessed May 8, 2024.
[36] O'Mary, Lisa. Insurers poised to crack down on off-label Ozempic prescriptions. *Web*MD, June 12, 2023. https://www.webmd.com/obesity/news/20230612/insurers-poised-crack-down-off-label-ozempic-prescriptions. Accessed May 8, 2024.
[37] Revised Prescription Drug Subset List. Data for board review on Nov. 15, 2023. Prescription Drug Data, Prescription Drug Affordability Board website. https://dfr.oregon.gov/pdab/Documents/2023-PDAB-Top-Drug-List-v2.0.xlsx. Accessed May 8, 2024.

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

Commercial carriers reported **63,212** claims for Ozempic in 2022. Of those claims **30,485** were paid and **32,727** were rejected.[38] Based on submitted information, an average of **52%** of Ozempic claims were rejected in 2022.

Pharmaceutical claims may be rejected for a variety of reasons including patients trying to fill the prescription too soon or errors in the submitted claim. Pharmacists may also submit multiple claims for the same prescription should the initial claim be rejected. Therefore, claims information should only be used as a general baseline.

As part of the carrier data call, information was collected regarding prior authorizations and approval for the drug. Insurers reported a wide variety of plan designs for Ozempic. Unfortunately, the data call did not include the number of Oregonians under each plan listed, so DCBS was unable to determine the volume of Oregonians under plans that required prior authorization. Carriers reported a variety of plans, some with a more restrictive plan design and other plans with a more accessible plan design for the drug.

Information on how many carrier and market combinations were evaluated that had at least one plan that represented the following for Ozempic:

Table 8 Plan design analysis

Percent of carrier/market combinations that had one or more plans that:[39]	
Required prior authorization	68%
Did not require prior authorizations	32%
Drug was excluded on the plan formulary	5%
Drug was non-preferred on the plan formulary	20%
Drug was preferred on the plan formulary	75%
Required step therapy	45%
Did not require step therapy	55%

Note: percentages can equal over 100% 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.

[38] For the purpose of this review the terms "denied" and "rejected" for claims are used interchangeable.
[39] Less than 5% of all total Rx claims was omitted from carrier entries that were considered unusable.

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.

According to recent statistics from the Centers for Disease Control and Prevention (CDC), nearly 40% of Medicare enrollees are battling obesity.[40] In light of this, the "Treat and Reduce Obesity Act" was introduced last year, with the aim of enabling Medicare to cover anti-obesity medications. However, given that this is a presidential election year, it is still being determined whether this measure will be signed into law.

If Medicare begins covering weight loss medications, this could have a significant impact on private health insurance coverage. The National Council on Aging's Center for Healthy Aging suggests that Medicare typically influences private-sector insurance coverage, meaning that many insurers may follow suit if Medicare decides to cover weight loss drugs.[41]

Ozempic is a weight loss medication that has been gaining significant attention in the treatment of obesity. However, until the Treat and Reduce Obesity Act is passed, and Medicare is authorized to offer this new class of weight loss medications, it is still too early to predict the potential costs under Medicare.

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.[42]

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.[43] The cost of uncontrolled diabetes is estimated to be $327 billion annually in the U.S., including $237 billion

[40] Adult Obesity Facts. Centers for Disease Control and Prevention, May 17, 2022. https://www.cdc.gov/obesity/data/adult.html. Accessed May 8, 2024.
[41] Wynn, Paul, and Gang, Emily. Does Medicare Cover Ozempic. U.S. News & World Report Health, May 2, 2024. https://health.usnews.com/medicare/articles/does-medicare-cover-ozempic#:~:text=“Medicare%20typically%20affects%20private%2Dsector,starts%20covering%20weight%20loss%20drugs.” Accessed May 8, 2024.
[42] 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/. Accessed May 8, 2024.
[43] Ozempic Costs: Pricing, Coverage, and Affordability. Concierge MD 2024. https://conciergemdla.com/blog/ozempic-costs-pricing-coverage-affordability/#:~:text=In%20the%20USA%2C%20Ozempic's%20price,involves%20evaluating%20its%20cost%2Deffectiveness. Accessed May 8, 2024.

in direct medical costs and $90 billion in reduced productivity.[44] 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.[45] Copayments for Ozempic can vary, with patients typically paying a percentage of the drug's total cost, often ranging from $30 to $100.[46] 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

The APAC database[47] and the carrier data call were analyzed to determine the average patient copayment for commercially insured enrollees or other cost-sharing for the prescription drug.

Table 9 Out of pocket costs

2022 Average annual patient out of pocket costs		
Value	**APAC (commercial plans only)[48]**	**Data Call[49]**
Average Co-Pay	$174	$130
Average Coinsurance	$77	$52
Average Deductible	$47	$92
Total Out-of-Pocket Costs for Patients[50]	**$299**	**$277**

Table 9 shows the breakdown of out-of-pocket costs based on APAC data for Ozempic. A majority of patients taking Ozempic could spend almost **$300** in out-of-pocket costs. Table 10 represents the central tendency of Ozempic data, with patients spending an average of **$422,** with a maximum spend of **$12,119**. Figure 5 illustrate the distribution of patient out-of-pocket

[44] 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/. Accessed May 8, 2024.
[45] Ozempic Costs: Pricing, Coverage, and Affordability. Concierge MD 2024. https://conciergemdla.com/blog/ozempic-costs-pricing-coverage-affordability/#:~:text=In%20the%20USA%2C%20Ozempic's%20price,involves%20evaluating%20its%20cost%2Deffectiveness. Accessed May 8, 2024.
[46] Ibid.
[47] Costs from the APAC database are prior to any price concessions such as discounts or coupons. Cost information from the data call is the cost of the drug after price concessions.
[48] Medicaid and Medicare were excluded from cost information.
[49] Data call refers to cost information collected from the health insurance plans by DCBS on prescription drugs under both pharmacy and medical benefits after price concessions.
[50] For patients who used the drug at least once in the 2022 calendar year.

costs, indicating many patients pay **$0**, but a significant number pay the median amount of **$150** or more, depending on insurance coverage and plan.

Table 10 OoP costs central tendency of Ozempic costs in 2022

Out of Pocket costs per patient per year[51]		
Min	*The lowest amount any one patient paid*	$0
Average	*Patients pay this much on average*	$422
Median	*Half of patients pay more than this amount and half pay less*	$150
Mode	*The largest number of patients pay this amount*	$0
Max	*The highest amount any one patient paid*	$12,119

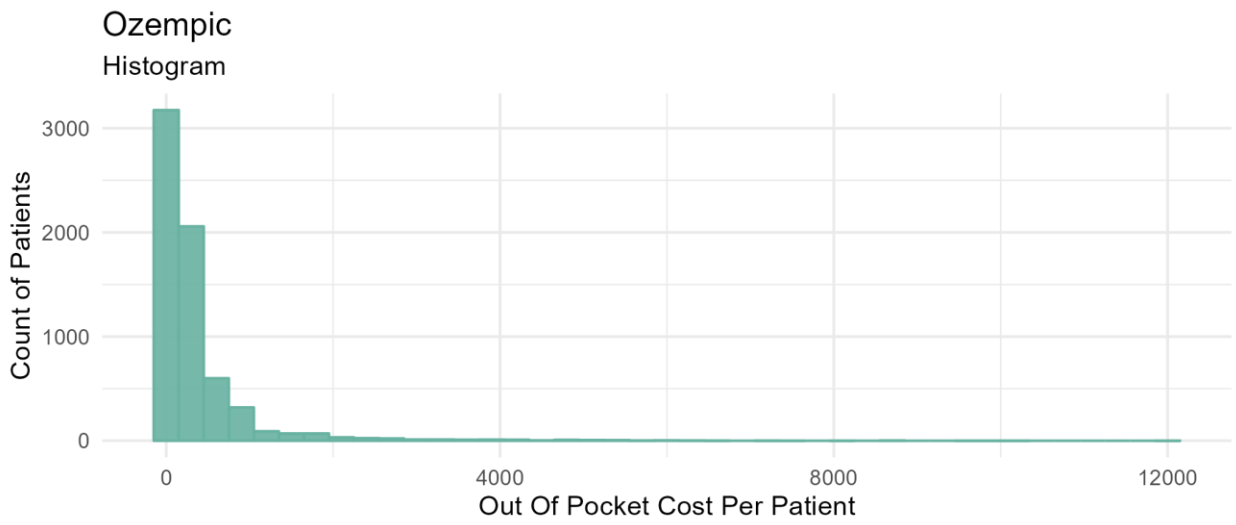

Figure 4 Patient count to OoP cost per patient

For plan designs reported in the carrier data call, when a co-pay was greater than $0, the co-pay ranged from $5.00 up to $250.00. If the coinsurance was greater than 0%, the coinsurance ranged from 10% up to 50%.

The average patient out-of-pocket costs for the APAC data may be impacted by mandatory state reporting requirements, the exclusion of data from health plans with fewer than 5,000

[51] For patients who used the drug at least once in the 2022 calendar year.

covered lives and is prior to price concessions. The carrier data call out-of-pocket costs are from reports collected by DCBS from commercial carriers and may be affected by price concessions.

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).

Refer to Appendix A for manufacturers' information.

- Jennifer Duck, JD, Vice President, US Public Affairs, with Novo Nordisk, submitted information on January 31, 2024.
- Kelsey Lovell, on behalf of Ryan Urgo, Head of Policy, with Novo Nordisk, submitted May 5, 2024.

Drug indications[52,53]

- FDA Approved:
  - 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 (CV) events in adults with T2DM who have established cardiovascular disease or multiple cardiovascular risk factors.

- Off Label Uses:
  - Type 1 diabetes mellitus (T1DM)
  - Weight loss

Clinical efficacy

- Semaglutide is a long-acting glucagon-like peptide-1 (GLP-1) receptor agonist used to improve glycemic control in T2DM. Ozempic comes in an injectable formulation that is dosed once weekly. Ozempic is also indicated for CV risk reduction in adults with T2DM. Evidence is insufficient to make recommendations for use in T1DM and it is currently not recommended in this population.
- All GLP-1 receptor agonists are FDA approved for T2DM. However, only liraglutide (Saxenda) and semaglutide (Wegovy) are currently FDA-approved for chronic weight management in people with a body mass index (BMI) of 30 kg/m^2 or greater, or 27 kg/m^2 or greater with at least one weight-related comorbid condition. The doses and branded products approved for chronic weight management are different from doses approved for T2DM.

[52] Ozempic Prescribing Information. Novo Nordisk. Plainsboro, NJ 09/2023.
[53] Rybelsus Prescribing Information. Novo Nordisk. Plainsboro, NJ 01/2024.

- Although not FDA approved, oral semaglutide (Rybelsus) has been studied in adults with overweight or obesity without T2DM at a higher dose (50 mg daily) than currently approved for T2DM (14 mg daily) and led to a -15.1% change from baseline in weight compared to -2.4% with placebo.[54]
- 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 change in hemoglobin A1c (HbA1C) from baseline to week 30 or 52.[55]
- 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.[56] Semaglutide SC resulted in a dose-dependent weight loss of 3.5 to 6.5 kg in clinical trials.[57]
- In January 2020, the FDA labeling of semaglutide SC (Ozempic) was expanded to include the reduction of risk of major adverse CV events.[58] 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.[59] 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 the risk of stroke (HR 0.61; 0.38 to 0.99).[60] 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). [61]

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[54] 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.

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

[56] 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.

[57] Ibid.

[58] Ozempic Prescribing Information. Novo Nordisk. Plainsboro, NJ 09/2023.

[59] 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

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

[61] Ibid.

Clinical safety[62,63]

- FDA safety warnings and precautions:
  - Pancreatitis
  - Hypoglycemia in combination with insulin or an insulin secretagogue
  - Hypersensitivity reactions
  - Acute kidney injury
  - Diabetic Retinopathy complications
  - Acute gallbladder disease

- Contraindications:
  - Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2.
  - Hypersensitivity to semaglutide.

- Common side effects:
  - Gastrointestinal effects (32 to 41%), including diarrhea (8 to 9%), nausea (15 to 20%), and vomiting (5 to 9%), abdominal pain (6 to 11%), and constipation (3 to 6%).

- Safety advantages or disadvantages:
  - The most common side effects associated with GLP-1 receptor agonists include gastrointestinal side effects. These are dose-related and likely due to delayed gastric emptying or activation of centers involved in appetite regulation, satiety, and nausea. These are most common soon after initiation and during dose escalation. Rapid titration is associated with higher risk of GI symptoms. There is no evidence that one GLP-1 is associated with higher rates of GI symptoms than 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).[64] The risk

[62] Ozempic Prescribing Information. Novo Nordisk. Plainsboro, NJ 09/2023.
[63] Rybelsus Prescribing Information. Novo Nordisk. Plainsboro, NJ 01/2024.
[64] 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. 2022;182(5):513–519. doi:10.1001/jamainternmed.2022.0338.

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.[65] Despite, an increased risk compared to placebo, the absolute risk remains small (additional 27 cases per 10,000 persons treated per year).[66]

Input from Specified Stakeholders

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

Patients and Caregivers

- No input provided.

Individuals with Scientific or Medical Training

- No input provided.

Safety Net Providers

- No input provided.

Payers

- Mary Anne Cooper, Director of Government Relations, with Regence BlueCross BlueShield of Oregon, submitted information on January 30, 2024. Information can be reviewed under Appendix B.

Other

- Carissa Kemp, Director, State Government Affairs, Oregon, American Diabetes Association, submitted information on February 20, 2024. Information can be viewed under Appendix C.

[65] 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.
[66] Marso SP, Bain SC, Consoli A, Eliaschewitz FG, et al. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. N Engl J Med. 2016 Nov 10;375(19):1834-1844.

January 31, 2024

VIA ELECTRONIC FILING

Oregon Division of Financial Regulation
ATTN: Oregon Prescription Drug Affordability Review Board (PDAB)
350 Winter St. NE
Room 410
Salem, OR 97309-0405

RE: February 21, 2024 Oregon Prescription Drug Affordability Board Meeting and Review of Ozempic® and Rybelsus®

Dear Members of the Oregon Prescription Drug Affordability Board:

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

The Board intends to review together collectively Ozempic® and Rybelsus® for the purpose of determining if these medications might pose an affordability challenge for Oregonians. We have serious concerns regarding the underlying data used by the Board that grouped together these two separate and distinct drug products, Ozempic® and Rybelsus®, under one review. Additionally, the review process does not provide an avenue for manufacturers to work with the Board to correct errors and misinformation. We urge the Board to forebear from identifying either of these products in any report to the Oregon Legislative Assembly based on an inaccurate and inappropriate combined review of these products that does not separately evaluate each product based on its distinct characteristics.

We provide the Board with further information that illustrates that grouping these products together is flawed. As each of these products provides a distinctly different treatment option for patients.

Ozempic® Clinical Overview

Ozempic® (semaglutide injection) is a once weekly GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (T2D) and to reduce the risk of major adverse cardiovascular (CV) events (MACE) (CV death, non-fatal myocardial infarction (MI) or non-fatal stroke) in adults with T2D and established CV disease.[1]

[1] Ozempic® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. https://www.novo-pi.com/ozempic.pdf

The efficacy and safety of Ozempic® was evaluated in the SUSTAIN clinical trial program. For glycemic efficacy, Ozempic® was compared to several other antidiabetic medications including sitagliptin 100 mg, exenatide ER 2 mg, insulin glargine U-100, dulaglutide 0.75 mg and 1.5 mg, canagliflozin 300 mg, and liraglutide 1.2 mg. Mean reductions in A1C from baseline ranged from 1.2%-1.5% and 1.5-1.8% for Ozempic® 0.5 mg and 1 mg, respectively, after 30 to 56 weeks of treatment, compared to 0–1.4% with placebo and active comparators. Throughout the glycemic control trials, both the 0.5 mg and 1 mg doses of Ozempic® demonstrated superior improvements in A1C vs. comparators. Significant reductions in body weight from baseline were observed with Ozempic® 0.5 mg and 1 mg with mean decreases ranging from -7.6 lb. to -10.1 lb. and -9.0 to -14.3 lb., respectively.[2] [3] [4] [5] [6] [7] [8] [9] [10] [11] In a cardiovascular outcomes trial, Ozempic® 0.5 mg or 1 mg compared to placebo demonstrated a relative risk reduction of 26% for the primary composite outcome of time to first occurrence of a 3-point MACE (CV death, non-fatal MI and non-fatal stroke). [12]

Rybelsus® Clinical Overview

Rybelsus® (semaglutide oral) is co-formulated with an absorption enhancer to achieve adequate bioavailability with oral administration. It is administered once daily, in the morning at least 30 minutes before the first meal of the day with up to half a glass of water (approximately 4 fl oz).[13]

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[2] Sorli C, Harashima S, Tsoukas GM, et al. Efficacy and safety of once-weekly semaglutide monotherapy versus placebo in patients with type 2 diabetes (SUSTAIN 1): a double-blind, randomised, placebo-controlled, parallel-group, multinational, multicentre phase 3a trial. 2017;5(4):251-260. Link to Access the Full Text

[3] Ahren B, Masmiquel L, Kumar H, et al. Efficacy and safety of once-weekly semaglutide versus once-daily sitagliptin as an add-on to metformin, thiazolidinediones, or both, in patients with type 2 diabetes (SUSTAIN 2): a 56-week, double-blind, phase 3a, randomised trial. *Lancet Diabetes Endocrinol.* 2017 Link to Access the Full Text

[4] Ahmann AJ, Capehorn M, Charpentier G, et al. Efficacy and Safety of Once-Weekly Semaglutide Versus Exenatide ER in Subjects With Type 2 Diabetes (SUSTAIN 3): A 56-Week, Open-Label, Randomized Clinical Trial*. *Diabetes Care.* 2017 Link to Access the Full Text

[5] Aroda V, Sc B, Cariou B, et al. Efficacy and safety of once-weekly semaglutide versus once-daily insulin glargine as add-on to metformin (with or without sulfonylureas) in insulin-naive patients with type 2 diabetes (SUSTAIN 4): a randomised, open-label, parallel-group, multicentre, multinational, phase 3a trial. *Lancet Diabetes Endocrinol.* 2017 Link to Access the Full Text

[6] Rodbard HW, Norwood P, Lingvay I, et al. Semaglutide Added to Basal Insulin in Type 2 Diabetes (SUSTAIN 5): A Randomized, Controlled Trial. *The Journal of Clinical Endocrinology & Metabolism.* 2018;103(6):2291-2301. Link to Access the Full Text

[7] Pratley RE, Aroda VR, Lingvay I, et al. Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes (SUSTAIN 7): a randomised, open-label, phase 3b trial. *Lancet Diabetes Endocrinol.* 2018 Link to Access the Full Text

[8] Lingvay I, Catarig AM, Frias JP, et al. Efficacy and safety of once-weekly semaglutide versus daily canagliflozin as add-on to metformin in patients with type 2 diabetes (SUSTAIN 8): a double-blind, phase 3b, randomised controlled trial. *Lancet Diabetes Endocrinol.* 2019;7(11):834-844. Link to Access the Full Text

[9] Zinman B, Bhosekar V, Busch R, et al. Semaglutide once weekly as add-on to SGLT-2 inhibitor therapy in type 2 diabetes (SUSTAIN 9): a randomised, placebo-controlled trial. *The Lancet Diabetes & Endocrinology.* 2019 Link to Access the Full Text

[10] Capehorn MS, Catarig AM, Furberg JK, et al. Efficacy and safety of once-weekly semaglutide 1.0 mg vs once-daily liraglutide 1.2 mg as add-on to 1-3 oral antidiabetic drugs in subjects with type 2 diabetes (SUSTAIN 10). *Diabetes Metab.* 2019 Link to Access the Full Text

[11] Kellerer M, Kaltoft MS, Lawson J, et al. Effect of once-weekly semaglutide versus thrice-daily insulin aspart, both as add-on to metformin and optimized insulin glargine treatment in participants with type 2 diabetes (SUSTAIN 11): a randomized, open-label, multinational, phase 3b trial. *Diabetes, Obesity and Metabolism.* 2022 Link to Access the Full Text

[12] Marso S, Bain S, Consoli A, et al. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes (SUSTAIN 6). *New Engl J Med.* 2016;375(19):1834-1844. Link to Access the Full Text

[13] Rybelsus® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. Rybelsus PI (novo-pi.com)

Rybelsus® should be initiated with the 3 mg dose, and use a 4-week dose escalation, up to 14 mg, to reduce the risk of GI AEs. The pharmacokinetic and pharmacodynamic profiles were preserved in patient populations independent of age, ethnicity, and in patients with renal or hepatic impairment. Rybelsus® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2D. The PIONEER Phase 3a clinical development program was comprised of 10 clinical trials that evaluated the safety and efficacy of once-daily Rybelsus® in more than 9,500 adult patients with T2D. All studies were designed to be randomized, parallel-group, multicenter trials. For glycemic efficacy, Rybelsus® was compared to several other antidiabetic medications, including empagliflozin 25 mg, sitagliptin 100 mg, and liraglutide 1.8 mg. The program also included a cardiovascular outcomes trial (CVOT), PIONEER 6, and 2 studies in Japanese patients (PIONEER 9 and 10). Rybelsus® demonstrated superior improvements in HbA_{1c} (all doses) compared to placebo and most comparators in the PIONEER trials. It also provided superior reductions in body weight compared with placebo and most comparators. Participants who had a serious adverse event was similar in the Rybelsus® vs placebo or comparator group. In PIONEER 6, its primary objective of ruling out an 80% excess CV risk, confirming noninferiority to placebo for the primary outcome and CV safety. [14] [15] [16] [17] [18] [19] [20] [21] [22] [23] [24]

[14] Aroda VR, Rosenstock J, Terauchi Y, et al. PIONEER 1: randomized clinical trial comparing the efficacy and safety of oral semaglutide monotherapy with placebo in patients with type 2 diabetes. *Diabetes Care.* 2019 Link to Access the Full Text

[15] Rodbard HW, Rosenstock J, Canani LH, et al. Oral Semaglutide Versus Empagliflozin in Patients With Type 2 Diabetes Uncontrolled on Metformin: The PIONEER 2 Trial. *Diabetes Care.* 2019;42(12):2272-2281. Link to Access the Full Text

[16] Rosenstock J, Allison D, Birkenfeld AL, et al. Effect of Additional Oral Semaglutide vs Sitagliptin on Glycated Hemoglobin in Adults With Type 2 Diabetes Uncontrolled With Metformin Alone or With Sulfonylurea: The PIONEER 3 Randomized Clinical Trial. *JAMA.* 2019;321(15):1466-1480. Link to Access the Full Text

[17] Pratley R, Amod A, Hoff ST, et al. Oral semaglutide versus subcutaneous liraglutide and placebo in type 2 diabetes (PIONEER 4): a randomised, double-blind, phase 3a trial. *Lancet.* 2019;394(10192):39-50. Link to Access the Full Text

[18] Mosenzon O, Blicher TM, Rosenlund S, et al. Efficacy and safety of oral semaglutide in patients with type 2 diabetes and moderate renal impairment (PIONEER 5): a placebo-controlled, randomised, phase 3a trial. *Lancet Diabetes Endocrinol.* 2019;7(7):515-527. Link to Access the Full Text

[19] Husain M, Birkenfeld AL, Donsmark M, et al. Oral Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med.* 2019;381(9):841-851. Link to Access the Full Text

[20] Pieber TR, Bode B, Mertens A, et al. Efficacy and safety of oral semaglutide with flexible dose adjustment versus sitagliptin in type 2 diabetes (PIONEER 7): a multicentre, open-label, randomised, phase 3a trial. *Lancet Diabetes Endocrinol.* 2019;7(7):528-539. Link to Access the Full Text

[21] Buse JB, Bode BW, Mertens A, et al. Long-term efficacy and safety of oral semaglutide and the effect of switching from sitagliptin to oral semaglutide in patients with type 2 diabetes: a 52-week, randomized, open-label extension of the PIONEER 7 trial. *BMJ Open Diabetes Res Care.* 2020;8(2) Link to Access the Full Text

[22] Zinman B, Aroda VR, Buse JB, et al. Supplement to: Efficacy, Safety and Tolerability of Oral Semaglutide Versus Placebo Added to Insulin +/- Metformin in Patients with Type 2 Diabetes: the PIONEER 8 Trial. *Diabetes Care.* 2019 Link to Access the Full Text

[23] Yamada Y, Katagiri H, Hamamoto Y, et al. Dose-response, efficacy, and safety of oral semaglutide monotherapy in Japanese patients with type 2 diabetes (PIONEER 9): a 52-week, phase 2/3a, randomised, controlled trial. *Lancet Diabetes Endocrinol.* 2020;8(5):377-391. Link to Access the Full Text

[24] Yabe D, Nakamura J, Kaneto H, et al. Safety and efficacy of oral semaglutide versus dulaglutide in Japanese patients with type 2 diabetes (PIONEER 10): an open-label, randomised, active-controlled, phase 3a trial. *Lancet Diabetes Endocrinol.* 2020;8(5):392-406. Link to Access the Full Text

Endogenous glucagon-like peptide-1 (GLP-1) has a <2-minute half-life. [25] Therefore, Novo Nordisk has developed injectable analogs with 13 hour (Victoza®) and 7-day half-lives (Ozempic®) for the treatment of type 2 diabetes.[26] With Rybelsus®, Novo Nordisk continued to expand its portfolio in this area to include different delivery options. Timely treatment of type 2 diabetes is needed to reduce the risk of type 2 diabetes complications and yet many patients do not achieve current glycosylated hemoglobin (A1C) targets with the currently available treatment options. GLP-1 receptor agonists (RAs) provide effective glycemic control along with weight reduction and low risk of hypoglycemia. Rybelsus®, an oral GLP-1 RA may lead to initiation of GLP-1 RA treatment earlier in the continuum of the disease and may improve acceptance and adherence for some patients compared with injectable formulations of GLP-1 RA. Rybelsus® is not intended to replace Ozempic® injection.

The Board has incorrectly considered Ozempic® and Rybelsus® to be one product for purposes of its review

Pursuant to OAR 925.200.0010[27], one factor the Board considers in developing the prioritized subset is if the drug appeared on the insurer reported top 25 list required under ORS 743.025.[28] However, information submitted by insurers is aggregated using a 10-digit generic drug identifier (GPI) that does not provide for a single therapeutic classification. While the full 14-character GPI consists of seven subsets, it still does not subdivide into package size or parse out manufacturers. The imprecision of the GPI-10 classification system does not provide an accurate cost report on a specific drug product, as it results in multiple distinct products being combined together. As such, the underlying insurer data used by the Board is predicated off an aggregated list that includes two different drug products, each of which is approved under a separate new drug application (NDA) and has its own separate national drug codes. [29] [30] Without having access to raw data, we are unable to ascertain how the aggregation of these two distinct and separate drug products impacted their combined placement on the insurer's top 25 list. It is possible that, if these products would have been appropriately treated/evaluated as separate and distinct products, then they may not have even met the Board's threshold inclusion criteria for review.

In contrast to the insurer reports, we note that prescription drug manufacturers reporting into the Drug Price Transparency Program must submit information on each unique 11-digit national drug code (NDC) that meets reporting criteria. Reporting at the NDC-11 level appropriately identifies each distinct drug product. It remains unclear to us whether or how the Board considered the reports that manufacturers submitted in making its determinations regarding which drug products to select.

Clinically, both Ozempic® and Rybelsus® provide important and distinct treatment options for adult patients with type 2 diabetes. As described above, although semaglutide is the active

[25] *Drucker DJ et al. Proc Natl Acad Sci USA 1987;84:3434–8; 2. Drucker DJ, Nauck MA. Lancet 2006;368:1696–705; 3. Holst JJ. Physiol Rev 2007;87:1409–39*
[26] Victoza® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. Victoza PI (novo-pi.com)
[27] OAR 925.200.0010; https://dfr.oregon.gov/pdab/Documents/PDAB-1-2023-affordability-review-rule.pdf
[28] ORS 743.025; https://www.oregonlegislature.gov/bills_laws/ors/ors743.html
[29] NDA 209637: 209637Orig1s000SumR.pdf (fda.gov)
[30] NDA 213182: Review (fda.gov)

ingredient in both medications, each is a distinct and separate therapy with a different profile, and therefore represents a distinctly different treatment option for patients. These differences can have very important implications for individualized patient therapy. In recognition of those differences, there are different recommendations regarding place in therapy of Ozempic® and Rybelsus® in various clinical guidelines such as the American Diabetes Association Standards of Care.[31] For example there may be a reluctance by patients to administer injectable therapies, which could lead to delays in initiating treatment and/or lower adherence. [32] Additionally, there practical considerations for patients, who are unable to administer injectable therapies as they require visual, motor, and cognitive skills for proper administration. These drugs are not interchangeable and need to be considered separately from one another.

Novo Nordisk is committed to ensuring patients living with diabetes can afford our medications, a responsibility we take seriously

At Novo Nordisk, we strive to develop sustainable affordability options that balance patient affordability, market dynamics, and evolving policy changes. For example, Novo Nordisk contracts with payers throughout the state, offering rebates to ensure formulary placement and appropriate patient access to our medications. We also pay rebates to Oregon's Medicaid program. Under the current reimbursement paradigm, rebates play a central role in how insurers manage the prescription drug benefit. However, when examining the overall costs to health care systems in Oregon, the Board focused on WAC price changes, which are not a reliable indicator of whether a medication is affordable for most patients.

For patients that continue to struggle to afford their medication, either due to inadequate plan benefit design or a lack of coverage altogether, Novo Nordisk also provides additional financial support through our affordability programs. We allow uninsured patients with affordability challenges to access our products at no cost, and we also provide copay assistance for Ozempic® that reduces a commercially insured patient's out-of-pocket cost to as little as $25 or for Rybelsus® to as little as $10.[33] Novo Nordisk remains committed to ensuring affordable access to our medications by reducing the out-of-pocket cost burden, helping to transform the complex pricing system and fostering better pricing predictability.

[31] *American Diabetes Association (ADA). Diabetes Care 2023; 46(Suppl.1): S140–S157* doi: https://doi.org/10.2337/dc23-S009

[32] Diana M. Isaacs, Davida F. Kruger, Geralyn R. Spollett; Optimizing Therapeutic Outcomes With Oral Semaglutide: A Patient-Centered Approach. *Diabetes Spectr* 1 February 2021; 34 (1): 7–19. https://doi.org/10.2337/ds20-0016

[33] https://www.novocare.com/

Thank you for the opportunity to provide comments and for considering our concerns. Should you have any questions or concerns, please contact Ryan Urgo, Head of Policy, at RVUR@novonordisk.com with any questions or for further information.

Sincerely,

Jennifer Duck, JD

Vice President
US Public Affairs

May 5, 2024

VIA ELECTRONIC FILING

Oregon Division of Financial Regulation
ATTN: Oregon Prescription Drug Affordability Board
350 Winter St. NE
Room 410
Salem, OR 97309-0405

RE: May 15, 2024, Oregon Prescription Drug Affordability Board Meeting and Re-Review of Ozempic®

Dear Members of the Oregon Prescription Drug Affordability Board:

Novo Nordisk appreciates the opportunity to resubmit written comments to the Oregon Prescription Drug Affordability Board (Board) regarding the re-review of Ozempic®. As we have stated previously, we disagree with the Board's inclusion of Ozempic® on the list of drugs that are subject to an affordability review - on both procedural and substantive grounds - and respectfully request that Ozempic® be removed from the list. Our previous comments to the Board focused on our concerns regarding the inconsistent data that the Board relied on to compile its' selected drug list and the incorrect grouping of Ozempic® and Rybelsus® together for its' initial review. The Board's own spending data demonstrated that Ozempic's average annual gross spending per enrollee and average patient out-of-pocket (OOP) costs were not meaningfully different than the other GLP-1 treatments selected by the Board as "therapeutic alternatives". While we appreciate the Board's attempt to update its affordability review process, significant concerns remain around transparency, data, metrics, standards, and decision-making processes used by the Board to determine the affordability of a drug. Additionally, as the Board intends to explore a framework for implementing an upper payment limit (UPL), we reiterate our concerns regarding the unintended consequences that setting an UPL will have on patients' access to their medications.

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

Given the substantial burden that diabetes and related chronic diseases have on patients, the Board should reconsider its selection of Ozempic for an affordability review, as this could adversely impact access to treatment and worsen health outcomes over time.

Throughout our company's hundred-year history, we have had a steadfast focus on improving the lives of patients living with chronic diseases. Chronic diseases are the single biggest threat to life expectancy in the United States, erasing more than twice as many years as all car accidents, suicide, homicides, and overdoses combined. Furthermore, chronic diseases are responsible for 7 in 10 deaths each year,[1] and they are the primary reason that Americans have lower life expectancy than those in peer nations.[2] Despite these statistics, real progress in treating and preventing serious chronic diseases continues to be undermined by misguided policies that singularly focus on a drug's list price. Novo Nordisk respectfully requests that the Board reconsider its decision to pursue Ozempic® for an affordability review, summarized in greater detail below:

Ozempic is a highly effective treatment option for Oregonians, and average patient costs are in line with other treatments evaluated by the Board.

Diabetes represents a particularly high lifetime burden of illness, but thanks to decades of research and development, people with diabetes now have highly effective new treatment options to treat and prevent complications arising from metabolic-related chronic diseases. Ozempic® is a once weekly GLP-1 receptor agonist (RA) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (T2D) and to reduce the risk of major adverse cardiovascular (CV) events (MACE) (CV death, non-fatal myocardial infarction (MI) or non-fatal stroke) in adults with T2D and established CV disease.[3] Research and clinical trials have demonstrated the superiority of GLP-1 RA to other antihyperglycemic drugs in improving glycemic efficacy, reducing weight and blood pressure, and delivering a cardioprotective effect – all without the risk of hypoglycemia.[4] These drugs have transformed treatment guidelines for the management of patients with diabetes and are widely recognized as a standard of care.[5]

The efficacy and safety of Ozempic® was evaluated in the SUSTAIN clinical trial program. For glycemic efficacy, Ozempic® was compared to several other antidiabetic medications including sitagliptin 100 mg, exenatide ER 2 mg, insulin glargine U-100, dulaglutide 0.75 mg and 1.5 mg, canagliflozin 300 mg, and liraglutide 1.2 mg. Mean reductions in A1C from baseline ranged from 1.2%-1.5% and 1.5-1.8% for Ozempic® 0.5 mg and 1 mg, respectively, after 30 to 56 weeks of treatment, compared to 0–1.4% with placebo and active comparators.

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[1] US Centers for Disease Control and prevention. Chronic Diseases https://www.cdc.gov/chronicdisease/center/index.htm
[2] "An Epidemic of Chronic Illness is Killing Us Too Soon." Washington Post. October 3, 2023. https://www.washingtonpost.com/health/interactive/2023/american-life-expectancy-dropping/
[3] Ozempic® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. https://www.novo-pi.com/ozempic.pdf
[4] Latif W, Lambrinos KJ, Rodriguez R. Compare and Contrast the Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) [Updated 2023 Mar 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572151/
[5] American Diabetes Association. Standards of care in diabetes—2024. Diabetes Care. 2024;47(suppl 1):S1- S321.

Throughout the glycemic control trials, both the 0.5 mg and 1 mg doses of Ozempic® demonstrated superior improvements in A1C vs. comparators. Moreover, spending data compiled by the Board ("All Payer, All Claims") revealed that Ozempic® had lower annual patient OOP costs than the average for all GLP-1 treatments analyzed by the Board.[6] Taken together, Ozempic® is both highly effective and no more costly for Oregonians than other treatments evaluated. The Board's decision to singularly target Ozempic® for an affordability review is not supported by the totality of the evidence.

Novo Nordisk is committed to ensuring patients living with diabetes can afford our medications, and this is a responsibility we take seriously.

At Novo Nordisk, we strive to develop sustainable affordability options that balance patient affordability, market dynamics, and evolving policy changes. Novo Nordisk contracts with payers throughout the state, offering rebates to ensure formulary placement and appropriate patient access to our medications. In 2023, Novo Nordisk's cumulative rebates and discounts across our entire US portfolio amounted to 74% of gross sales (75% in 2022 and 75% in 2021).[7] In addition to paying rebates in the commercial market, manufacturers are also required to pay significant statutory discounts and rebates to the government. Under the current reimbursement paradigm, rebates play a central role in how insurers manage the prescription drug benefit. A recent analysis of data from SSR Health's net price database across 10 major manufacturers showed that the gap in value between list prices and net prices (after rebates and other reductions) among brand name drugs reached $300 billion in 2022. The unweighted average discount off the list price was 53.5%, or less than half the price.[8]

However, when examining the overall costs to health care systems in Oregon, the Board focused on wholesale acquisition costs (WAC), i.e. list prices, a poor indicator of the cost of a medication for most patients and health insurers. According to a recent analysis, brand-name drugs' list prices grew at mid-single-digit rates in 2023, however, net prices dropped for a sixth consecutive year – and by 7% after adjusting for inflation.[9] Despite the growing divergence between list and net prices, average OOP spending for most diabetes prescriptions in the U.S. remains low. According to an analysis by IQVIA, OOP spending was less than $30 across 83% of diabetes prescriptions (based on April 2020 claims data across payers).[10]

For patients who continue to struggle to afford their medication, either due to inadequate plan benefit design or a lack of coverage altogether, Novo Nordisk provides additional financial support through our affordability programs. We allow uninsured patients in financial need to access our products at no cost, and we also provide copay assistance for Ozempic® that

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[6] Oregon Prescription Drug Affordability Review Board. Affordability Review of Ozempic 20240221-PDAB-document-package.pdf (oregon.gov)
[7] Novo Nordisk. 2023 Annual Report. Novo Nordisk Annual Report 2023 (PDF)
[8] Fein, AJ. Gross-to-Net Bubble Update: 2022 Pricing Realities at 10 Top Drugmakers. *Drug Channels Institute*. 2023 Jun 13 [cited 2024 Jan 18]. Available from: https://www.drugchannels.net/2023/06/gross-to-net-bubble-update-2022-pricing.html
[9] Fein, AJ. U.S. Brand-Name Drug Prices Fell for an Unprecedented Sixth Consecutive Year (And Will Fall Further in 2024). https://www.drugchannels.net/2024/01/tales-of-unsurprised-us-brand-name-drug.html. January 3, 2024.
[10] IQVIA. *Diabetes Costs and Affordability in the United States*. 2020 Jun 29 [cited 2024 Feb 7]. Available from: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/diabetes-costs-and-affordability-in-the-united-states

reduces a commercially insured patient's out-of-pocket cost to as little as $25. Novo Nordisk remains committed to ensuring access to our medications by reducing the out-of-pocket cost burden, simplifying a complex pricing system, and fostering better pricing predictability for the patients we serve.

A UPL could disrupt patient access to diabetes treatments in Oregon.

While we share the Board's interest in making prescription drugs affordable to patients, shortsighted policies that impose price controls will only undermine these efforts, as patient access is likely to be compromised. The largest Pharmacy Benefit Managers (PBMs) in the US exert significant control over the treatment options available to patients[11] through formulary designs that direct patients to medications that can generate the highest rebates from manufacturers. A recent GAO report found that "…plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which generally had lower rebates".[12] Because of these perverse incentives, products subject to a UPL may be *less* attractive to insurers and PBMs relative to competitors that can continue to offer higher rebates.

Numerous case studies underscore these unintended consequences within the prescription drug supply chain. In one recent example, a drug manufacturer launched a biosimilar of the long-acting insulin glargine at a 65% lower price relative to the reference product's WAC. After little formulary uptake, the biosimilar manufacturer opted to launch a higher-priced version of the same product, with the ability to now pay rebates at a similar level to the reference product. According to an IQVIA analysis, PBMs largely favored the higher-priced version because it allowed them to generate rebate revenue.[13]

Despite these risks, the Board has not taken steps to ensure that patients will be able to access products subjected to a UPL. There are presently no beneficiary protections or formulary requirements for patients seeking treatment for a product facing a UPL. This heightens the risk of downstream access barriers for patients, including an interruption in continuity of care, prior authorization hurdles in accessing a prescribed therapy, and improper utilization management tactics that force patients to switch or delay treatment.

The Board assumes that a UPL will work for all Oregonians—but recent evidence suggests otherwise. Policies that focus narrowly on list prices fail to recognize the complex dynamics within the supply chain and are more likely to cause foreseeable harm to patients' ability to access prescribed medications.

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[11] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022. https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html

[12] Government Accountability Office (GAO). CMS Should Monitor Effects of Rebates on Drug Coverage and Spending. Statement of John E. Dicken, Director, Health Care Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives. https://www.gao.gov/assets/gao-23-107056.pdf. September 19, 2023.

[13] IQVIA. Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars. 2022 [cited 2024 Apr 25]. Available from: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2022/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars.pdf

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

Appendix B: Regence

Regence

200 SW Market Street, 11th Floor
Portland, OR 97201

January 30, 2024

SUBMITTED VIA EMAIL

RE: PDAB Review of Rybelsus/Ozempic

Dear Members of the Oregon Prescription Drug Affordability Board,

On behalf of Regence BlueCross BlueShield of Oregon and our members, we thank the Prescription Drug Affordability Board and Staff for the opportunity to comment on Rybelsus/Ozempic, one of the 15 drugs the PDAB has selected for review.

As one of the state's largest health insurers, Regence is committed to addressing persistent and emerging health needs for the nearly 1 million Oregonians we serve. In keeping with our values as a tax-paying nonprofit, 85% of every premium dollar goes to pay our members' medical claims and expenses.

In Oregon, prescription drugs account for 20-30% of all plan spending. To narrow this down, coverage of Ozempic has an annual cost of roughly $12,000 per member. At the start of 2024, Novo Nordisk raised the price of Ozempic by 3.5%, raising a month's supply to roughly $1100. While rebates are available for this drug, our members are still struggling to afford these medications at the pharmacy when they go to fill their prescriptions, and for these medications, adherence is paramount for efficacy.

We acknowledge the complexities surrounding these drugs and GLP-1s in general. Currently, Regence covers Ozempic for members with type-2 diabetes after appropriate prior authorizations are met. Over the last two years, we have seen an increase in the use of GLP-1s, consistent with changes in standards of care in treating diabetes. We know the annual cost of this medication will continue to rise, as market utilization steadily increases.

Costs to health plans are costs to our members. We want our members to have access to their lifesaving medications and are adamant that the cost of these medications needs to be reviewed. A 2020 article by Diabetes Care estimated that the cost of glucose-lowering drugs was roughly 15-20% of the estimated annual costs for all prescription drugs in the U.S between 2015-2017. These costs have only continued to rise and as demand for some drugs in the weight management space steadily increases, the cost to members and the health plan will follow.

We will be happy to discuss any additional follow-up items. Thank you for your consideration of our feedback.

Sincerely,

Mary Anne Cooper
Director of Government Relations
Regence BlueCross BlueShield of Oregon

Appendix C: American Diabetes Association

Thank you for the opportunity to comment on the discussion of the affordability of glucagon-like peptide (GLP-1) agonists. These medications are essential for people with type 2 diabetes as ways to lower their blood glucose and help them manage their diabetes. In particular GLP-1 can result in large benefits both in lowering blood glucose and body weight.

The American Diabetes Association (ADA) has been the leading organization advocating for people with diabetes for more than eight decades. Much of this work centers around access and affordability of care. People with diabetes must have access to medications and tools they need to manage the disease. Managing diabetes requires a holistic, multifaceted, person-centered approach that accounts for the complexities associated with diabetes and the complications and comorbidities people with diabetes are at risk for across an individual's life span. The American Diabetes Association *Standards of Care* recommends that person-specific factors for treatment should be individualized for achieving glycemic goals and should consider weight goals, the individual's risk for hypoglycemia, and the individual's history of risk factors for cardiovascular, kidney, liver, and other comorbidities and complications of diabetes.[1]

The ADA *Standards of Care* recommends that pharmacologic therapy be started at the same time type 2 diabetes is diagnosed and that approaches that provide the efficacy to achieve treatment goals should be considered. In general, higher-efficacy approaches have a greater likelihood of achieving glycemic goals, with the following having a very high efficacy for glucose lowering: the GLP-1 RAs dulaglutide and semaglutide. Weight management is a distinct treatment goal, along with glycemic management in individuals with type 2 diabetes, as it has multifaceted benefits, including improved glycemic management, reduction in hepatic steatosis, and improvement in cardiovascular risk factors. The glucose-lowering treatment plan should therefore consider approaches that support weight management goals, with semaglutide and tirzepatide currently having the highest weight loss efficacy among agents approved for glycemic management.[2]

While we share concerns over cost and wanting to ensure that patients can afford their medication, we must also balance that with ensuring access to treatment and minimizing barriers to care. We encourage the committee to take steps to ensure that the discussion, decisions, and policy-recommendations are patient-centered and do not result in access issues for patients.

Ensuring people with diabetes have access to the treatment and tools necessary to manage their disease can help them reduce the risk of developing devastating and costly complications including cardiovascular disease, kidney disease, and amputations. Protecting access to these medications and interventions to control diabetes can create cost savings and are ultimately cost-effective.[3] The ADA *Standards of Care* highlights the importance of weight loss, which can be achieved through the use of the medications, to reduce A1C and fasting glucose and may promote sustained diabetes remission.[4] The 2024 *Standards of Care* recommends that GLP-1 as preferred pharmacotherapy for obesity management in people with diabetes because of the greater weight loss efficacy.[5] We respectfully encourage the

[1] https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment
[2] https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2909081/
[4] https://diabetesjournals.org/care/article/47/Supplement_1/S145/153942/8-Obesity-and-Weight-Management-for-the-Prevention
[5] https://diabetesjournals.org/care/article/47/Supplement_1/S5/153943/Summary-of-Revisions-Standards-of-Care-in-Diabetes

committee to take the efficacy of these medications into account along with the cost-savings from preventing complications that increase the burden on both the patients and the health care system.

If you have any questions please contact me at ckemp@diabetes.org.

Carissa Kemp, Senior Policy Director, American Diabetes Association

Oregon Prescription Drug
Affordability Board

Email: pdab@dcbs.oregon.gov Phone: 971-374-3724 Website: dfr.oregon.gov/pdab

Trulicity
Affordability Review[1]

[1] Image source: https://www.trulicity.com/hcp/efficacy-weight. Accessed Jan. 23, 2024.

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Review Summary

Price history

Trulicity initially began marketing in December 2017. Over the past five years, Trulicity's wholesale acquisition cost (WAC) has increased by **5.0% YoY**[2] on average. This increase outpaced inflation in 2019, 2020, and 2023.[3]

Therapeutic alternatives

A clinical review found 4 therapeutic alternatives for Trulicity. Average gross spend per enrollee per year for Trulicity was **$5,061.** vs. an average of **$4,436** across this drug and all identified therapeutic alternatives. Average out of pocket cost for patients was **$296** per patient per year[4], vs. an average of **$328** across this drug and all identified therapeutic alternatives.

Cost to the healthcare system

In 2022, total gross spend for Trulicity in Oregon was **$125.5 million** across **24,793 enrollees,** with a gross per patient spend of **$5,061**.[5] Net spend for private insurers was estimated to be **$2,315 per enrollee per year**.[6]

Cost to patients

On average, the annual patient out-of-pocket costs for Trulicity in 2022 ranged from **$296** to **$401**[7] including deductibles, copays, and coinsurance.[8]

[2] Based on data from Medi-Span.
[3] Consumer Price Index: Archived Consumer Price Index Supplemental Files. U.S. Bureau of Labor Statistics, April 10, 2024. https://www.bls.gov/cpi/tables/supplemental-files/. Accessed Jan. 11, 2024.
[4] APAC total copay, deductible, and coinsurance spend for drug and total enrollees for drug. Averages across commercial, Medicaid, and Medicare plans.
[5] Based on Oregon's 2022 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information are prior to any price concessions such as discounts or coupons. For more information regarding APAC data: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[6] 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.
[7] Ibid
[8] Medicaid and Medicare were excluded from cost information.

Review Background

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.

In accordance with OAR 925-200-0020, PDAB will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010, and identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

This review addresses the affordability review criteria in OAR 925-200-0020, to the extent practicable. Therefore, due to limitations in scope and resources, some criteria will have minimal or no consideration in this review.

In addition to information provided by the Department of Consumer and Business Services (DCBS) pursuant to ORS 646A.694, this review reflects information from various sources, including Oregon's APAC database, state licensed insurance carriers responding to a DCBS data call, Medi-Span, and resources from the U.S. Food and Drug Administration (FDA) such as the Orange Book (small molecule drugs) and the Purple Book (biologics).

Drug Information

Drug proprietary name(s): **Trulicity**

Non-proprietary name: **Dulaglutide**

Manufacturer: **Eli Lilly and Company**

FDA approval

Trulicity was first approved by the FDA on 9/18/2014.[9]

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

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

[9] 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.

Information on the impact of GLP-1 agonists on health inequities has been identified, particularly concerning communities of color and under-resourced communities. An editorial published by Healthline in November 2023 discusses the disparities in access to the anti-obesity and diabetes medication, semaglutide. The article highlights that people belonging to Black and Hispanic communities are the most eligible for this medication due to their higher prevalence of type 2 diabetes.[10] However, white individuals are four times more likely to receive a prescription than other ethnic groups.[11] The article acknowledges the potential role of financial incentives in driving this disparity and it suggests solutions such as spreading awareness GLP-1 medications, making discounted programs more accessible, and addressing insurance coverage issues. The article concludes that access to GLP-1 medications should be equitable and available to those who would benefit from them the most.[12]

It is important to note that, while specific data about Native American and Pacific Islander populations was not found in the search results, these communities also face health disparities. People belonging to Black, Hispanic, Native American, Alaska Native, and Pacific Islander communities have the highest rates of obesity. Research shows that semaglutide can help people with overweight or obesity lower their weight by 9.6%-17.4%.[13] Unfortunately, access to medications like Trulicity can be a significant issue. Therefore, it is crucial to continue advocating for equitable access to these medications for all populations, especially those most at risk and in need.

Residents prescribed

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

Based on APAC claims, **24,793** Oregonians filled a prescription for Trulicity in 2022.[14]

[10] Cassata, Cathy. Black People Are Facing Greater Challenges Accessing Anti-Obesity Drugs Like Ozempic and Wegovy. Healthline, Nov. 15, 2023. https://www.healthline.com/health-news/ozempic-access-racial-disparities. Accessed May 8, 2024.
[11] Ibid.
[12] Ibid.
[13] Chao AM, Tronieri JS, Amaro A, Wadden TA. Clinical Insight on Semaglutide for Chronic Weight Management in Adults: Patient Selection and Special Considerations. Drug Des Devel Ther. 2022 Dec 29;16:4449-4461. doi: 10.2147/DDDT.S365416. PMID: 36601368; PMCID: PMC9807016.
[14] Number of 2022 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 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

The package wholesale acquisition cost (WAC) for Trulicity (NDC 00002143480, 1.5 mg / 0.5 mL Injection Prefilled Injection Pen 4 Pens) was **$931** as of 12/31/2023.[15]

The WAC for the drug was evaluated using Medi-Span's price history tables for the package WAC from 2019 to 2023 – see Figure 1. As of January 1, 2024, the WAC price increased another **5.0%** to **$977**.

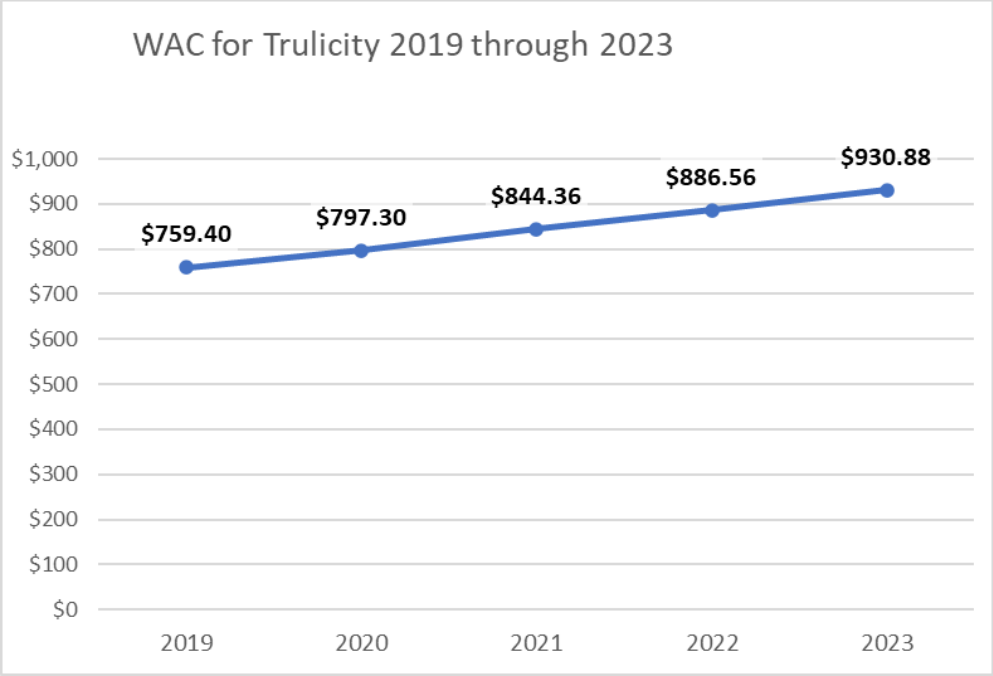

Figure 1 Trulicity WAC from 2019-2023

From 2019-2023, the average year-over-year change to the package WAC was calculated to be **5.0%**. The year-over-year percentage change in WAC for Trulicity compared to inflation rates[16] is displayed in Figure 2.

[15] To determine which NDC to use for the WAC price history, the available 2022 utilization data was analyzed and the NDC with the highest volume of claims in 2022 was used.

[16] Consumer Price Index: Archived Consumer Price Index Supplemental Files. U.S. Bureau of Labor Statistics, April 10, 2024. https://www.bls.gov/cpi/tables/supplemental-files/. Accessed Jan. 11, 2024.

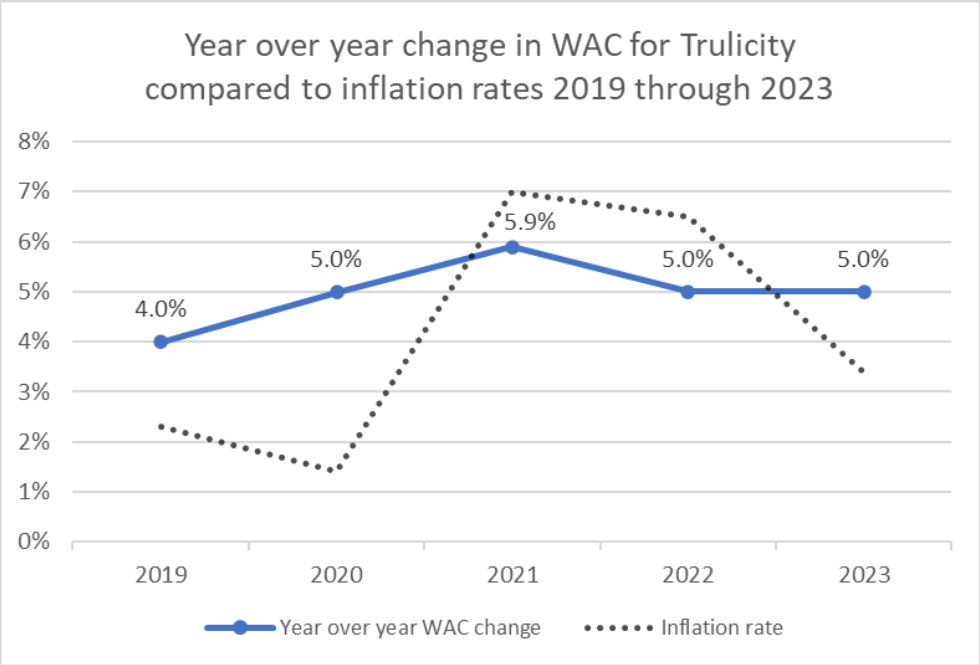

Figure 2 Year over year change in WAC compared to inflation rates[17]

Package WAC 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.

Pharmacy acquisition costs

Figure 3 shows the Oregon actual average acquisition cost (AAAC) for Trulicity (NDC 00002143480, 1.5 mg / 0.5 mL Injection Prefilled Injection Pen 4 Pens) from January 2020 to December 2023. The AAAC as of 12/31/2023 was **$448**. This is a discount of **54.2%** relative to WAC on that date.

AAAC is updated weekly by the Oregon Health Authority (OHA) using pharmacy survey data. The survey reflects the actual cost for pharmacies to purchase a given drug across all Medicaid enrolled pharmacies on a rolling basis. AAAC is used to calculate reimbursement to pharmacies for fee-for-service (or "open card") Medicaid claims.[18]

[17] Consumer Price Index: Archived Consumer Price Index Supplemental Files. U.S. Bureau of Labor Statistics, April 10, 2024. https://www.bls.gov/cpi/tables/supplemental-files/. Accessed Jan. 11, 2024.
[18] Average Actual Acquisition Cost (AAAC) Questions and Answers. Oregon Health Authority, Health Systems Division, Medicaid Programs, Jan. 19, 2023. https://www.oregon.gov/oha/HSD/OHP/Tools/aaac-qa.pdf. Accessed April 18 2024.

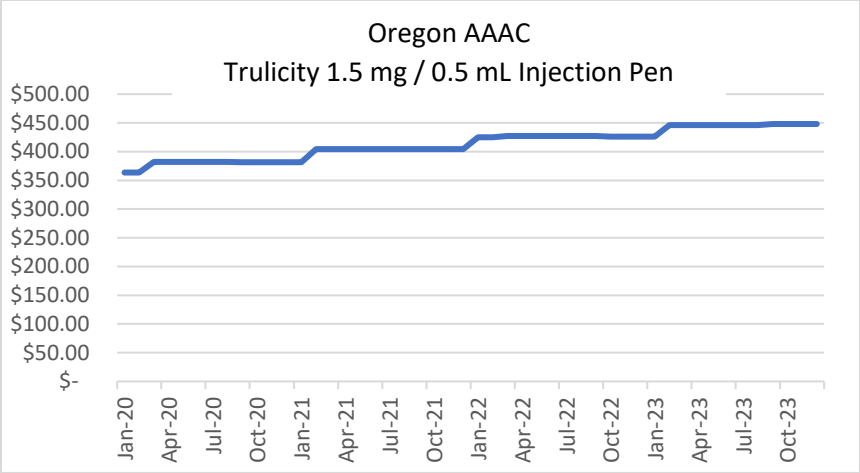

Figure 3 AAAC for Trulicity from Jan. 2020 to Oct. 2023

Effect of price on consumers' access to the drug

The Oregon Prescription Drug Price Transparency Program asks consumers to submit stories about the impact of high prescription drug prices in their personal experience in advance of its annual public hearing. No consumers have referenced the price of Trulicity as a barrier to access in submissions to the program in the last three years.

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.

Based on the information received from the carrier data call, the average gross cost of the drug per enrollee for commercial carriers was **$4,792** before any discounts, rebates, or other price concessions. The average net cost per enrollee after discounts, rebates, and other price concessions was **$2,315**, meaning that insurers reported an average of **52%** discount on the initial drug cost.

Table 1 Net cost estimate based on carrier submitted 2022 data

Payer line of business	Total enrollees	Average spend per enrollee pre-discount	Average spend per enrollee post discount
Commercial	5,642	$4,792	$2,315

The carrier data call[19] submissions were analyzed to determine the total gross annual spend, total number of claims and enrollees, the average amount paid for claim and per enrollee, and

[19] Cost information from the data call is the cost of the drug after price concessions.

out-of-pocket (OoP) costs for enrollees. Additional OoP information can be found in Table 2 below.

The total gross drug cost reported from the carrier data call prior to price concessions for Trulicity in 2022 was **$18,316,352**.

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.

No information was provided by the manufacturer or found in data review for price concession, discount or rebate the manufacturer provided to pharmacy benefit managers in this state for Trulicity.

Estimated price for therapeutic alternatives[20]

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, Trulicity injection, 1.5 mg/0.5 mL has limited availability due to increase in demand of the drug.[21]

[20] 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.

[21] FDA Drug Shortages: Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Federal Drug Administration, Dec. 15, 2022. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Dulaglutide%20Injection&st=c. Accessed May 8, 2024.

Comparative effectiveness to therapeutic alternatives:

Table 2 Alternative glucagon-like peptide-1 receptor agonists

Drug	FDA Approved Indications	~A1C Decrease	Short term weight loss	Rates of nausea	Formulation	Dosing frequency
Subject drug **Dulaglutide (Trulicity)**	• T2DM • CV risk reduction	1.5% - 1.8 %	2.5 – 4.6 kg	12% - 20%	SubQ	Weekly
Exenatide (Byetta)	• T2DM	1.0%	2 kg	8% - 11%	SubQ	Twice Daily
Exenatide ER (Bydureon)	• T2DM	1.5%	1.5 - 2.5 kg	8% - 11%	SubQ	Weekly
Liraglutide (Victoza)	• T2DM • CV risk reduction	1.5%	2.5 kg	18% - 20%	SubQ	Daily
Semaglutide (Ozempic)	• T2DM • CV risk reduction	1.5%	4.0 – 6.0 kg	15% - 20%	SubQ	Weekly
Semaglutide (Rybelsus)	• 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.[22] 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.
- There are no studies directly comparing GLP-1 agonists on CV outcomes.
- Within the GLP-1 agonists, the highest dose of dulaglutide (4.5 mg) is considered to have very high efficacy in lowering HgA1c and 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.

[22] 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.

- Compared to exenatide, dulaglutide was shown to be superior in reduction in HgA1C (-1.5% for dulaglutide 1.5 mg, -1.3% dulaglutide 0.75 mg, and -0.99% with exenatide).[23] Compared to liraglutide, dulaglutide was non-inferior in its ability to lower HgA1c (-1.36% vs. -1.42%, respectively).[24] Weight reduction was significantly greater with liraglutide compared to dulaglutide (-3.6kg vs. -2.9 kg; p=0.011).
- 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).[25] 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, is 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.

Table 3 Average healthcare and average patient OoP costs for Trulicity vs therapeutic alternatives

Drug	Average gross healthcare costs per enrollee per year[26]	Average patient out-of-pocket cost per year[27]
Subject drug Trulicity	$5,061	$296
Ozempic	$4,439	$326
Byetta	$4,784	$405
Victoza	$5,645	$299
Rybelsus	$2,252	$315
Average	**$4,436**	**$328**

Table 3 shows the average gross cost per enrollee per year was **$5,061** vs. an average of **$4,436** across this drug and all identified therapeutic alternatives. The average out of pocket cost for

[23] Wysham C, Blevins T, Arakaki R, et al. Efficacy and safety of dulaglutide added onto pioglitazone and metformin versus exenatide in type 2 diabetes in a randomized controlled trial (AWARD-1). Diabetes Care 2014; 37: 2159–2167.
[24] Dungan KM, Povedano ST, Forst T, et al. Once-weekly dulaglutide versus once-daily liraglutide in metformin-treated patients with type 2 diabetes (AWARD-6): a randomized, open-label, phase 3, non-inferiority trial. Lancet 2014; 384: 1349–1357.
[25] 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
[26] APAC total gross spend for drug and total unique enrollees for drug.
[27] APAC total copay, deductible, and coinsurance spend for drug and total unique enrollees for drug. Averages across commercial, Medicaid, and Medicare plans.

patients was **$296** per patient per year, vs. an average of **$328** across this drug and all identified therapeutic alternatives.

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.

No information was provided by manufacturers or found in data review for price concession, discount or rebate manufacturers provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives.

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.

In 2022, Trulicity had **118,149** total claims across **24,793** enrollees. Total gross cost of the drug was **$125,476,482** or **$5,061** per enrollee per year, and **$1,062** per claim per year.

Table 4 2022 Gross cost estimates based on APAC data[28]

Payer line of business	Total enrollees	Total claims	Total spend amount	Average spend amount per enrollee	Average spend amount per claim
Commercial	9,364	44,232	$45,311,398	$4,839	$1,024
Medicaid	5,681	29,094	$24,706,235	$4,349	$849
Medicare	9,748	44,823	$55,458,849	$5,689	$1,237
Total	**24,793**	**118,149**	**$125,476,482**	**$5,061**	**$1,062**

[28] Based on 2022 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

Table 5 2022 commercial carrier data call reported costs to Oregon payers and enrollees

Market	Data call total annual spend (payer paid)	Total unique claims	Total of paid claims	Total unique enrollees	Average paid claim	Average paid per enrollee	Total annual out-of-pocket cost for enrollees	Out-of-pocket cost per enrollee
Individual	$2,862,181	6,094	3,933	916	$728	$3,125	$693,333	$757
Small Group	$2,158,234	5,883	3,800	854	$568	$2,527	$327,367	$383
Large Group	$7,084,829	15,449	9,592	2,206	$738	$3,212	$716,140	$325
OEBB	$3,508,060	6,106	4,194	676	$836	$5,189	$352,671	$522
PEBB	$2,703,048	6,369	4,495	990	$601	$2,730	$173,981	$176
TOTAL	**$18,316,352**	**39,901**	**26,014**	**5,642**			**$2,263,492**	

Figure 4 represents the percentage of annual spend by market type reported in the carrier data call by commercial carriers. Large Groups represent the largest annual spend of thirty-nine percent of the Oregon commercially insured market.

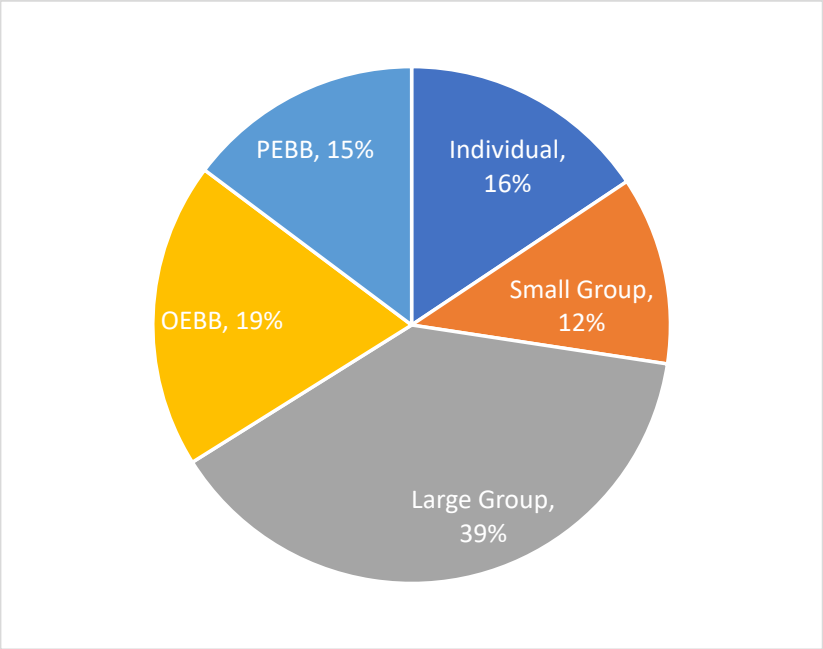

Figure 4 Data call total annual spend (payer paid)

Cost to the state medical assistance showed that the fee-for-service program had an average quarterly cost of **$125,892** for approximately **220** Trulicity claims. The drug was listed as a preferred drug and required prior authorization**.** Oregon's coordinated care organizations (CCOs) paid **$22,160,892** for **25,783** claims, averaging **$860** per paid claim.

Table 6 2022 Gross amount paid for Medicaid/Oregon Health Plan fee-for-service

Fee for Service[29]							
2022 Quarter	Drug name on report	Amount paid	% Total fee-for-service costs	Claim count	Average paid per claim	Preferred drug list (PDL)	Prior auth
Q1	TRULICITY*	$13,7204	1.40%	241	$569	Preferred	Yes
Q2	TRULICITY*	$139,987	1.40%	235	$596	Preferred	Yes
Q3	TRULICITY*	$127,279	1.40%	227	$561	Preferred	Yes
Q4	TRULICITY*	$99,097	1.10%	176	$563	Preferred	Yes
Annual Average:		**$125,892**	**1.33%**	**220**	**$572**		

Quarterly reports from the pharmacy utilization summary report provided by the Oregon State University drug use research and management program.

Table 7 2022 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	Amount paid	Claim count	Average paid per claim
Trulicity	$22,160,892	25,783	$860

Label and off-label indications and budget impact

Trulicity has a black box label warning regarding for the possible development of medullary thyroid cancer (MTC) and multiple endocrine neoplasia syndrome type 2 (MEN-2).[30]

[29] Drug Use and Research Management (DUR) utilization reports 2022. College of Pharmacy, Oregon State University. https://pharmacy.oregonstate.edu/drug-policy/oregon-p-t-committee/dur-reports. Accessed May 8, 2024.

[30] Trulicity: highlights of prescribing information, Eli Lilly. Federal Drug Administration. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125469s007s008lbl.pdf. Accessed May 8, 2024.

Trulicity can have an off-label indication for weight loss and for the treatment of Type 1 diabetes mellitus (T1DM). According to the manufacturer's website for Trulicity, clinical trials weight changes were a secondary endpoint of the effects of the drug indicating changes in weight with higher doses.[31,32]

For the 2022 Oregon insurer reported data **89%** of health insurances carriers reported a budget impact with Trulicity identifying it as one of their top 25 most costly prescription drugs. According to submitted information provided by the carriers the average costs per prescription was **$681**, with **13,176** prescriptions for **2,702** enrollees. It was estimated that the total annual spend was **$8,970,087** with a total annual spend per enrollee of **$3,320**.[33]

Additional label and off label indication information is provided under the Information from manufacturer sections.

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

Carriers reported **39,901** claims for Trulicity in 2022. Of those claims **26,014** were paid and **13,887** were rejected.[34] Based on this information, on average, **35%** of Trulicity claims were rejected in 2022.

Pharmaceutical claims may be rejected for a variety of reasons including patients trying to fill the prescription too soon or errors in the submitted claim. Pharmacists may also submit multiple claims for the same prescription should the initial claim be rejected. Therefore, claims information should only be used as a general baseline.

As part of the carrier data call, information was collected regarding prior authorizations and approval for the drug. Insurers reported a wide variety of plan designs for Trulicity. Unfortunately, the data call did not include the number of Oregonians under each plan listed, so DCBS was unable to determine the volume of Oregonians under plans that required prior authorization. Carriers reported a variety of plans, some with a more restrictive plan design and other plans with a more accessible plan design for the drug.

[31] Trulicity. Eli Lilly. https://trulicity.lilly.com/hcp/efficacy-weight/weight-loss-dosing?redirect-referrer=https%3A%2F%2Fwww.singlecare.com%2F. Accessed May 8, 2024.
[32] Amos, Audrey, and Marshall, Helen. Trulicity vs. Mounjaro: What you should know. Healthline, May 1, 2024. https://www.healthline.com/health/drugs/trulicity-vs-mounjaro#faq
[33] Revised Prescription Drug Subset List. Data for board review on Nov. 15, 2023. Prescription Drug Data, Prescription Drug Affordability Board website. https://dfr.oregon.gov/pdab/Documents/2023-PDAB-Top-Drug-List-v2.0.xlsx. Accessed May 8, 2024.
[34] For the purpose of this review the terms "denied" and "rejected" for claims are used interchangeable.

Information on how many carrier and market combinations were evaluated that had at least one plan that represented the following for Trulicity:

Table 8 Plan design analysis

Percent of carrier/market combinations that had one or more plans that:[35]	
Required prior authorization	82%
Did not require prior authorizations	18%
Drug was excluded on the plan formulary	0%
Drug was non-preferred on the plan formulary	32%
Drug was preferred on the plan formulary	68%
Required step therapy	45%
Did not require step therapy	55%

Note: percentages can equal over 100% 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.

According to recent statistics from the Centers for Disease Control and Prevention (CDC), nearly 40% of Medicare enrollees are battling obesity.[36] In light of this, the "Treat and Reduce Obesity Act" was introduced last year, with the aim of enabling Medicare to cover anti-obesity medications. However, given that this is a presidential election year, it is still being determined whether this measure will be signed into law.

If Medicare begins covering weight loss medications, this could have a significant impact on private health insurance coverage. The National Council on Aging's Center for Healthy Aging

[35] Less than 5% of all total Rx claims was omitted from carrier entries that were considered unusable.
[36] Adult Obesity Facts. Centers for Disease Control and Prevention, May 17, 2022. https://www.cdc.gov/obesity/data/adult.html. Accessed May 8, 2024.

suggests that Medicare typically influences private-sector insurance coverage, meaning that many insurers may follow suit if Medicare decides to cover weight loss drugs.[37]

Trulicity has been shown to be effective as a weight loss medication and has gained attention in the treatment of obesity. However, until the Treat and Reduce Obesity Act is passed, and Medicare is authorized to offer this new class of weight loss medications, it is still too early to predict the potential costs under Medicare.

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.[38]

The price of Trulicity is notably higher in the U.S., at around $600-$700 per month, than in other countries like Canada and the U.K., where it can cost between $200-$300 per package.[39,40,41] 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.[42] Copayments for Trulicity can vary, with patients typically paying a percentage of the drug's total cost, often ranging from $25 to $50.[43] 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.

[37] Wynn, Paul, and Gang, Emily. Does Medicare Cover Ozempic. U.S. News & World Report Health, May 2, 2024. https://health.usnews.com/medicare/articles/does-medicare-cover-ozempic#:~:text="Medicare%20typically%20affects%20private%2Dsector,starts%20covering%20weight%20loss%20drugs." Accessed May 8, 2024.
[38] 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/. Accessed May 8, 2024.
[39] Wynn, Paul, and Gang, Emily. Does Medicare Cover Ozempic. U.S. News & World Report Health, May 2, 2024. https://health.usnews.com/medicare/articles/does-medicare-cover-ozempic#:~:text="Medicare%20typically%20affects%20private%2Dsector,starts%20covering%20weight%20loss%20drugs." Accessed May 8, 2024.
[40] PharmaGiant 2024. https://pharmagiant.com/product/trulicity/. Accessed May 8, 2024.
[41] Trulicity: Once-weekly injection treatment for type 2 diabetes. Treated. https://uk.treated.com/diabetes/trulicity. May 8, 2024.
[42] 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/. Accessed May 8, 2024.
[43] Ibid.

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

The APAC database[44] and the carrier data call were analyzed to determine the average patient copayment for commercially insured enrollees or other cost-sharing for the prescription drug.

Table 9 Out of pocket costs

2022 Average annual patient out of pocket costs		
Value	**APAC (commercial plans only)[45]**	**Data Call[46]**
Average Co-Pay	$149	$142
Average Coinsurance	$98	$120
Average Deductible	$49	$139
Average Total Out-of-Pocket Costs for Patients[47]	**$296**	**$401**

Table 9 shows the breakdown of out-of-pocket costs based on APAC data for Trulicity. A majority of patients taking Trulicity could spend an average of **$300 - $400** in out-of-pocket costs. Table 10 represents the central tendency of Trulicity cost data, with patients spending an average of **$487,** with a maximum spend of **$15,755**. Figure 5 illustrate the distribution of patient out-of-pocket costs, indicating many patients pay **$0**, but a significant number pay near the median amount of **$110** or more, depending on insurance coverage and plan.

Table 10 OoP central tendency of Trulicity costs in 2022

Out of Pocket costs per patient per year[48]		
Min	*The lowest amount any one patient paid*	$0
Average	*Patients pay this much on average*	$487
Median	*Half of patients pay more than this amount and half pay less*	$110
Mode	*The largest number of patients pay this amount*	$0
Max	*The highest amount any one patient paid*	$15,755

[44] Costs from the APAC database are prior to any price concessions such as discounts or coupons. Cost information from the data call is the cost of the drug after price concessions.
[45] Medicaid and Medicare were excluded from cost information.
[46] Data call refers to cost information collected from the health insurance plans by DCBS on prescription drugs under both pharmacy and medical benefits after price concessions.
[47] For patients who used the drug at least once in the 2022 calendar year.
[48] For patients who used the drug at least once in the 2022 calendar year.

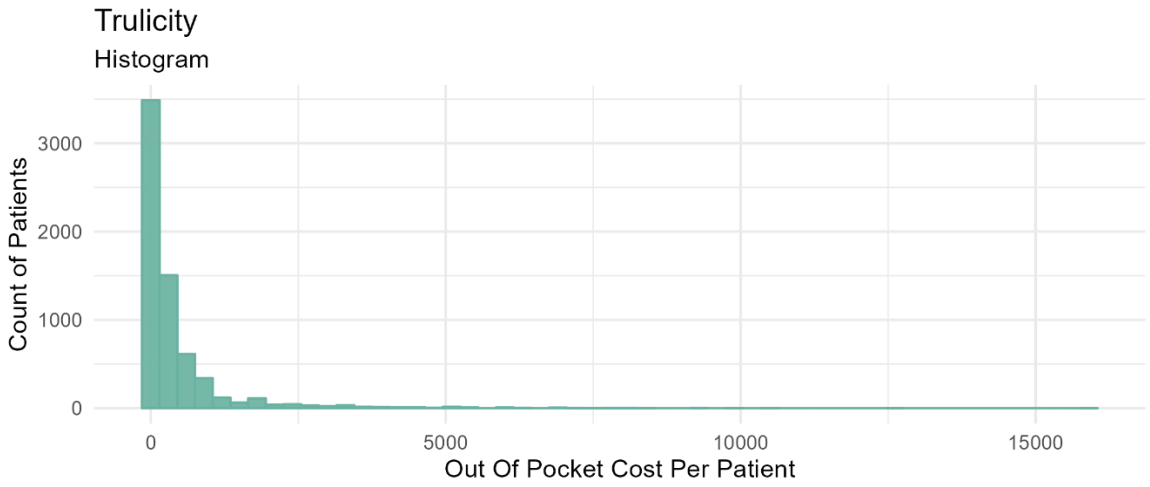

Figure 5 Patient count to OoP cost per patient

For plan designs reported in the carrier data call, when a co-pay was greater than $0, the co-pay ranged from $5.00 up to $250. If the coinsurance was greater than 0%, the coinsurance ranged from 10% up to 50%.

The average patient out-of-pocket costs for the APAC data may be impacted by mandatory state reporting requirements, the exclusion of data from health plans with fewer than 5,000 covered lives and is prior to price concessions. The carrier data call out-of-pocket costs are from reports collected by DCBS from commercial carriers and may be affected by price concessions.

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).

Refer to Appendix A for manufacturers' information.

- Cynthia Ransom, Senior Director, Government Strategy, with Jennifer Duck, JD, Vice President, US Public Affairs, with Eli Lilly and Company, submitted information on February 19, 2024.

Drug indications[49]

- FDA Approved:

[49] Trulicity Prescribing Information. Eli Lilly and Company. Indianapolis, IN: 11/2022.

- 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 (CV) events in adults with T2DM who have established cardiovascular disease or multiple cardiovascular risk factors.

- Off Label Uses:
  - Type 1 diabetes mellitus (T1DM)
  - Weight loss

Clinical efficacy

- Dulaglutide is a long-acting injectable glucagon-like peptide-1 (GLP-1) receptor agonist used to improve glycemic control and prevent CV events in T2DM. It is dosed subcutaneously, once weekly.[50] Evidence is insufficient to make recommendations for use in T1DM and it is currently not recommended in this population.[51]

- 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.[52]

- These initial studies provided moderate quality evidence 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.[53] Dulaglutide resulted in a dose-dependent weight loss of 1 to 3 kg in clinical trials.[54]

- In February 2020, the FDA labeling of dulaglutide was expanded to include the reduction of risk of major adverse CV events.[55] 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

[50] Trulicity Prescribing Information. Eli Lilly and Company. Indianapolis, IN: 11/2022.
[51] Ibid.
[52] 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
[53] Ibid.
[54] Ibid.
[55] Trulicity Prescribing Information. Eli Lilly and Company. Indianapolis, IN: 11/2022.

for glycemic control.[56] 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 treat [NNT] 71) and an absolute difference of 0.9% in the risk of stroke (HR 0.76; 0.62 to 0.94). There was no significant difference in the individual outcomes of myocardial infarction, CV death, or all-cause death. The mean difference in HgA1c between dulaglutide and placebo was -0.61%.[57]

- 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 ≥ 25 kg/m2, and on metformin therapy.[58] 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 -0.23 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).[59] The effects of these higher doses on cardiovascular outcomes have not been studied.

Clinical safety[60]

- <u>FDA safety warnings and precautions:</u>
  - Thyroid C-cell tumors
  - Pancreatitis
  - Hypoglycemia in combination with insulin or an insulin secretagogue
  - Hypersensitivity reactions
  - Acute kidney injury
  - Severe gastrointestinal disease
  - Diabetic Retinopathy complications
  - Acute gallbladder disease
- <u>Contraindications:</u>

[56] Gerstein HC, Colhoun HM, Dagenais GR, et al. Dulaglutide and cardiovascular outcomes in type 2 diabetes (REWIND): a double-blind, randomized 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.
[57] Gerstein HC, Colhoun HM, Dagenais GR, et al. Dulaglutide and cardiovascular outcomes in type 2 diabetes (REWIND): a double-blind, randomized 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.
[58] 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.
[59] Ibid.
[60] Trulicity Prescribing Information. Eli Lilly and Company. Indianapolis, IN: 11/2022.

- Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2.
- Hypersensitivity to dulaglutide.

- 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%).
- Safety advantages or disadvantages:
  - The most common side effects associated with GLP-1 receptor agonists include gastrointestinal side effects. These are dose-related and likely due to delayed gastric emptying or activation of centers involved in appetite regulation, satiety, and nausea. These are most common soon after initiation and during dose escalation. Rapid titration is associated with higher risk of GI symptoms. There is no evidence that one GLP-1 is associated with higher rates of GI symptoms than others.
  - 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).[61] 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.[62] Despite, an increased risk compared to placebo, the absolute risk remains small (additional 27 cases per 10,000 persons treated per year).[63]
  - In contrast to the other GLP-1 agonists, dulaglutide, liraglutide, and semaglutide do not require dose changes in patients with renal impairment.

Input from Specified Stakeholders

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

[61] 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. 2022;182(5):513–519. doi:10.1001/jamainternmed.2022.0338.
[62] Trulicity Prescribing Information. Eli Lilly and Company. Indianapolis, IN: 11/2022.
[63] Ibid.

Patients and Caregivers

- No input provided.

Individuals with Scientific or Medical Training

- No input provided.

Safety Net Providers

- No input provided.

Payers

- No input provided.

Other

- Carissa Kemp, Director, State Government Affairs, Oregon, American Diabetes Association, submitted information on February 20, 2024. Information can be viewed under Appendix B

Appendix A: Eli Lilly and Company

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

January 31, 2024

By Email (*PDAB@DCBS.oregon.gov*)

Oregon Department of Consumer and Business Services
ATTN: Oregon Prescription Drug Affordability Board (the "Board")
P.O. Box 14480
Salem, OR 97309

Re: Prescription Drug Affordability Review of Trulicity®

Dear Board,

I write on behalf of Eli Lilly and Company ("Lilly"), the manufacturer of Trulicity®. According to the "Oregon PDAB prescription drug and insulin list for affordability review (PDF)"[1] published on the public website for the Oregon Prescription Drug Affordability Board ("Board"), the Board intends to review prescription drugs, including Trulicity®, as outlined in OAR 925.200.0010 and OAR 925.200.0020 during the February 21, 2024 Board meeting and determine whether the selected products "may create affordability challenges for health care systems or high out-of-pocket costs for patients."[2]

Trulicity® is for adults and children 10 years of age and older with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose). Trulicity® is also used in adults with type 2 diabetes to reduce the risk of major cardiovascular (CV) events (problems having to do with the heart and blood vessels) such as death, heart attack, or stroke in people who have heart disease or multiple cardiovascular risk factors. Trulicity® is the only GLP-1 RA that provides this combination of benefits: powerful A1C reduction across 4 doses, proven CV benefit in both primary and secondary prevention patients, simply delivered.[3] In fact, in AWARD-11, Trulicity® provided sustained A1C reduction at 1 year of <7%.[4] Trulicity® acts like the natural human hormone, GLP-1, helping the body do what it's supposed to do naturally: reduces hepatic glucose production by decreasing glucagon secretion, slows gastric emptying

[1] Division of Financial Regulation : Prescription drug data : Oregon Prescription Drug Affordability Board : State of Oregon; https://dfr.oregon.gov/pdab/Pages/data.aspx
[2] ORS 646A.694.
[3] Treating Adults with Type 2 Diabetes | HCP | Trulicity (dulaglutide)
[4] Clinical Trials: Lowering A1C, Weight Change & CV Data | HCP | Trulicity (dulaglutide)

and releasing glucose-dependent insulin. Reductions in fasting and postprandial serum glucose were observed as quickly as 48 hours after the first dose of Trulicity®.[5]

We appreciate that you share Lilly's desire to help more Oregonians access lower-cost prescription drugs, including Trulicity®, and we are proud to lead the industry in making our products affordable. Lilly continues to advocate for patient choice, with most patients having the ability to choose the GLP-1 that is appropriate for them with the help of their healthcare provider. This choice has maintained healthy competition in the broader GLP-1 market. We feel we are both competitively priced based on the clinical value we provide and the class in which we compete. All eligible, commercially insured patients with coverage for Trulicity® pay as little as $25 for up to 12 pens with the $25 Trulicity ® Savings Card Program. Due to the combination of formulary access provided by payers and affordability programs provided by Lilly, patients in Oregon paid an average of $53 to $83 per month for their therapy in 2023.

As a cutting-edge pharmaceutical company, innovation is at the heart of what we do, particularly for people with diabetes. With the first animal-derived insulin, Lilly extended life expectancy for people with type 1 diabetes from a couple of years into a person's thirties. Now, following a century of innovation, life expectancy for people with type 1 diabetes is in their sixties. Type 2 diabetes is the most common diabetes diagnosis in adults, and the mortality rate for diabetes in the US remains higher than the average rate for other comparable countries. In addition, the share of the total population diagnosed has been increasing, from 2.5% in 1980, to 7.2% in 2017.[6] Diabetes significantly reduces a person's life expectancy. Even with modern insulin and devices, two thirds of people struggle to keep their disease under control. Trulicity® plays an important role as an innovative option accessible to patients. There's more work to do, not only on diabetes, but also many other diseases like Alzheimer's and cancer.

That's why Lilly consistently invests 25% of our total revenue into research and development—$7.1 billion last year and $8.5 billion budgeted this year. That enables us to introduce new medicines—19 in the last decade, including the first Covid antibody therapy, and more medicines in the pipeline. Earlier this year, we shared exciting results from a study on a promising new Alzheimer's medicine, which followed approximately $8.5 billion in research

[5] How Trulicity Works, MOA & FPG and PPG Reductions | HCP | Trulicity (dulaglutide)
[6] How have diabetes costs and outcomes changed over time in the U.S.? - Peterson-KFF Health System Tracker

and development for Alzheimer's and other neurodegenerative afflictions and literally decades of work, including previous late-stage failures of three other potential Alzheimer's medicines.

We appreciate that the Board shares our commitment to prescription drug affordability. We are proud of the impact that our efforts have had on making prescription drugs more affordable and believe the Board's review of Trulicity® will demonstrate the meaningful impact Trulicity® and our solutions have had for patients with type 2 diabetes.

Sincerely,

Cynthia Ransom
Sr. Director, Government Strategy

Appendix B: American Diabetes Association

Thank you for the opportunity to comment on the discussion of the affordability of glucagon-like peptide (GLP-1) agonists. These medications are essential for people with type 2 diabetes as ways to lower their blood glucose and help them manage their diabetes. In particular GLP-1 can result in large benefits both in lowering blood glucose and body weight.

The American Diabetes Association (ADA) has been the leading organization advocating for people with diabetes for more than eight decades. Much of this work centers around access and affordability of care. People with diabetes must have access to medications and tools they need to manage the disease. Managing diabetes requires a holistic, multifaceted, person-centered approach that accounts for the complexities associated with diabetes and the complications and comorbidities people with diabetes are at risk for across an individual's life span. The American Diabetes Association *Standards of Care* recommends that person-specific factors for treatment should be individualized for achieving glycemic goals and should consider weight goals, the individual's risk for hypoglycemia, and the individual's history of risk factors for cardiovascular, kidney, liver, and other comorbidities and complications of diabetes.[1]

The ADA *Standards of Care* recommends that pharmacologic therapy be started at the same time type 2 diabetes is diagnosed and that approaches that provide the efficacy to achieve treatment goals should be considered. In general, higher-efficacy approaches have a greater likelihood of achieving glycemic goals, with the following having a very high efficacy for glucose lowering: the GLP-1 RAs dulaglutide and semaglutide. Weight management is a distinct treatment goal, along with glycemic management in individuals with type 2 diabetes, as it has multifaceted benefits, including improved glycemic management, reduction in hepatic steatosis, and improvement in cardiovascular risk factors. The glucose-lowering treatment plan should therefore consider approaches that support weight management goals, with semaglutide and tirzepatide currently having the highest weight loss efficacy among agents approved for glycemic management.[2]

While we share concerns over cost and wanting to ensure that patients can afford their medication, we must also balance that with ensuring access to treatment and minimizing barriers to care. We encourage the committee to take steps to ensure that the discussion, decisions, and policy-recommendations are patient-centered and do not result in access issues for patients.

Ensuring people with diabetes have access to the treatment and tools necessary to manage their disease can help them reduce the risk of developing devastating and costly complications including cardiovascular disease, kidney disease, and amputations. Protecting access to these medications and interventions to control diabetes can create cost savings and are ultimately cost-effective.[3] The ADA *Standards of Care* highlights the importance of weight loss, which can be achieved through the use of the medications, to reduce A1C and fasting glucose and may promote sustained diabetes remission.[4] The 2024 *Standards of Care* recommends that GLP-1 as preferred pharmacotherapy for obesity management in people with diabetes because of the greater weight loss efficacy.[5] We respectfully encourage the

[1] https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment
[2] https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2909081/
[4] https://diabetesjournals.org/care/article/47/Supplement_1/S145/153942/8-Obesity-and-Weight-Management-for-the-Prevention
[5] https://diabetesjournals.org/care/article/47/Supplement_1/S5/153943/Summary-of-Revisions-Standards-of-Care-in-Diabetes

committee to take the efficacy of these medications into account along with the cost-savings from preventing complications that increase the burden on both the patients and the health care system.

If you have any questions please contact me at ckemp@diabetes.org.

Carissa Kemp, Senior Policy Director, American Diabetes Association

2024 Report for the Oregon Legislature

Generic Drug Report Pursuant to Senate Bill 844 (2021)

Oregon Prescription Drug
Affordability Board

Board members

Shelley Bailey, chair

Dr. Amy Burns, vice chair

Dr. Dan Hartung

Robert Judge

Dr. Christopher Laman

John Murray

Akil Patterson

For more information:

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Jessica Knecht, lead designer, DCBS

Table of contents

Background

What are prescription drugs and what role do generics play? Prescription drugs are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease.[1] Generics are created to be the same as already-marketed, brand-name prescription drugs in dosage, safety, strength, performance, and use, working the same way and providing the same clinical benefit.[2] However, generic drugs usually cost less for patients and the Oregon health care system. In 2021, the use of generics and biosimilars in Oregon brought about a savings of $951 million in the Medicare program.[3]

The work of the Prescription Drug Affordability Board (PDAB) is to consider prescription drugs that may create affordability challenges for Oregonians and the state's health care system. If medications are not affordable, Oregonians may be unable to take them as prescribed, resulting in poor health outcomes. When the Oregon Legislature created PDAB in 2021 through Senate Bill 844, it asked the board to study generic drugs and their affordability for patients. The board has prepared two generic drug reports for the Legislature so far. In 2022, the board's report focused on the supply chain, drug shortages, and the need to reform patent laws to encourage the use of generics. The 2023 report looked at the cost savings from biosimilars, which work the same as biologic drugs but are less expensive to manufacture. This 2024 generic drug report evaluates the use of generic drugs to lower the cost of medications for consumers and the health care system.

[1] Prescription Drugs and Over-the-Counter (ORC) Drugs: Questions and Answers. *U.S. Food & Drug Administration*. Nov. 13, 2017. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers.

[2] Generic Drugs: Questions & Answers. *U.S. Food & Drug Administration*. March 16, 2021. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#q1.

[3] Generic and Biosimilar Medicines Save Oregon Patients Billions. *Biosimilars Council*, a division of *Association for Accessible Medicines*. https://accessiblemeds.org/sites/default/files/2023-01/AAM-2022-generic-biosimilar-savings-Oregon.pdf.

Authorized generics

Authorized generics refer to drugs sold by brand-name drug manufacturers or their licensees under generic labels. Although authorized generics constitute a small portion of filled prescriptions, brand manufacturers often use authorized generics to maintain high drug prices that can undermine generic competition.[4] There are three primary reasons why brand manufacturers use authorized generics:

1. To maintain market share after generic drugs have entered the market.
2. As a bargaining chip in pay-for-delay settlement deals with generic manufacturers before the entry of independent generic drugs, thereby delaying generic competition.
3. To allay public concern and criticisms concerning the high prices of brand-name drugs.[5]

A recent study of entacapone, a medication used for Parkinson's disease, showed that the presence of multiple authorized generics can lead to increased spending when there is limited independent generic competition. Almatica Pharma, the manufacturer of brand-name entacapone (Comtan) successfully delayed effective competition by signing settlement agreements with several generic manufacturers. These generic manufacturers produced and sold authorized generics instead of independent generics, which undermined the ability of generic competition to lower the drug's price.[6]

[4] Rome BN, Gunter SJ, Kesselheim AS. Market dynamics of authorized generics in Medicaid from 2014 to 2020. *Health Services Research*. 2023;58(4):953-959. doi:10/gs3g4m

[5] Dusetzina SB, Keating NL, Huskamp HA. Authorized Generics and Their Evolving Role in Prescription Drug Pricing and Access. *JAMA Internal Medicine*. 2021;181(4):423-424. doi:10.1001/jamainternmed.2020.8450

[6] Rome BN, Egilman AC, Patel NG, Kesselheim AS. Using Multiple Authorized Generics to Maintain High Prices: The Example of Entacapone. *Value Health*. 2023;26(3):370-377. doi:10.1016/j.jval.2022.08.013

Manufacturer strategies to prevent/delay generic or biosimilar competition

Manufacturers use various tactics to prevent generics from entering the market and delay competition. These tactics include "pay-for-delay" settlements, misuse of citizen petitions, product hopping, secondary patenting, limited supply agreements, and patenting Food and Drug Administration (FDA)-mandated risk evaluation and mitigation strategies (REMS).[7]

Pay-for-delay settlements

Delaying the introduction of new generics to the market can significantly influence health care costs, particularly for Medicaid programs. According to a study published in Health Affairs, the cost of delays in generic drug entry, primarily due to patent litigation, resulted in around $761 million in excess spending by state programs.[8] From 2010 to 2016, 69 brand-name drugs were expected to lose market exclusivity. Of these, 45 percent either did not face competition from generics by the end of the study period or had the introduction of generics delayed by more than a quarter.[9]

Pay-for-delay agreements occur when brand-name pharmaceutical companies pay generic competitors to delay the entry of lower-cost generic drugs into the market. These agreements arise during patent litigation settlements between brand-name and generic drug manufacturers.[10]

This works by brand-name pharmaceutical companies delaying generic competition by paying a generic competitor to hold its competing product off the market for a certain period of time. These agreements are often considered a win-win for the companies involved: brand-name pharmaceutical prices remain high, and both the brand and generic drug share the benefits of the brand's monopoly profit. However, consumers lose because they miss out on the significant cost savings that generic drugs offer. Generic medications can be as much as 90 percent less expensive than their brand-name counterparts. For example, a brand-name drug costing $300 per month might have a generic version available for as little as $30 per month.[11]

The influence on consumer affordability is substantial. Pay-for-delay agreements are estimated to cost American consumers $3.5 billion per year, which adds up to $35 billion over the next 10 years.[12] These anticompetitive deals effectively block other generic drug competition, preventing consumers from accessing more affordable alternatives. The Federal Trade Commission (FTC)

[7] Vokinger KN, Kesselheim AS, Avorn J, Sarpatwari A. Strategies That Delay Market Entry of Generic Drugs. *JAMA Internal Medicine*. 2017;177(11):1665-1669. doi:10.1001/jamainternmed.2017.4650
[8] Dave CV, Sinha MS, Beall RF, Kesselheim AS. Estimating the Cost of Delayed Generic Drug Entry to Medicaid. *Health Affairs (Millwood)*. 2020;39(6):1011-1017. doi:10.1377/hlthaff.2019.00673
[9] Ibid.
[10] Pay-for-delay: When Drug Companies Agree Not to Compete. *Federal Trade Commission*. June 20, 2023. https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay
[11] Ibid.
[12] Ibid.

has been actively investigating and taking enforcement actions against pay-for-delay agreements to deter their use. The FTC recommends that the U.S. Congress pass legislation to protect consumers from such anticompetitive practices as these agreements significantly postpone consumer savings from lower generic drug prices, ultimately affecting affordability and access to essential medications.

Citizen petitions

A 2020 study revealed that misuse of the FDA's citizen petition process by brand-name manufacturers resulted in a financial burden of $1.9 billion to the government and American taxpayers.[13] This process is intended to provide individuals and advocates an avenue to shape FDA decision-making. Yet, it has been observed that pharmaceutical companies sometimes misuse citizen petitions to delay the entry of generic drugs into the market. Even a delay of 90 days can generate hundreds of millions of dollars in revenue for brand-name drug companies, making the filing of these petitions worthwhile despite their spurious nature.[14]

Product hopping

Manufacturers also have been known to engage in product hopping, a tactic in which a newer, ostensibly improved version of a drug is released as the original product nears generic competition. Patients are then encouraged to switch to the newer version, often generating increased profits for the manufacturer. An analysis found that product hopping for just five drugs prevented generic competition and cost the U.S. health care system $4.7 billion annually for the past 20 years.[15]

For example, in the early 2000s, as generic competition for the drug TriCor was close to coming to market, the manufacturer slightly reformulated the drug preventing the launch of any generic options. The manufacturer engaged in multiple reformulations between 2000 and 2008 resulting in nearly $1.4 billion in annual U.S. sales.[16] Other drugs observed engaging in product hopping include Prilosec, Suboxone, Doryx, and Namenda.

Regulatory reforms and policies should be implemented so manufacturers are prevented from product hopping and generics can enter markets in a timely manner.[17]

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[13] Feldman R. The Burden on Society from Eleventh-Hour "Citizen Petitions" Filed to Slow Generic Drugs. *Maryland Law Review Online*. 2020; 79:1. https://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1061&context=endnotes

[14] Ibid.

[15] Brand Drug Product Hopping Costs US $4.6B Annually. *PharmaNews Intelligence*. Sept. 17, 2020; https://pharmanewsintel.com/news/brand-drug-product-hopping-costs-us-4.7b-annually

[16] Downing N, Ross J, Jackevicius C, Krumholz H. Avoidance of generic competition by Abbott Laboratories' fenofibrate franchise. *NIH Archives of Internal Medicine*. 2021; 172 (9): 724–30. https://pubmed.ncbi.nlm.nih.gov/22493409/.

[17] Wouters OJ, Feldman WB, Tu SS. Product Hopping in the Drug Industry - Lessons from Albuterol. *New England Journal of Medicine*. 2022;387(13):1153-1156. doi:10.1056/NEJMp2208613

Limited supply agreements

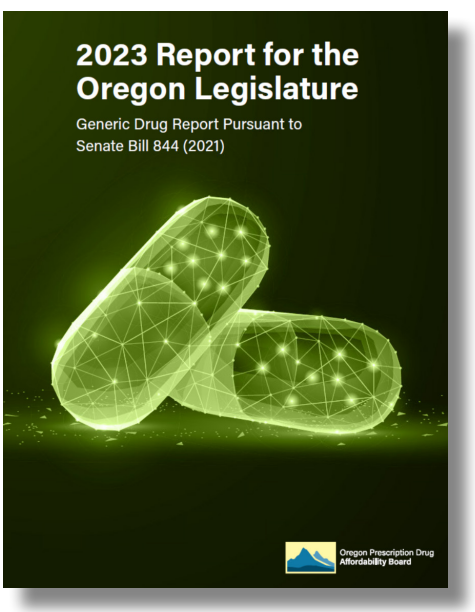
Like generic drugs, biosimilars face challenges upon entering the market, including various delay tactics from manufacturers. From 2016 to 2019, the FDA approved five biosimilars for the popular drug adalimumab (Humira); however, patent litigation delayed the market entry of these biosimilars until 2023. It is estimated that if adalimumab biosimilars had been launched upon approval, biosimilar competition would have saved Medicare $2.19 billion between 2016 and 2019, highlighting the importance of timely biosimilar entry.[18]

Despite biosimilars entering the market in 2023, Humira, manufactured by AbbVie, continues to dominate the market due to the release of an updated version in 2018. This has complicated biosimilar competition because biosimilar versions of adalimumab need to mimic changes made by the brand-name manufacturer to be considered interchangeable with Humira.

Drug tier placement

When prescription drug formularies place biologics and biosimilars on the same tier, it can create market issues. In a recent example, one biosimilar manufacturer attempted a two-price strategy to improve formulary coverage. This led to pharmacy benefit managers preferring the higher priced biosimilar for payer coverage formularies, which potentially negatively effects the ability of Humira biosimilars to generate savings through competition.[19] Indeed, recent analyses suggest that biosimilar competition has yet to translate into lower out-of-pocket costs for patients using biologics.[20]

One obstacle to timely biosimilar competition is the results of litigation. The Biologics Price Competition and Innovation Act (BPCIA), established in 2010 as part of the Affordable Care Act, aimed to create an abbreviated approval pathway for biosimilars. However, according to an article published in Health Affairs, the BPCIA has faced two main challenges that limit biosimilar competition: (1) noncompliance from biosimilar manufacturers with the litigation process outlined in the BPCIA biosimilar approval pathway; and (2) the enforcement of a large number of patents by biologic manufacturers.[21] As a result, patent infringement litigation often delays biosimilar entry for years after biosimilars receive FDA approval. Although there are differences between the biosimilar approval pathway and their reference product, generally biosimilars are priced lower. Lowered drug prices can lead to significant cost savings for the health care system through better drug tier placement and potentially reduce patient costs. Additional information on cost savings from biosimilars can be found in the 2023 generic drug report for the Oregon Legislature.[22]



[18] Lee CC, Najafzadeh M, Kesselheim AS, Sarpatwari A. Cost to Medicare of Delayed Adalimumab Biosimilar Availability. *Clinical Pharmacology & Therapeutics*. 2021;110(4):1050-1056. doi:10.1002/cpt.2322

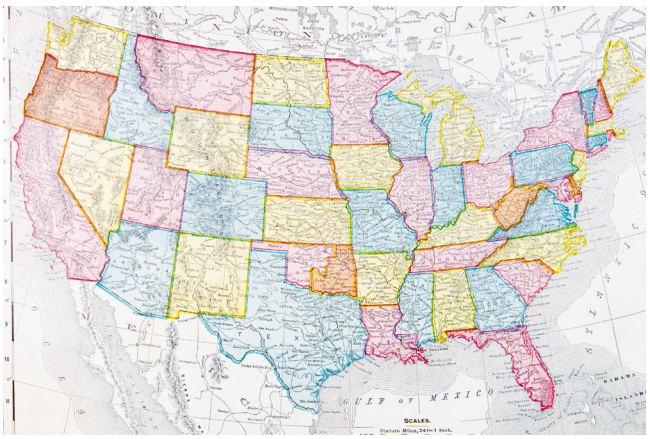
[19] Rome BN, Kesselheim AS. Biosimilar Competition for Humira Is Here: Signs of Hope Despite Early Hiccups. *Arthritis Rheumatol*. 2023;75(8):1325-1327. doi:10/gs3g33

[20] Feng K, Russo M, Maini L, Kesselheim AS, Rome BN. Patient Out-of-Pocket Costs for Biologic Drugs After Biosimilar Competition. *JAMA Health Forum*. 2024;5(3):e235429. doi:10.1001/jamahealthforum.2023.5429

[21] Van de Wiele VL, Kesselheim AS, Sarpatwari A. Barriers to US Biosimilar Market Growth: Lessons from Biosimilar Patent Litigation. *Health Affairs (Millwood)*. 2021;40(8):1198-1205. doi:10.1377/hlthaff.2020.02484

[22] 2023 Report for the Oregon Legislature. *Oregon Prescription Drug Affordability Board*. June 2023. https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Generic-Drug-Report-2023.pdf

Generic- and biosimilar-related litigation and legislation



The Hatch-Waxman Act of 1984 is the primary federal law in the U.S. that governs how generic drugs are brought to the market. It provides some significant provisions, such as enticing generics to challenge a brand-name drug patent with a lucrative 180-day exclusivity for being the first to come to market. Additionally, it allows generics to show bioequivalence to a reference brand drug without undergoing expensive and duplicative clinical trials. It also enables patent infringement litigation as soon as generics file for approval from the FDA. This helps determine whether the brand manufacturer's patents prevent generic entry and whether the generic does not have to enter "at risk."[23] Despite federal laws supporting prompt generic market entry, litigation concerning trade agreements and limiting "skinny labeling," in which generic manufacturers can enter the market only for drug indications that no longer have market exclusivity, have further delayed generic entry and produced excess costs in the U.S. health care system.[24] This same issue affects biosimilar drugs. An assessment was performed on the frequency of biosimilars marketed with skinny labels from 2015 to 2021, finding that the use of skinny labels led to a median of 2.5 years of earlier biosimilar competition through 2021. The investigators estimate this saved Medicare $1.5 billion through 2020, emphasizing the importance of skinny labels to ensure timely biosimilar competition for high-cost biologics.[25]

Recently, a U.S. judge of the Eastern District of Pennsylvania approved a settlement in an antitrust class action brought by direct pharmaceutical purchasers. The plaintiffs alleged that Sun Pharmaceutical Industries Ltd., Taro Pharmaceutical Industries Ltd., and others participated in a scheme to fix generic drug prices. The approved settlement amounted to $85 million.[26] However, it is important to note that on another front, a federal district court judge in Pennsylvania ruled that states were not entitled to a share of the profits that generic manufacturers allegedly made from their price-fixing scheme.[27] The case encompasses potential class action lawsuits related to price fixing of generic drugs in violation of the Sherman Act and state antitrust laws. Currently, there are claims concerning 18 drugs against several pharmaceutical manufacturers, and the scope has been expanded to include claims brought by 40 states through their attorneys general.[28]

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[23] The Kesselheim AS, Darrow JJ. Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era? *Yale Journal of Health Policy, Law, and Ethics*. 2015;15(2):293-347. http://hdl.handle.net/20.500.13051/5929

[24] Walsh BS, Bloomfield D, Kesselheim AS. A Court Decision on "Skinny Labeling": Another Challenge for Less Expensive Drugs. *JAMA*. 2021;326(14):1371-1372. doi:10.1001/jama.2021.0006

[25] Egilman AC, Van de Wiele VL, Rome BN, et al. Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings. *JAMA Internal Medicine*. 2023;183(1):82-84. doi:10.1001/jamainternmed.2022.5419

[26] Generic pharmaceutical drugs direct purchasers $85M class action settlement. *Top Class Actions*. Feb. 16, 2024. https://topclassactions.com/lawsuit-settlements/prescription/generic-pharmaceutical-drugs-direct-purchasers-85m-class-action-settlement/.

[27] Dunleavy K. Generic drugmakers win one, lose one in sweeping price-fixing case involving 49 states, 20 companies. *Fierce Pharmacy*. June 9, 2022. https://www.fiercepharma.com/pharma/generic-drugmakers-win-one-lose-one-price-fixing-sweeping-case-involving-49-states-20.

[28] MDL 2724 In Re: Generic Pharmaceuticals Pricing Antitrust Litigation. *United States District Court Eastern District of Pennsylvania*. 2016. https://www.paed.uscourts.gov/mdl/mdl-2724-re-generic-pharmaceuticals-pricing-antitrust-litigation

Generic and biosimilar drug pricing

Although generic drug prices are meant to offset the high initial prices of brand-name drugs, rising prices of generic products are a cause for concern. A study using Medicaid State Drug Utilization Data (2012-2018) found that price spikes for generic drugs are associated with injectable products, fewer manufacturers, and shortages.[31] While fewer price spikes seem to be occurring over time, the costs can still be substantial.

The high prices of some off-patent drugs are influenced by various market dynamics and manufacturer behaviors, including market consolidation, drug shortages, and anticompetitive practices among generic drug manufacturers. Articles reviewed highlight recent trends in the regulatory approval, manufacturing, and pricing of generic drugs in the U.S. This includes the influence of competition on generic drug prices, strategies that manufacturers use to delay generic entry, such as pay-for-delay or reverse-payment settlements, and the role of the FDA in prioritizing review of generic drug applications for markets with few manufacturers.[29] Suggested potential policy solutions to address these issues include greater antitrust enforcement, reducing barriers to generic drug entry, and novel solutions to minimize drug shortages, such as drug importation and nonprofit drug manufacturing.[30]

A study assessed whether generic competition will be an effective mechanism for high-priced specialty drugs, using commercial claims data to investigate treatments for chronic myeloid leukemia. The analysis found that, between 2001 and 2016, the list price of imatinib, a lifesaving anticancer drug, more than doubled. Generic imatinib was highly anticipated to provide more cost savings compared to the high price of the brand. Imatinib, an effective cancer drug, was first approved in 2003, but it had low patient adherence due to its costs. The first generic imatinib entered the market in 2016, but the launch price was only 8 percent lower than that of the brand-name drug.[32] Using data from Medicare Part D, a study was done to estimate spending on imatinib to see if this changed upon generic entry. While the acquisition cost for imatinib fell, the markup cost increased substantially, and Medicare

[29] Gupta R, Shah ND, Ross JS. Generic Drugs in the United States: Policies to Address Pricing and Competition. *Clinical Pharmacology & Therapeutics*. 2018;105(2):329-337. doi:10.1002/cpt.1314

[30] Tessema FA, Kesselheim AS, Sinha MS. Generic but Expensive: Why Prices Can Remain High for Off-Patent Drugs. *Hastings Law Journal*. 2020;71:1019

[31] Patel AN, Kesselheim AS, Rome BN. Frequency of Generic Drug Price Spikes and Impact on Medicaid Spending. *Health Affairs (Millwood)*. 2021;40(5):779-785. doi:10.1377/hlthaff.2020.02020

[32] Cole AL, Dusetzina SB. Generic Price Competition for Specialty Drugs: Too Little, Too Late? *Health Affairs*. 2018;37(5):738-742. doi:10.1377/hlthaff.2017.1684

beneficiaries faced out-of-pocket costs of $80 to $400 per fill.[33] This indicates that barriers to entry may be significant, and few firms entered the generic market to sell the drug, leading to minimal price reduction.

Despite the expected post-Hatch-Waxman trends, high point-of-sale prices have led to more costs for Medicare Part D patients. Another article highlighted the complex financial dynamics of the drug supply chain, including rebates offered by drug manufacturers to incentivize expensive drugs and the spread pricing method adopted by pharmacy benefit managers to generate profits and benefit from higher drug prices. However, implementing the Inflation Reduction Act of 2022 should lead to annual out-of-pocket costs of $2,000 for Part D beneficiaries starting in 2025. Furthermore, the Pharmacy Benefit Manager Transparency Act of 2023 will require pharmacy benefit managers to report their fees, leading to more transparency and accountability.[34]

Lastly, a study examining the association between generic drug prices and market competition showed nearly half of the 1,120 generic drugs examined exist in a baseline duopoly-like state. Generic drugs with low competition were associated with greater price increases (63.8 percent) than drugs with high competition (9.7 percent).[35] Reviews showed several potential reasons for this trend, including the lack of a financial incentive in smaller markets and consolidation among generic drug manufacturers. Those with low competition were associated with greater price increases than those with high competition.

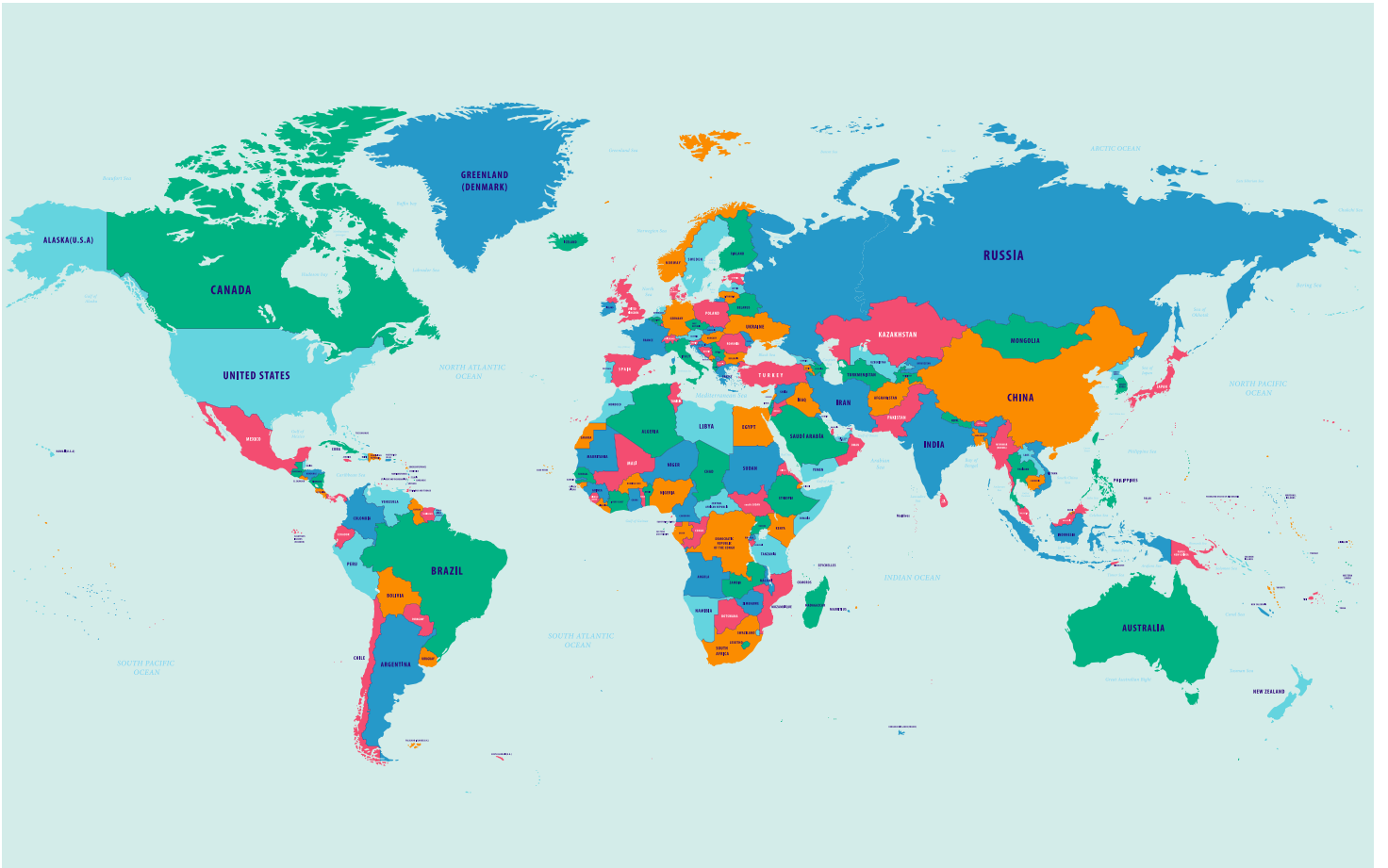
Overall, studies show the complexities of the U.S. drug market, highlighting the need for greater competition and policy solutions to ensure affordable access to necessary medications.

[33] Dusetzina SB. Medicare Part D Payments for Generic Imatinib From 2017 to 2023. *JAMA Internal Medicine*. 2024;184(1):104-105. doi:10.1001/jamainternmed.2023.3932

[34] Crosson FJ, Kesselheim AS. Why Some Patients Overpay for Specialty Generic Drugs. *JAMA Internal Medicine*. Published online November 20, 2023. doi:10.1001/jamainternmed.2023.6071

[35] Dave CV, Kesselheim AS, Fox ER, Qiu P, Hartzema A. High Generic Drug Prices and Market Competition: A Retrospective Cohort Study. *Annual Internal Medicine*. 2017;167(3):145-151. doi:10.7326/M16-1432

Generics in other countries



It is widely known that Americans pay more for prescription drugs than people in other developed countries. A 2017 study compared the prices of generic drugs in the U.S. with 13 European countries. The study found that generic drug prices varied significantly among European countries and were generally higher than in the U.S. However, the U.S. has recently seen sharp price increases for some generic products. The study also noted that uptake of generic prescriptions is slower in Europe than in the U.S. The report highlights differences between U.S. regulatory and pricing strategies and those used in Europe, where internal reference pricing and tendering (when payers buy generic drugs in bulk from the manufacturers that offer the best prices) for generic drugs are more common.[36]

Another report compared U.S. drug prices to those of 32 comparable Organization of Economic Co-operation and Development (OECD) countries. The report found that while U.S. prices for brand-name drugs were more than four times higher than in other countries, average prices for unbranded generics were 33 percent lower in the U.S. than in peer countries.[37] This finding emphasizes the effect of robust competition on price.

[36] Wouters OJ, Kanavos PG, McKee M. Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. *The Milbank Quarterly*. 2017;95(3):554-601. doi:10.1111/1468-0009.12279

[37] Mulcahy AW, Schwam D, Lovejoy SL. International Prescription Drug Price Comparisons: Estimates Using 2022 Data. *RAND Corporation*; 2024. https://www.rand.org/pubs/research_reports/RRA788-3.html

Generic formulary placement

Formulary decisions for generic drugs can vary across health plans and pharmacy benefit managers, particularly between commercial and government plans (e.g., Medicare and Medicaid). A formulary outlines which drugs are covered and any restrictions such as prior authorization requirements, quantity limits, or step therapy prerequisites. Typically, health plans only pay for drugs listed on their formulary, and most plans require copays. Most drug formularies are organized into tiers, with Tier 1 usually covering generics and having the lowest copay cost. The higher the tier number, the higher the out-of-pocket costs for patients with the goal of directing the patient to the lowest cost. Concerns have been raised that some generic drugs may be providing less favorable formulary placement over their branded counterparts, as brand-name manufacturers offer more substantial rebates or discounts on their products to payers.

A study conducted in 2021 analyzed the plan coverage of brand-name drugs and their associated generics across Medicare Part D plans (2013-2019). The results indicated that shifting from a lower to a high-cost-sharing tier could increase out-of-pocket patient costs.[38] Even if generic drugs have favorable formulary placement, branded drugs may be placed on a better coverage tier due to rebates or other price concessions manufacturers offer. Findings from a study done on Medicare Part D found that 72 percent of Part D formularies placed at least one branded drug on a lower cost-sharing tier than its generic.[39] In comparison, 30 percent of formularies had at least one branded drug with fewer utilization management controls than its associated generic.[40]

The study's author highlighted rebates' role in this brand-over-generic placement and how such practices can increase patient out-of-pocket costs and overall health care spending.

[38] Dusetzina S, Juliette Cubanski P, Andrew W. Roberts P, et al. Trends in Medicare Part D Coverage of Generics With Equivalent Brand-Name Drugs. *The American Journal of Managed Care*. 2021;27. doi:10.37765/ajmc.2021.88701

[39] Socal MP, Bai G, Anderson GF. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available. *JAMA Internal Medicine*. 2019;179(6):832-833. doi:10.1001/jamainternmed.2018.7824

[40] Ibid.

Generic drug shortages

Drug shortages are a widespread problem that affects certain medications more frequently than others. Multiple causes of these shortages exist, with significant economic and clinical implications. An article addressing the causes and effects of drug shortages proposes several strategies countries can implement to manage present and prevent future shortages. These strategies include addressing the current shortage, making operational improvements to identify possible shortages in advance, making policy changes, and enhancing education and training for health care professionals on managing these shortages.[41]

A literature review of more than 400 papers conducted between 2001 and 2019 studied drug shortages. Most of the documents described the shortages and their negative effects, while fewer papers discussed strategies to prevent or respond to the shortages. The review recommends that more attention be given to working toward long-term policy solutions to address this issue.[42]

Policy solutions aimed at addressing drug shortages must target the root cause of the shortage. Policymakers have three levers at their disposal to tackle the issue:

- Reducing the likelihood of a shortage
- Minimizing the size or scope of a shortage
- Mitigating the effect of a shortage[43]

An effective policy solution should incorporate all three levers and create a framework for existing

legislative proposals on drug shortages. This framework should assess the strengths and weaknesses of each proposal, such as hospital billing changes, transparency, and domestic manufacturing.

Several factors have been shown to increase the risk of generic drug shortages. A study assessed the association between generic shortages, price, market competition, and market size, finding that only the price was associated with a risk of shortage.[44] Low-priced generic drugs were found to be more likely to experience shortages, while shortages were associated with a modest increase in drug prices.

Another research letter examined the influence of shortages on generic drug prices, finding that prices for generic drugs in shortage between

[41] Shukar S, Zahoor F, Hayat K, et al. Drug Shortage: Causes, Impact, and Mitigation Strategies. *Frontiers in Pharmacology*. 2021;12. doi:10.3389/fphar.2021.693426

[42] Tucker EL, Cao Y, Fox ER, Sweet BV. The Drug Shortage Era: A Scoping Review of the Literature 2001–2019. Clinical *Pharmacology & Therapeutics*. 2020;108(6):1150-1155. doi:10.1002/cpt.1934

[43] Wosińska ME. Drug Shortages: A Guide to Policy Solutions. *Brookings Institution*. Published March 14, 2024. https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/

[44] Dave CV, Pawar A, Fox ER, Brill G, Kesselheim AS. Predictors of Drug Shortages and Association with Generic Drug Prices: A Retrospective Cohort Study. *Value Health*. 2018;21(11):1286-1290. doi:10.1016/j.jval.2018.04.1826

2015 and 2016 increased more than twice as quickly (7.3 percent before the shortage, 16.0 percent after the shortage) in the absence of a shortage.[45] This phenomenon was more pronounced among drugs with three or fewer manufacturers.

Drug shortages particularly influence generic drugs. A study published in Value in Health in 2018 found that generic low-priced medicines were more likely to experience shortages, while shortages were associated with a modest increase in drug prices. Another analysis of a cohort of 77 drugs losing market exclusivity between 2010 and 2013 found that oral small-molecule drugs and drugs with large markets tended to have more stable prices and competition.[46] On the other hand, smaller markets and injectable drugs had fewer market entrants, higher exit rates, greater price instability, and an increased risk of shortages.[47]

Potential drivers of generic drug shortages include weak market incentives, supply chain complexities, and inadequate incentives for high-quality manufacturing practices, which are considered primary issues that lead to shortages.[48] Increased consolidation among group purchasing organizations and offshoring of supply chain entities can create further market imbalances. Researchers propose involving the FDA and payers in strategies to incentivize high-quality generic drug production to remedy these dynamics.[49]

[45] Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. Changes in Drug Pricing After Drug Shortages in the United States. *Annals of Internal Medicine*. 2019;170(1):74-76. doi:10.7326/M18-1137

[46] Frank RG, McGuire TG, Nason I. The Evolution of Supply and Demand in Markets for Generic Drugs. *The Milbank Quarterly*. 2021;99(3):828-852. doi:10.1111/1468-0009.12517

[47] Ibid.

[48] Hernandez I, Hershey TB, Donohue JM. Drug Shortages in the United States: Are Some Prices Too Low? *JAMA*. 2020;323(9):819-820. doi:10.1001/jama.2019.20504

[49] Ibid.

Generic and biosimilar substitution

State laws surrounding generic substitution can significantly affect the adoption and use of generic drugs. According to a 2022 Value in Health report, patients in states that require consent or pharmacist notification to substitute with generics tend to use generics less, while mandating versus permitting generic substitution and protecting pharmacists from liability had no significant effects. [50]

In Oregon, pharmacists may substitute a drug product with a generic that is the same in strength, quantity, dose, dosage form, and therapeutic equivalency. State law requires pharmacists to post a sign at the counter that reads, "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." Doctors may also specify that no substitutions be allowed.[51]

Another study surveyed state-level generic drug substitution regulations that dictate how pharmacists can substitute prescriptions for brand-name drugs with lower-cost generics or biosimilars. The survey found that there is significant variation in these laws across states, with only one-third of states requiring that pharmacists automatically substitute branded prescriptions with an FDA-approved generic. Additionally, 15 percent of states require patient consent for substitution.[52] When examining substitution of biologics with an interchangeable biosimilar, 45 states had more stringent requirements, such as mandatory physician notification. This highlights the potential barriers to biosimilar uptake in the U.S. In Oregon, pharmacies can substitute a biologic for an FDA-approved biosimilar under the following conditions: (1) it must be designated as "interchangeable" by the FDA; (2) the prescriber must not have explicitly prohibited substitution; (3) the pharmacy must notify the patient of the substitution; and (4) the pharmacy must maintain records of the substitution.[53]

[50] Rome BN, Sarpatwari A, Kesselheim AS. State Laws and Generic Substitution in the Year After New Generic Competition. *Value Health*. 2022;25(10):1736-1742. doi:10.1016/j.jval.2022.03.012

[51] Oregon Revised Statutes 689.515. https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

[52] Sacks CA, Van De Wiele VL, Fulchino LA, Patel L, Kesselheim AS, Sarpatwari A. Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions. *JAMA Internal Medicine*. 2021;181(1):16. doi:10/gjjdfn

[53] Oregon Revised Statutes 689.515. https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

Conclusion

Generic drugs are an essential component in the process of making prescription drugs more affordable for patients and the health care systems in Oregon. However, brand manufacturers often use strategies to prevent or delay generic drug competition, such as creating authorized generics and pay-for-delay or biosimilar competition agreements, which can increase health care costs by keeping drug prices inflated. The Prescription Drug Affordability Board's focus on studying generic drugs' affordability for patients, as well as opportunities for supply chain reform, can help address these challenges to encourage generic use and prevent brand manufacturers from undermining generic competition. Policymakers should continue exploring strategies to promote generic competition and lower drug prices to ensure affordable and high-quality health care for all Oregonians.

Oregon Prescription Drug Affordability Board

Constituent Focus Groups Survey

Under the authority granted by Senate Bill 192 (2023), the Oregon Prescription Drug Affordability Board (PDAB) is soliciting feedback on the use of upper payment limits (UPLs) for drugs sold in Oregon that are subject to affordability reviews. Specifically, the PDAB is evaluating a scenario whereby it would establish UPLs that leverage current discounts in the system (i.e., rebates and other price concessions), and that serve as the maximum price to be paid by wholesalers and others in the prescription drug supply chain, thereby replacing Wholesale Acquisition Cost (WAC). When responding to the questions that follow, please consider the impact that use of a UPL might have on your organization and/or your patients. At the end of the survey, you will have an opportunity to provide detailed narrative responses and recommendations. This survey will not only provide input as the Board develops a model for establishing UPLs, it will also be used to guide ongoing stakeholder engagement activities.

*Name of person completing survey:

*Name of facility/entity:

*Email:

*Organization Type (Carrier, Hospital or Health System, 340B Covered Entity, Pharmacy)

For all constituent groups:

When thinking about drug affordability within your organization, how much concern do you have about the impact of the cost of drugs on your organization?

- Very concerned
- Somewhat concerned
- Not concerned

When thinking about drug affordability within your organization, how much concern do you have about the impact of the cost of drugs on your patient population?

- Very concerned
- Somewhat concerned
- Not concerned

How do you anticipate that an upper payment limit would impact your organization's drug spending and budgetary considerations?

- Positive impact
- Neutral impact
- Negative impact

How do you perceive the potential effects of an upper payment limit on patient *access* to necessary medications?

- Create opportunities for a positive impact on patient access
- Neutral impact on patient access
- Create challenges to patient access

What kind of impact do you think an upper payment limit would have on a patient's *ability* to afford their medications?

- Positive impact
- Neutral impact
- Negative impact

What challenges might your organization face in adjusting to the constraints imposed by an upper payment limit (select all that apply)?

- Increased administrative burden
- Disruptions in drug supply chains
- Compliance with regulatory requirements
- Other (please specify)

For example, imagine a high-cost drug in a market with limited competition and few manufacturer price concessions or rebates offered. How much of a discount from wholesale acquisition cost (WAC) would an upper payment limit need to be set at to be meaningful?

- 10 percent less than WAC
- 30 percent less than WAC
- 50 percent less than WAC
- Other (please specify)

Please elaborate on your choice in the previous question.

- Free text

Insurers/Payers:

In what ways could an upper payment limit create opportunities for your organization to optimize drug coverage and improve affordability for enrollees? (select all that apply)

- Enhanced negotiation power with drug manufacturers
- Ability to develop innovative cost-sharing models
- Increased member satisfaction and retention
- Other (please specify)

Do you anticipate that an upper payment limit would impact the premiums paid by your members?

- Yes, in a positive way
- Yes, in a negative way
- No, no impact on premiums

- Unsure if there would be an impact

What other impacts do you anticipate an upper payment limit would have on members' costs? (select all that apply)

- Lower claims payment costs/spend
- Reduced out of pocket expenses
- No impact
- Other (please specify)

Hospitals:

In your opinion, what impact would the implementation of an upper payment limit have on your hospital's drug procurement and supply chain management?

- Positive impact
- Neutral impact
- Negative impact

How would the implementation of an upper payment limit affect how chargemaster prices are set?

- Chargemaster prices would increase
- Chargemaster prices would decrease
- No anticipated change to chargemaster prices

340B:

In your opinion, what impact would the implementation of an upper payment limit have on your organization's 340B program?

- Positive impact
- Neutral impact
- Negative impact

How would the implementation of an upper payment limit impact patient costs? (select all that apply)

- Lower cost for services
- Reduced out of pocket expenses for drugs
- Higher out of pocket costs for services
- Higher out of pocket expenses for drugs
- No impact
- Other (please specify)

Pharmacies:

How do you anticipate that an upper payment limit would impact your pharmacy's revenue and financial viability?

- Positive impact
- Neutral impact
- Negative impact

Oregon Prescription Drug Affordability Board

Follow-up questions for all constituent groups:

The Oregon PDAB is also interested in hearing about alternative policy approaches and recommendations that you may have. The following questions will provide you with an opportunity to provide more detailed information on approaches, recommendations, or concerns.

How could upper payment limits create meaningful cost savings for all consumers and purchasers?

- Free text

How would your organization utilize savings resulting from an upper payment limit?

- Free text

What could be potential administrative burdens or operational challenges associated with implementing an upper payment limit?

- Free text

What recommendations, if any, do you have regarding the potential administrative burdens or operational challenges associated with implementing an upper payment limit?

- Free text

Are there alternative policy approaches that you believe would be more effective in addressing drug affordability while preserving innovation and investment in research and development?

- Free text

How can policymakers ensure that an upper payment limit policy is implemented in a manner that promotes transparency, fairness, and affordability for both payers and patients?

- Free text

What specific factors or considerations should policymakers take into account when setting an upper payment limit for prescription drugs?

- Free text

Oregon Prescription Drug
Affordability Board

Senate Bill 192
UPL Constituent Group Engagement
Status Update

May 15, 2024

Targeted Focus Groups

Constituent Group	Group Description
Pharmacy	Independent pharmacies, 340B pharmacies and tribal pharmacies NACDS & grocery chain pharmacies
Hospital	Hospital Association of Oregon distributed the link via newsletter PDAB-developed list
Carrier	Registered insurers/carriers
340B/FQHC	FQHCs and other 340B entities

Constituent Group Outreach: Methods

Two methods of outreach

- Survey
  - Contains general questions and questions targeted to the specific focus group
- Focus Group Meetings
  - Intended to dive more deeply into issues, concerns and alternatives identified through the surveys
  - 2 one-hour meetings with each focus group

Constituent Group Outreach: Status

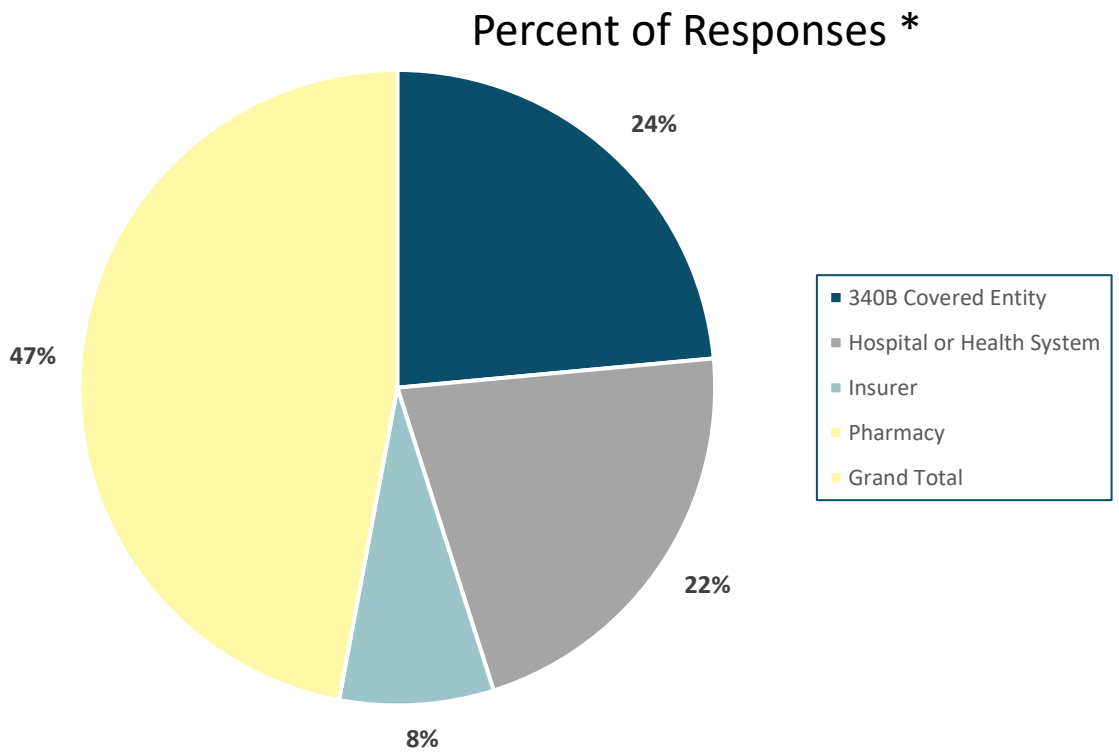
- Survey has been distributed with all groups
  - Survey closed on May 10
- Focus Group Sessions have been tentatively scheduled with all groups

Targeted Focus Groups – *Subject to change*

Constituent Group	Survey Date	Meeting 1	Meeting 2
Pharmacy	4/24/2024	5/16/2024	5/22/2024
Grocery Pharmacy	4/24/2024	5/17/2024	5/29/2024
Hospital	4/24/2024	5/16/2024	5/29/2024
Insurers	4/24/2024	5/20/2024	5/30/2024
340B/FQHC	4/24/2024	5/22/2024	5/30/2024

Survey Status as of 5/7/2024

Constituent Group	Sent	Responses*
340B Covered Entity	209	12
Hospital or Health System	51	11
Insurer	53	4
Pharmacy	34	24
Grand Total	**347**	**51**



*Usable responses as of 5/7/24

Constituent Group Outreach: Next Steps

- Data clean up
- Stratifying responses to
  - Identify common themes
  - Identify differences between focus groups
  - Identify themes or specific areas from the survey to explore more fully in the virtual sessions