Oregon Prescription Drug Affordability Board

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Agenda

This is a regular meeting. *Date*: **July 16, 2025** | *Time*: **9 a.m.**

This is a draft agenda and subject to change

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

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

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

Purpose	Subject	Presenter
Informational and vote	Call to order and roll call	Chair Shelley Bailey
Informational	Board declarations of conflict of interest and meetings with entities or individuals related to board activities	Chair Shelley Bailey
Discussion and vote	**Board approval of 6/18/2025 minutes**	Chair Shelley Bailey
Informational	PDAB program update	DCBS Staff
Informational	General public comment: limited to 3 minutes	Chair Shelley Bailey
Discussion	Board discussion about a process for measuring affordability to determine drug review cost impact	Chair Shelley Bailey, Cortnee Whitlock, senior policy analyst
Review and discussion	**Drug review: Antipsychotics & Antimanic agents – Vraylar**[1]	Cortnee Whitlock
Review and discussion	**Drug review: Cardiovascular agents – Entresto**[1]	Cortnee Whitlock
Review and discussion	**Drug review: Migraine products – Ajovy**[1]	Cortnee Whitlock

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

Purpose	Subject	Presenter
Review and discussion	**Drug review: Migraine products – Emgality**[1]	Cortnee Whitlock
Review and discussion	**Drug review: Migraine products – Nurtec**[1]	Cortnee Whitlock
Review and discussion	**Drug review: Migraine products – Ubrelvy**[1]	Cortnee Whitlock
Break	The board will take a break around 10:30	Chair Shelley Bailey
Informational	Announcements	Chair Shelley Bailey
Vote	Adjournment	Chair Shelley Bailey

Accessibility

Anyone needing assistance due to a disability or language barrier can contact Melissa Stiles at least 48 hours ahead of the meeting at pdab@dcbs.oregon.gov or 971-374-3724. American sign language will be available during the July 16 board meeting.

How to provide testimony to the board

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

Open and closed sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed to everyone but news media and staff. No action will be taken in executive session.

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

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting
Wednesday, June 18, 2025
Draft Minutes

Web link to the meeting video: https://youtu.be/RP3A5s6hiwc
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20250618-PDAB-document-package.pdf

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Call to order: Chair Shelley Bailey called the meeting to order at 9:03 a.m. and roll was called.
Board members present: Chair Shelley Bailey, Dan Hartung, Lauri Hoagland, Robert Judge, Chris Laman, John Murray (arrived at 9:26 am due to a local power outage)
Absent: Vice Chair Amy Burns, Dan Kennedy

The board provided American Sign Language during the meeting.

Declaration of conflict of interest, meetings with entities or individuals related to board activities, or testifying before the Legislature: John Murray provided a statement later in the meeting. View at video minute **01:24:03**.

Approval of board minutes: Chair Bailey asked for a motion and second to approve the board minutes as shown on **Pages 3-5** of the agenda materials. The minutes were revised to include all the speakers from the May 21, 2025 meeting. Chris Laman made a motion to approve the minutes and Lauri Hoagland provided a second. The motion failed. The board voted again near the end of the meeting when more board members were present and the motion passed. View the first vote at video minute **00:04:15** and the second vote at video minute **03:01:48**.

First MOTION to approve the May 21, 2025, minutes
Board Vote:
Yes: Dan Hartung, Lauri Hoagland, Chris Laman, Chair Shelley Bailey
No: None
Abstain: Robert Judge
Absent: Vice Chair Amy Burns, Dan Kennedy, John Murray
Motion failed 4-0

Second MOTION to approve the May 21, 2025, minutes
Board Vote:
Yes: Dan Hartung, Lauri Hoagland, Chris Laman, John Murray, Chair Shelley Bailey
No: None
Abstain: Robert Judge
Absent: Vice Chair Amy Burns, Dan Kennedy,
Motion passed 5-0

Executive director's program update: Ralph Magrish, executive director, Oregon Prescription Drug Affordability Board & Drug Price Transparency Program, provided a program update. View the video at minute **00:04:39**.

Legislative update: Jesse O'Brien, Division of Financial Regulation (DFR) policy manager, provided an update on prescription drug-related bills proposed in the Oregon Legislative session as shown on **Pages 6-7** of the agenda materials. View the video at minute **00:4:47**.

General Public comment: Chair Bailey called on the people who signed up in advance to speak to the board: Gaby Gardiner, Basic Rights Oregon; Lorren Sandt, Caring Ambassadors Program, Inc.; Tiffany Westrich-Robertson, EACH Coalition; Mary Anne Cooper, Regence BlueCross BlueShield of Oregon; Katie Chandra, Genentech; Jessica McBride, Oregon Coalition for Affordable Prescriptions; and Dharia McGrew, PhRMA. The board received 14 written comments, which are posted on the **PDAB website**. View the speakers at video minute **00:16:42**.

Board review and vote for updated data subset list of prescription drugs and insulin products pursuant to OAR 925-200-0010: The board reviewed the patient survey results, the list of orphan drugs, the subset list of 27 prescription drugs from the March 19 meeting, and the subset list of insulin glargine from the April 16 meeting as shown on **Pages 8-23** in the agenda materials. The board also reviewed the data dashboard, which is posted on the **PDAB website**. The board voted on an updated list of 23 medications for review in 2025. See the list below. It is also posted on the **PDAB website**. View the discussion at video minute **00:43:30**.

MOTION to approve the data subset list of prescription drugs as discussed by the board today.
Motion made by Chris Laman with a second by Lauri Hoagland.
Board vote:
Yes: Dan Hartung, Lauri Hoagland, Robert Judge, Chris Laman, John Murray, Chair Shelley Bailey
No: None
Absent for the vote: Vice Chair Amy Burns, Dan Kennedy
Motion passed 6-0

MOTION to approve the data subset list of insulin as discussed by the board today.
Motion made by John Murray with a second by Lauri Hoagland.
Board vote:
Yes: Dan Hartung, Lauri Hoagland, Robert Judge, Chris Laman, John Murray, Chair Shelley Bailey
No: None
Absent for the vote: Vice Chair Amy Burns, Dan Kennedy
Motion passed 6-0

Announcements: Chair Bailey announced the next meeting will be July 16, 2025, at 9 a.m.

Adjournment: Chair Bailey adjourned the meeting at 12:15 p.m. with all board members in agreement. View at minute **03:03:54**.

Oregon Prescription Drug Affordability Board

Prescription medication list for the Oregon PDAB review in 2025

Review grouping number	Therapy class	Drug name	Non-proprietary name
1	Antipsychotics & Antimanic agents	Vraylar	Cariprazine HCl
1	Cardiovascular agents – misc.	Entresto	Sacubitril; Valsartan
1	Migraine product	Ajovy	Fremanezumab-vfrm
1	Migraine product	Emgality	Galcanezumab-gnlm
1	Migraine product	Nurtec	Rimegepant/rimegepant sulfate
1	Migraine product	Ubrelvy	Ubrogepant
2	Antiasthmatic and bronchodilator	Trelegy	Fluticasone furoate; Umeclidinum bromide; Vilanterol trifenatate
2	Anticoagulants	Eliquis	Apixaban
2	Anticoagulants	Xarelto	Rivaroxaban
2	Dermatological	Cosentyx	Secukinumab
2	Digestive Aids	Creon	Pancrelipase (Amylase; Lipase; Protease)
3	Antidiabetics	Jardiance	Empagliflozin
3	Antidiabetics	Mounjaro	Tirzepatide
3	Antidiabetics	Ozempic	Semaglutide
3	Antidiabetics	Rybelsus	Semaglutide
3	Antidiabetics	Trulicity	Dulaglutide
4	Insulin product	Basaglar KwikPen	Insulin Glargine
4	Insulin product	Insulin Glardine-yfgn	Insulin Glargine
4	Insulin product	Lantus	Insulin Glargine
4	Insulin product	Lantus SolorStar	Insulin Glargine
4	Insulin product	Semglee (yfgn)	Insulin Glargine
4	Insulin product	Toujeo Max SolorStar	Insulin Glargine
4	Insulin product	Toujeo SoloStar	Insulin Glargine

Oregon Prescription Drug
Affordability Board

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

Vraylar®
(*cariprazine/cariprazine HCl*)[1]

Version 2.0

[1] https://www.clinicaltrialsarena.com/projects/vraylar-cariprazine-for-the-treatment-of-bipolar-disorder-and-schizophrenia/

Table of Contents

Document version history

Version	Date	Description
v1.0	7/9/2025	Original Release
v2.0		Updated gross spend amounts in the “Cost to the healthcare system” section; added a “Cost to payers” section; updated table 3 to reflect costs to the healthcare system; added table 4 for payer paid amounts; updated sections referencing patients to reference enrollees; added the drug name to the footer; Table 2 removed Total for paid/enrollee & claims and indicated the number as an average.

Review summary

Price history

Vraylar® (*cariprazine*) was approved by the FDA in 2015. Since coming to market, its wholesale acquisition cost **(WAC) has increased at an average annual rate of 3.1 percent, outpacing inflation in 2020, 2023, and 2024**.[2,3] As of late 2024, the **WAC reached $48.22 per unit**, with Medicaid acquisition costs **(AAAC) tracking only 4.35 percent below**, suggesting minimal purchase discounts at the pharmacy level.

Cost to the healthcare system[4,5]

In 2023, Oregon's All Payers All Claims (APAC) database reported:

- **$38,657,889 in total gross** costs to the healthcare system for Vraylar across all lines of business for **4,085 enrollees** and **29,623 claims**.
- The gross healthcare spend across lines of businesses was **$9,920 per enrollee** and $**1,305 per claim**.

The commercial health plan 2023 data calls:

- **$5,116,449 in total net spending** for Vraylar across **997 enrollees** and **3,267 claims**.
- The net spend was **$5,132 per enrollee** and **$1,566 per claim**.

Cost to payers[6,7]

According to Oregon's 2023 APAC data:

- **$37,017,240** in payer spending for Vraylar, across **4,085enrollees** and **29,623 claims** across all lines of business with an estimated average cost **of $9,062 per enrollee and $1,250 per claim**.

According to 2023 information collected from commercial payers:

- **$4,207,403** in net spending across **997 enrollees** and **3,267 claims**.
- The net spend was **$4,220 per enrollee** and **$1,288 per claim**.

[2] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span
[3] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/
[4] Ibid.
[5] 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.
[6] Ibid.
[7] 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.

Cost to enrollees[8,9]

Enrollee out-of-pocket (OOP) costs varied by data source:

- APAC data showed **average OOP costs of $1,652 per commercial enrollee, $439 for Medicare enrollees,** and **$0 for Medicaid enrollees.**
- Carrier data showed commercial market variation: **$394 (large group), $1,853 (small group), and $1,982 (individual)** in average annual OOP costs. The average **OOP cost from the data call was $912 per enrollee** in 2023.

Price concessions[10]

- Carrier-submitted data estimated that **74.7 percent of claims included some form of price concessions**.
- Manufacturer and PBM discounts reduced the average payer cost by **approximately 8 percent**, **totaling $513,113 in reported discounts across markets**.

Therapeutic alternatives[11]

Six therapeutic alternatives were identified in this review, including **Caplyta, Fanapt, Invega, Paliperidone, Risperdal,** and **Risperidone**. Compared to Vraylar:

- Alternatives such as **Risperidone** and **Paliperidone** have significantly lower per-enrollee and per-claim costs.
- **Caplyta**, while similarly priced per enrollee, demonstrates higher payer spend and broader usage.
- **Fanapt** shows the highest per-enrollee cost, driven by low utilization and high per-claim pricing.

Access and equity considerations[12]

Only **2.9 percent of plans** listed Vraylar as a preferred formulary drug, while **51.1 percent required prior authorization** and **3.0 percent required step therapy.**

- Patients of color are statistically less likely to receive newer antipsychotics like Vraylar, exacerbating health disparities.
- Medicaid provides broader access due to preferred drug list inclusion, while commercial plans often apply access restrictions.

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[8] Based on Oregon's 2023 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 visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[9] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.
[10] Ibid.
[11] Based on Oregon's 2023 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.
[12] Ibid.

Review background

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

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

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

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

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

Drug information[13]

Drug proprietary name(s)	Vraylar®
Non-proprietary name (active ingredient)	*cariprazine*
Manufacturer	Forest Laboratories, LLC
Treatment	Vraylar is an atypical antipsychotic used in the treatment of schizophrenia, bipolar disorder, and as adjunctive therapy for major depressive disorder (MDD)
Dosage forms	Capsule, oral 1.5 mg, 3 mg, 4.5 mg, and 6 mg
Recommended dosing	• Schizophrenia: 1.5 mg to 6 mg daily • Bipolar Mania: 3 mg to 6 mg daily • Bipolar Depression: 1.5 mg or 3 mg daily • Adjunctive therapy to antidepressants for MDD: 1.5 mg or 3 mg daily
Physician administered	No

FDA approval

Vraylar was first approved by the FDA on 09/17/2015.[14]

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

At the time of review, the drug had no designation indications under the Orphan Drug Act.

Health inequities

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

Access to newer antipsychotic medications such as Vraylar (*cariprazine*) is marked by ongoing health disparities that disproportionately affect under-resourced communities and communities of color. Studies have shown that while racial and ethnic minorities are prescribed antipsychotics at similar rates to white patients, they are significantly less likely to receive newer, second-generation agents like Vraylar.[15] A comprehensive review found that African American patients had 38 percent lower odds, and Latino patients 23 percent lower odds, of being prescribed newer antipsychotics compared to white patients, even when controlling for

[13] U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf

[14] FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, the earliest approval date across all related FDA applications was used.

[15] Puyat, J. H., Daw, J. R., Cunningham, C. M., Law, M. R., Wong, S. T., Greyson, D. L., & Morgan, S. G. (2013). Racial and ethnic disparities in the use of antipsychotic medication: a systematic review and meta-analysis. Social psychiatry and psychiatric epidemiology, 48(12), 1861–1872. https://doi.org/10.1007/s00127-013-0753-4

diagnosis and healthcare access factors.[16] This disparity is particularly concerning, given that newer antipsychotics tend to have improved side effect profiles and can support better adherence and outcomes.[17]

Cost and systemic barriers further reinforce this inequity. Although Vraylar is available to many Medicaid and Medicare beneficiaries, access is not consistent across states, as utilization is frequently subject to step therapy, prior authorization, or exclusion from preferred drug lists. Commercially insured patients may qualify for co-pay assistance through the manufacturer, but those without coverage or in transition between public programs can face list prices exceeding $1,500 per month, depending on strength or monthly supply.[18] These access restrictions, coupled with historical patterns of under prescribing newer agents in Black and Latino populations, contribute to treatment gaps and reinforce cycles of under-treatment in marginalized communities.[19] As price negotiation reforms under the Inflation Reduction Act are implemented, patient advocacy groups have warned that cost containment measures must not come at the expense of equitable access to effective therapies.[20]

Residents prescribed

ORS 646A.694(1)(b) and OAR 925-200-0020(1)(b) & (2)(b). Data sources: Oregon All Payers All Claims (APAC) database and commercial carrier data call.

In 2023, the Oregon APAC database recorded **3,897 unique individuals** with at least one filled prescription for Vraylar.[21] In contrast, the **commercial health benefit plan data call**, which included submissions from 11 reporting carriers, identified **997 enrollees** with a Vraylar prescription fill during the same period.[22]

The substantial variance between the two figures is attributable to differences in data scope and reporting mandates. APAC is a comprehensive claims repository that aggregates utilization data across all payer types, including Medicaid, Medicare, and commercial lines of business. In

[16] Puyat, J. H., Daw, J. R., Cunningham, C. M., Law, M. R., Wong, S. T., Greyson, D. L., & Morgan, S. G. (2013). Racial and ethnic disparities in the use of antipsychotic medication: a systematic review and meta-analysis. Social psychiatry and psychiatric epidemiology, 48(12), 1861–1872. https://doi.org/10.1007/s00127-013-0753-4
[17] Centers for Medicare & Medicaid Services. (2025) Public Input on Medicare Drug Price Negotiation – Session 2 Transcript. https://www.cms.gov/files/document/session-2-redacted-transcript-pdf.pdf
[18] Vraylar (cariprazine) Cost & Savings, 2025. https://www.vraylar.com/cost-and-savings
[19] Puyat, J. H., Daw, J. R., Cunningham, C. M., Law, M. R., Wong, S. T., Greyson, D. L., & Morgan, S. G. (2013). Racial and ethnic disparities in the use of antipsychotic medication: a systematic review and meta-analysis. Social psychiatry and psychiatric epidemiology, 48(12), 1861–1872. https://doi.org/10.1007/s00127-013-0753-4
[20] Institute for Clinical and Economic Review (ICER). "2024 Update on Drug Access and Equity." https://icer.org/wp-content/uploads/2024/12/UPI_2024_Report_121224.pdf
[21] Number of 2023 unique enrollees in APAC database across commercial insurers, Medicaid, and Medicare. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[22] Based on 2023 data collected by DCBS under authorities granted in ORS 731.296 and OES 646A.963 through ORS 646A.697 from Oregon health insurance plans. Cost information from the data call is the cost of the drug after price concessions.

contrast, the data call process captures a limited subset of commercially insured enrollees and is restricted to the reporting obligations of participating health plans. As a result, APAC offers a more inclusive estimate of statewide utilization, while the carrier-submitted data reflects only a narrow segment of the insured population.

Price for the drug

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

This section examines the pricing dynamics of Vraylar, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of the wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), as well as the impact of negotiated prices concessions which include discounts, rebates, and other price reduction negotiations. Together, the data provides a comprehensive view of Vraylar's list price trajectory, pharmacy acquisition costs, and the degree to which price reductions are realized in practice by payers in Oregon.

Price history

The wholesale acquisition cost (WAC) of Vraylar, averaged across seven reported national drug codes (NDCs), was approximately **$48.22 per unit** at the end of 2024.[23] Between 2018 and 2024, the per unit WAC increased at an average annual rate of **3.2 percent**, exceeding the general inflation rate of the consumer price index (CPI-U).[24] See Figures 1 and 2.

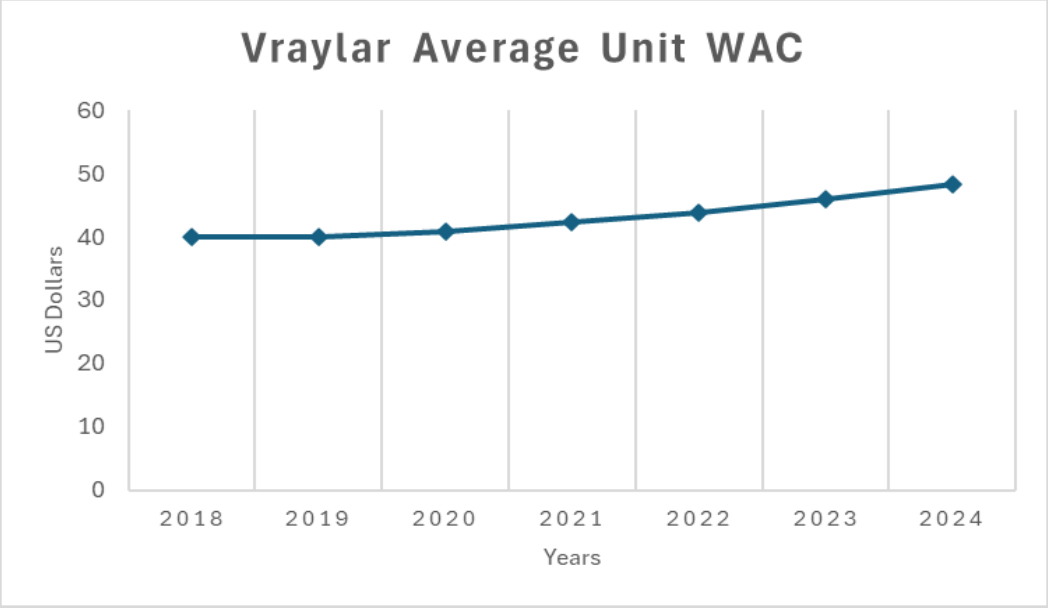

Figure 1 Vraylar WAC from 2018-2024

[23] To determine which NDC to use for the WAC price history, the available 2023 utilization data was analyzed and the NDC with the highest volume of claims in 2023 was used.
[24] Consumer Price Index, US Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/

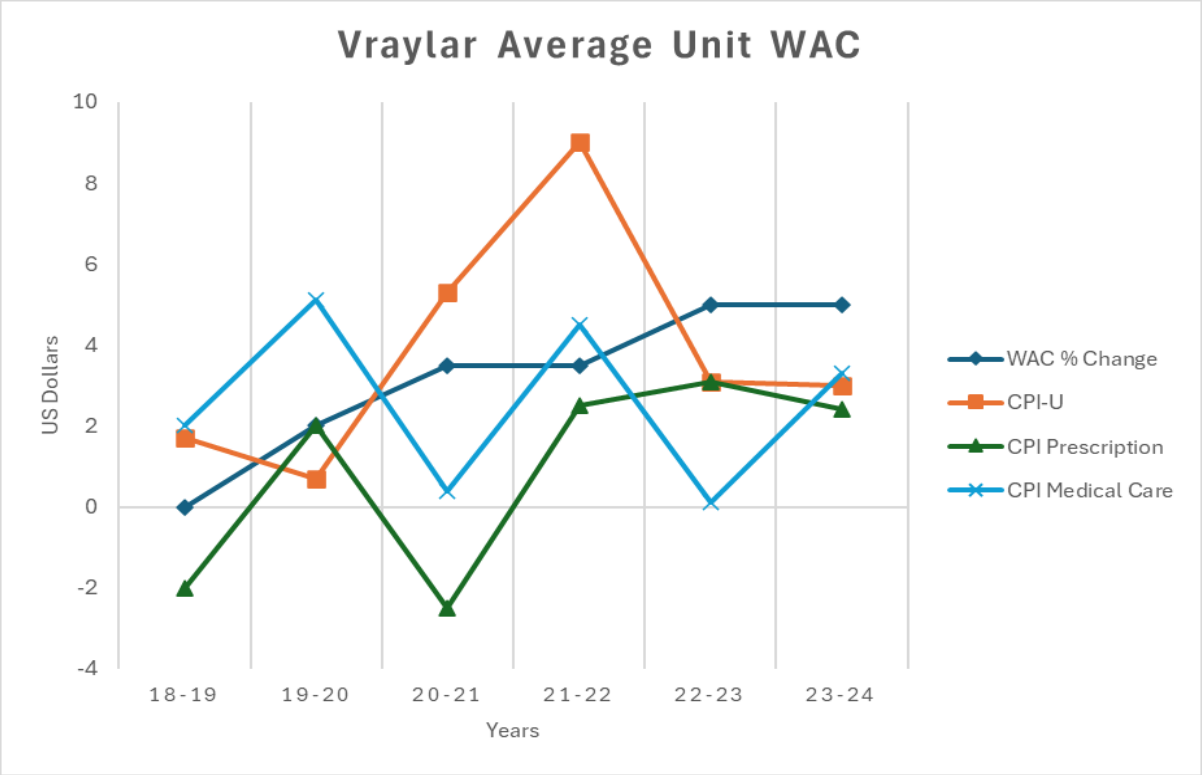

Figure 2 Year over year change in WAC compared to inflation rates[25]

Unit 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. This increase outpaced inflation in 2019-2020, 2022-2023, and 2023-2024.[26]

Pharmacy acquisition costs

Oregon actual average acquisition cost (AAAC) for Vraylar from Quarter 1 of 2020 to Quarter 4 of 2024 is shown in Figure 3. The AAAC for Vraylar rose from **$39 in Quarter 1 of 2020, to $46 in Quarter 4 of 2024**, an **increase of 17.95 percent** over the period.[27] Relative to the **$48 WAC** in end-of-year 2024, a AAAC decrease of 4.35 % percent 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

[25] Consumer Price Index, US Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/ Accessed May 20, 2025.
[26] Ibid.
[27] Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2023. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. https://myersandstauffer.com/client-portal/oregon/

enrolled pharmacies on a rolling basis. AAAC is used to calculate reimbursement to pharmacies for fee-for-service (or "open card") Medicaid claims.[28]

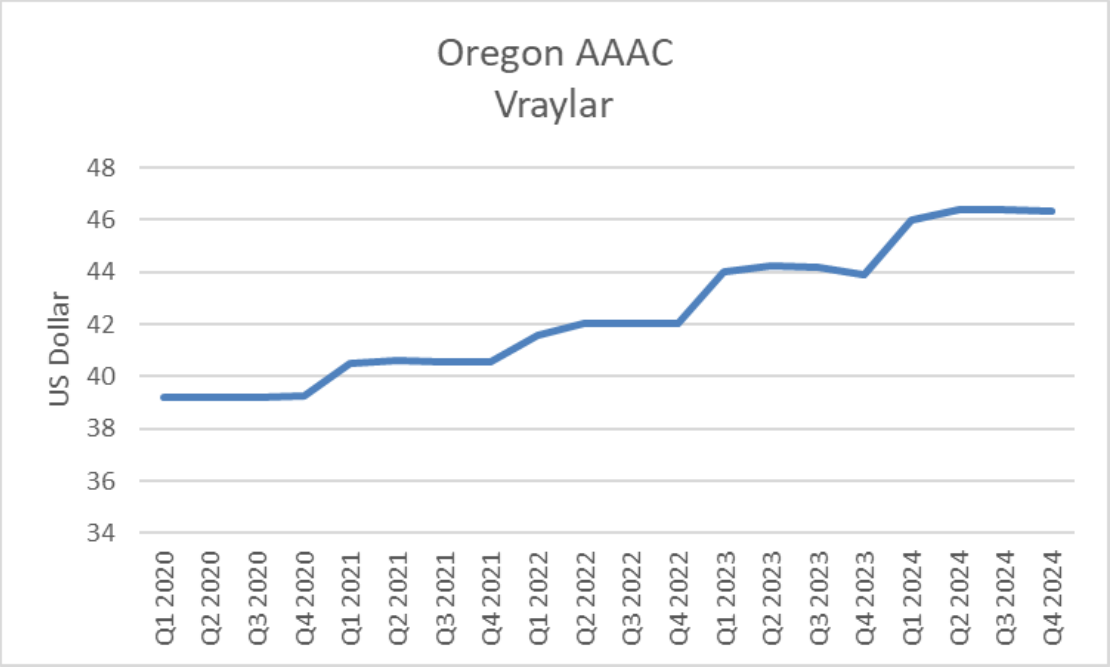

Figure 3 AAAC for Vraylar from Q1 2020 to Q4 2024

Estimated average monetary price concession

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

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

Based on carrier-submitted data for 2023, the **average gross cost of Vraylar per enrollee in the commercial market was approximately $4,932**. After accounting for manufacturer rebates, PBM discounts, and other price concessions, the **average net cost per enrollee declined to approximately $4,417**, reflecting an **estimated mean discount of 8.04 percent** relative to gross costs.

[28] 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.

Across all reporting carriers and market segments, the total cost of Vraylar before concessions was **$4,917,279**, with total reported price concessions amounting to approximately **$513,113**, as detailed in Table 1. Notably, **74.7 percent of claims benefited from some form of price concession**, **leaving 25.3 percent at full gross cost**. Figure 4 shows manufacturer concessions comprised the largest share, supplemented by PBM discounts and other adjustments across the payer types.

Table 1 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	997
Total number of claims	3,267
Total number of claims with price concessions applied	2,439
Percentage of claims with price concessions applied	74.7%
Percentage of cost remaining after concessions	89.6%
Manufacturer price concessions for all market types	$397,892
PBM price concessions for all market types	$108,423
Other price reductions for all market types	$6,798
Cost before price concessions across all market types	$4,917,279
Total price concessions across all market types	$513,113
Cost of after price concessions across all market types	$4,404,166
Avg. payer spend per enrollee without price concessions	$4,932
Avg. payer spend per enrollee with price concessions	$4,417

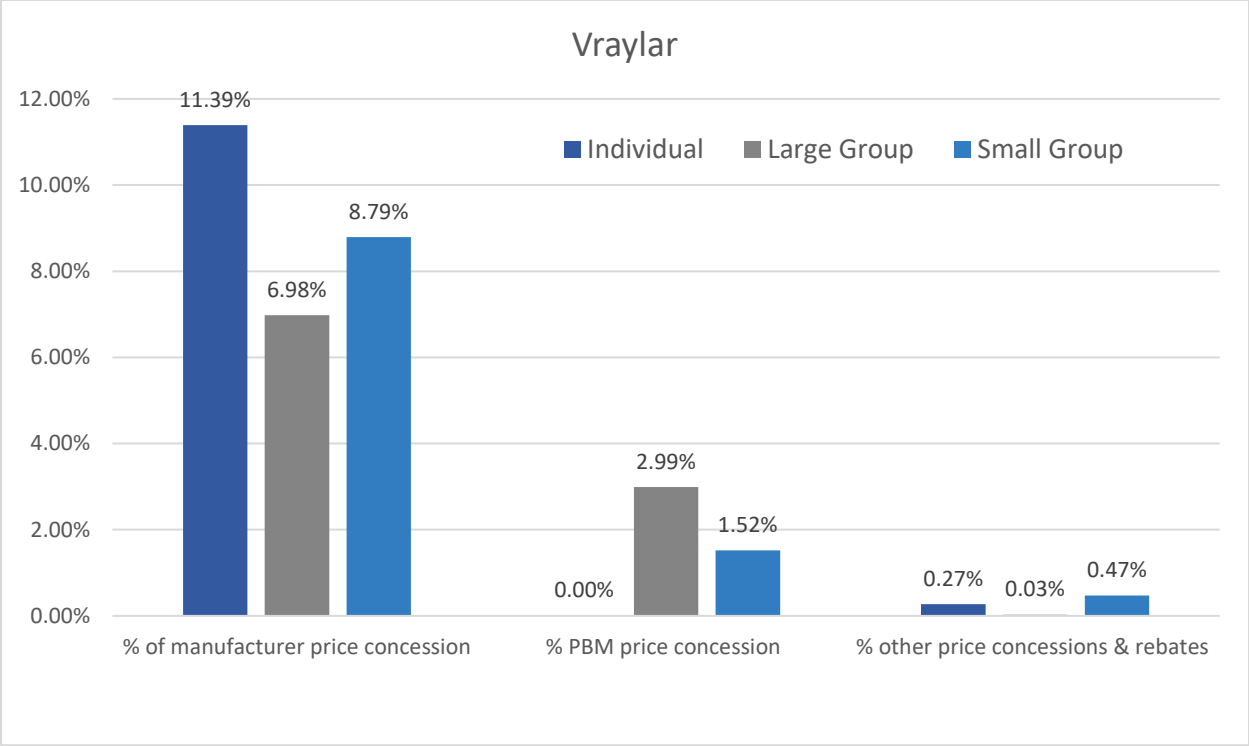

Figure 4 Percent of price concession in each market type

Estimated total amount of the price concession

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

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

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

Estimated price for therapeutic alternatives[29]

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

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

Vraylar's **gross cost per claim, based on APAC data, was $1,305**, while net cost data showed a higher per-claim amount of $1,566. Compared to Vraylar's gross cost per claim, Caplyta had a similar claim cost, while **Fanapt showed a higher cost per claim and per enrollee**, though it shows to have fewer claims. Risperidone and Paliperidone show lower per-claim and per enrollee costs with risperidone having the lowest average of $18 per claim.

Out-of-pocket costs also varied with enrollee payments for Vraylar in APAC, **averaging $55 per claim**. Therapeutic alternatives such as Caplyta and Paliperidone had lower reported enrollee-paid amounts, ranging from $5 to $42 per claim.

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

Table 2 Average healthcare and average enrollee OOP costs for Vraylar vs therapeutic alternatives

Drug	Total spend	No. of enrollees [30]	No. of claims	Avg. paid/ claim	Avg. Paid/ enrollee	Total payer paid	Total enrollees paid	Payer paid/ claim	Enrollee paid/ claim
Subject drug **Vraylar** (data call)	**$5,116,449**	**997**	**3,267**	**$1,566**	**$5,132**	**$4,207,403**	**$909,046**	**$1,288**	**$278**
Subject drug **Vraylar** (APAC)	**$38,657,888**	**3,897**	**29,623**	**$1,305**	**$9,920**	**$37,017,240**	**$1,640,648**	**$1,250**	**$55**
Caplyta	$7,222,248	730	4,987	$1,448	$9,893	$7,011,576	$210,672	$1,406	$42

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

[30] The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 2, as compared to other totals indicated in this report.

Drug	Total spend	No. of enrollees [30]	No. of claims	Avg. paid/ claim	Avg. Paid/ enrollee	Total payer paid	Total enrollees paid	Payer paid/ claim	Enrollee paid/ claim
Fanapt	$359,958	22	169	$2,130	$16,362	$357,648	$2,310	$2,116	$14
Invega	$112,784	212	638	$177	$532	$110,895	$1,889	$174	$3
Paliperidone	$2,362,475	1,892	13,523	$175	$1,249	$2,295,103	$67,372	$170	$5
Risperdal	$10,963	2	20	$548	$5,482	$10,953	$10	$548	$0
Risperidone	$189,549	1,291	10,511	$18	$147	$174,008	$15,540	$17	$1

Estimated average price concession for therapeutic alternatives

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

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

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this information as additional data becomes available through carrier reporting, manufacturer disclosures, or other sources.

Estimated costs to health insurance plans

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

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

In 2023, the Oregon APAC database recorded **29,623 total claims for Vraylar among 4,085 total enrollees**, corresponding to a **total system gross expenditure of $38,657,889**. This equates to a total of an average **annual cost of $28,893 per enrollee**, or approximately **$4,159 per claim**.

Table 3 provides gross cost estimates by the total APAC system spend across all lines of business:

- **Medicaid** accounted for the largest share of utilization, with 18,799 claims from 2,480 enrollees and a total spend of **$22.8 million**.
- **Medicare** and **commercial** payers reported smaller but notable expenditures of approximately **$8.9 million** and **$6.9 million**, respectively.

Table 3 Estimated 2023 APAC total gross costs to the healthcare system[31]

Payer line of business	Total enrollees	Total claims	Total gross cost amount to healthcare system	Average cost amount per enrollee	Average cost amount per claim
Commercial	772	4,549	$6,928,575	$8,975	$1,523
Medicaid	2,480	18,799	$22,793,380	$9,191	$1,212
Medicare	833	6,275	$8,935,934	$10,727	$1,424
Totals	**4,085**	**29,623**	**$38,657,889**	**$28,893**	**$4,159**

Table 4 provides gross APAC cost estimates for **payer spend across all lines of business** with **29,623 total claims for Vraylar among 4,085 total enrollees.** The **payers gross expenditure of $37,017,240**, equated to a total of an average **annual cost of $26,803 per enrollee**, or approximately **$3,821 per claim**.

Table 4 Estimated 2023 APAC gross cost to the payers[31]

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	772	4,549	$5,653,379	$7,323	$1,243
Medicaid	2,480	18,799	$22,793,380	$9,191	$1,212
Medicare	833	6,275	$8,570,481	$10,289	$1,366
Totals	**4,085**	**29,623**	**$37,017,240**	**$26,803**	**$3,821**

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (**64% of total**), followed by small group and individual markets. The collected **total net cost to the healthcare system was around $5.1 million**, with payer paying $4.2 million, and enrollees our-of-pocket estimating to be $909,045. Table 5 includes the average plan costs per enrollee in the commercial market ranged from **$4,968 (large group)** to **$5,707 (individual)** annually.

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

Table 5 Estimated 2023 data call total net costs to the healthcare system, payers, and enrollee OOP [32]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	561	165	$941,622	$614,595	$327,027
Large Group	2,136	658	$3,268,978	$3,009,407	$259,571
Small Group	570	174	$905,849	$583,401	$322,447
Total	**3,267**	**997**	**$5,116,449**	**$4,207,403**	**$909,045**

Market	Avg. plan spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plan spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Individual	$1,678	$1,096	$583	$5,707	$3,725	$1,982
Large Group	$1,530	$1,409	$122	$4,968	$4,574	$394
Small Group	$1,589	$1,024	$566	$5,206	$3,353	$1,853

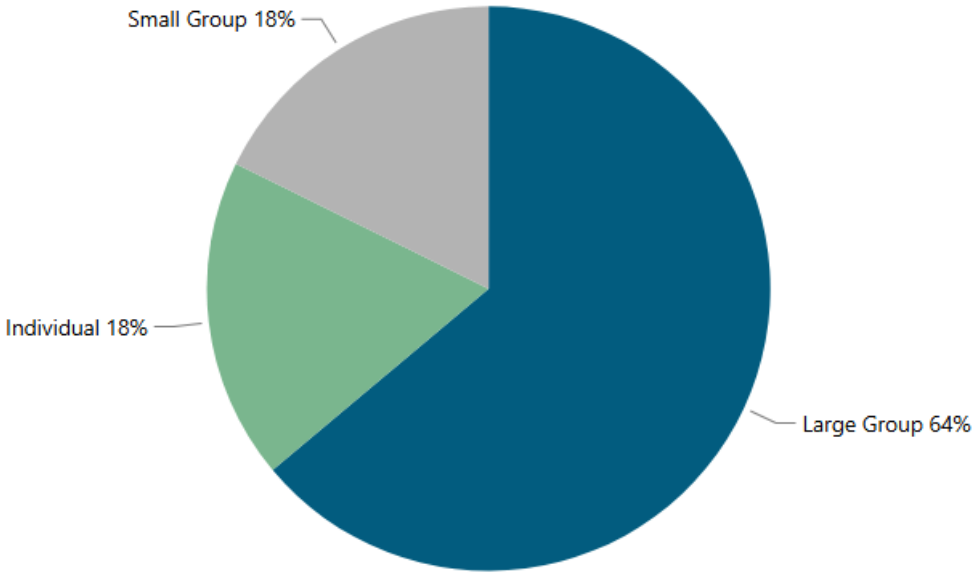

Figure 5 Data call total annual spend by market type (payer paid)

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

Medicaid fee-for-service data revealed approximately **$16.9 million in gross annual expenditures for about 13,831 claims**, with Vraylar designated as a preferred drug on the Medicaid Preferred Drug List and subject to prior authorization. Table 6 summarizes quarterly fee-for-service costs, while Table 7 reflects Vraylar was not on the Coordinated Care Organization (CCO) top 50 drugs by gross amount paid.

Table 6 2023 Gross amount paid for Medicaid/Oregon Health Plan fee for service

Fee-for-Service[33]							
2023 Quarter	Drug name on report	Amount paid	% Total FFS costs	Claim count	Average paid per claim	Preferred drug list (PDL)	Prior auth
Q1	Vraylar	$3,879,219	8.8%	3208	$1,209	Yes	Yes
Q2	Vraylar	$ 4,257,156	10.7%	3486	$1,221	Yes	Yes
Q3	Vraylar	$ 4,311,803	11%	3529	$1,222	Yes	Yes
Q4	Vraylar	$ 4,412,791	10.8%	3608	$1,223	Yes	Yes

Drug indicated in Q1-Q4 of top 40 quarterly reports of the pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Table 7 2023 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	Amount paid	Claim count	Average paid per claim
Drug not on report			

Pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Impact on patient access to the drug

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

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

[33] Oregon State University Drug Use and Research Management DUR utilization reports 2023. College of Pharmacy, Oregon State University. https://pharmacy.oregonstate.edu/research/pharmacy-practice/drug-use-research-management/dur-reports

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

Based on information reported through the carrier data call, the following plan design features were observed for Vraylar. In 2023, approximately **51.1 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **3.0 percent of plans required step therapy** before approving its use.

Among the **788 PA requests** recorded during the reporting period, **766 were approved (97.2%)** and **22 were denied (2.8%)**.

For formulary placement, **96.6 percent of plans categorized Vraylar as a non-preferred drug**, **2.9 percent listed it as preferred**, and **0.4 percent excluded it entirely from the formulary**.

Table 8 Plan design analysis from 2023 data call

Total prior authorizations	788
Number of approved prior authorizations	766
Number of denied prior authorizations	22
Percentage of approved prior authorizations	97.2%
Percentage of denied prior authorizations	2.8%
Percentage of plans requiring pre-authorization	51.1%
Percentage of plans requiring step therapy	3.0%
Percentage of plans where drug preferred on formulary	2.9%
Percentage of plans where drug non-preferred on formulary	96.6%
Percentage of plans where drug excluded on formulary	0.4%

Relative financial impacts to health, medical or social services costs

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

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

The statutory and regulatory criteria contemplate consideration of such impacts to the extent practicable. However, due to limitations in available evidence, data systems, and the challenges inherent in isolating the indirect effects of a single drug on broader healthcare or social service costs, this analysis was not performed.

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

Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Vraylar in Oregon, as reported in 2023 by the two data sources: the Oregon All Payers All Claims (APAC) database and the carrier data call.[34] These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type and commercial market segment.

Table 8 presents the average annual enrollee cost-sharing amounts derived from APAC and carrier-submitted data. The APAC data, which includes claims from commercial, Medicaid, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs that varied by payer line of business. For example, **commercially insured enrollees recorded higher average annual OOP costs** than Medicare enrollees, while Medicaid enrollees incurred no OOP costs.

Carrier-submitted data, which captures only commercially insured enrollees in Oregon's individual, small group, and large group markets, also showed variation across segments. On average, **enrollees in the individual market paid higher OOP costs per enrollee** compared to those in large group plans, while small group enrollee costs fell between the two. Copayment,

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

coinsurance, and deductible amounts are delineated separately within each data source, reflecting differences in plan design and reporting requirements.

Differences between the APAC and carrier data sources may reflect methodological and population differences, including the exclusion of health plans with fewer than 5,000 covered lives from the APAC reporting requirement and the effect of price concessions on carrier-reported figures.

Table 9 Average annual enrollee out-of-pocket costs between APAC and data call

APAC claim line of business	Commercial	Medicaid	Medicare
Number of claims	4,549	18,799	6,275
Number of enrollees	772	2,480	833
Total copay	$425,632	$0	$105,693
Total coinsurance	$603,956	$0	$179,319
Total deductible	$251,531	$0	$96,240
Total enrollee paid	$1,275,196	$0	$365,453
Average copay per claim	$94	$0	$17
Average coinsurance per claim	$133	$0	$29
Average deductible per claim	$55	$0	$15
Average cost across all claims	$280	$0	$58
Average copay per enrollee	$551	$0	$127
Average coinsurance per enrollee	$782	$0	$215
Average deductible per enrollee	$326	$0	$116
Average cost across all enrollee OOP	$1,652	$0	$439

Data call market type	Large Group	Small Group	Individual
Number of claims	2136	570	561
Number of enrollees	658	174	165
Total copay	$130,164	$4,349	$0
Total coinsurance	$65,969	$310,472	$218,801
Total deductible	$66,405	$5,424	$104,719

Data call market type	Large Group	Small Group	Individual
Total other (i.e. PAP)	($2,967)	$2,203	$3,508
Average copay per claim	$61	$8	$0
Average coinsurance per claim	$31	$545	$390
Average deductible per claim	$31	$10	$187
Average cost across all claims	$122	$566	$583
Average copay per enrollee	$198	$25	$0
Average coinsurance per enrollee	$100	$1,784	$1,326
Average deductible per enrollee	$101	$31	$635
Average cost across all enrollee OOP	$394	$1,853	$1,982

Table 10, further describes the distribution of annual enrollee OOP costs, providing measures of central tendency such as minimum, median, and maximum costs observed.

Table 10 OOP costs central tendency of Vraylar costs in 2023

Out of Pocket costs per enrollee per year[35]		
Minimum	*The lowest amount any one enrollee paid*	$0
Average	*Enrollees pay this much on average*	$421
Median	*Half of enrollees pay more than this amount and half pay less*	$0
Max	*The highest amount any one paid*	$4,092

Clinical information based on manufacturer material[36]

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

Drug indications

- FDA Approved:
  - Treatment of schizophrenia in adults

[35] For patients who used the drug at least once in the 2023 calendar year.
[36] U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf

- Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults
- Treatment of depressive episodes associated with bipolar 1 disorder (bipolar depression) in adults
- Adjunctive therapy to antidepressants for the treatment of MDD in adults.

- Off Label Uses: No off label uses determined

Clinical efficacy

- Schizophrenia in adults
  - The efficacy of cariprazine for schizophrenia was established in three, six-week randomized, placebo-controlled studies in 1,049 patients requiring hospitalization for active psychosis. The primary outcome was change from baseline in total positive and negative syndrome scale (PANSS), a tool to assess symptoms of schizophrenia. Cariprazine doses ranged from 1.5 to 9 mg daily.
  - A statistically-significant difference in change in PANSS scores at week six were evident at all doses compared to placebo and was similar to aripiprazole in one trial.
  - Effective dose range: 1.5 to 6 mg/day.
  - Doses above 6 mg did not increase efficacy but increased risk of adverse events.

- Manic or mixed episodes in bipolar 1 disorder
  - The efficacy of cariprazine for bipolar mania/mixed episodes was established in three 3-week randomized, placebo-controlled studies at doses from 3 to 12 mg daily (n=962). The primary outcome was changed from baseline in the Young Mania Rating Scale (YMRS).
  - A statistically significant difference in change in YMRS score at week three was observed in all trials.
  - Efficacy at daily doses up to 6 mg was demonstrated with no evidence to suggest higher daily doses are more efficacious.

- Depressive episodes in bipolar 1 disorder (bipolar depression)
  - The efficacy of cariprazine in bipolar depression is supported by two, phase three randomized, placebo-controlled, six-week trials. The primary outcome was change in the Montgomery-Asberg Depression Rating Scale (MADRS) total score.
  - A statistically significant change in MADRS score was observed with both 1.5 mg and 3 mg daily compared to placebo.
  - Effective doses: 1.5 mg and 3 mg/day, with most consistent benefits at 1.5 mg.

- Adjunctive therapy for major depressive disorder (MDD)

- The efficacy of cariprazine as adjunctive treatment in MDD was evaluated in two, six-week and one, eight-week placebo-controlled trials on a change from baseline in MADRS. These trials demonstrated a statistically significant change in MADRS score with doses of 1.5 mg to 3 mg daily compared to placebo.
- Another randomized, double-blind, placebo controlled study found no statistically significant difference between cariprazine 1.5 or 3 mg daily versus placebo on change in MADRS score.

Clinical safety[37]

- FDA safety warnings and precautions:
  - Increased mortality in elderly patients with dementia-related psychosis
  - Suicidal thoughts and behaviors in children, adolescents, and young adults
  - Cerebrovascular adverse reactions in elderly patients with dementia-related psychosis
  - Neuroleptic malignant syndrome
  - Tardive dyskinesia
  - Late-occurring adverse reactions
  - Metabolic changes, including hyperglycemia, diabetes, dyslipidemia and weight gain
  - Leukopenia, neutropenia, and agranulocytosis
  - Falls due to somnolence, postural hypotension and motor instability
  - Orthostatic hypotension and syncope
  - Seizures
  - Potential for cognitive and motor impairment
  - Dysphagia
  - Body temperature dysregulation

- Contraindications:
  - Hypersensitivity to cariprazine
- Common side effects:
  - Activating effects (e.g. akathisia, restlessness)
  - Sedating effects (e.g. drowsiness, somnolence)
  - Extrapyramidal symptoms
  - Hematologic abnormalities: leukopenia and neutropenia
  - Hyperglycemia
  - Weight gain
  - Nausea, abdominal pain, constipation, decreased appetite, diarrhea, dyspepsia

Comparative to therapeutic alternatives

[37] U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf

Table 11 FDA-Approved Indications

Indication	Cariprazine (Vraylar)[38]	Lumateperone (Caplyta)[39]
Schizophrenia	Yes (adults)	Yes (adults)
Bipolar depression	Yes	Yes
Bipolar mania	Yes	No
Adjunct in MDD	Yes (adjunctive)	No

Comparative efficacy: There is no data directly comparing cariprazine to lumateperone or evidence that one is more effective or safer than the other for the treatment of bipolar disorder or schizophrenia.

Table 12 Efficacy (Clinical Trials & Practice)

Comparison Point	Cariprazine (Vraylar)[40]	Lumateperone (Caplyta)[41]
Bipolar depression[42]	Efficacy for moderate to severe symptoms	Strong efficacy, especially in Bipolar II
Mania/Hypomania	**Proven** in bipolar I mania[43]	Not approved or studied for mania[44]
Schizophrenia	Effective, especially on negative symptoms[45]	Effective, especially for cognitive/mood symptoms[46]

[38] U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf
[39] U.S. Food & Drug Administration. Caplyta (lumateperone) Prescribing Information. Intra-Cellular Therapies, Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209500s011lbl.pdf
[40] U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf
[41] U.S. Food & Drug Administration. Caplyta (lumateperone) Prescribing Information. Intra-Cellular Therapies, Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209500s011lbl.pdf
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[44] U.S. Food & Drug Administration. Caplyta (lumateperone) Prescribing Information. Intra-Cellular Therapies, Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209500s011lbl.pdf
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[46] Kane, J. M., Durgam, S., Satlin, A., Vanover, K. E., Chen, R., Davis, R., & Mates, S. (2021). Safety and tolerability of lumateperone for the treatment of schizophrenia: a pooled analysis of late-phase placebo- and active-controlled clinical trials. International clinical psychopharmacology, 36(5), 244–250. https://pmc.ncbi.nlm.nih.gov/articles/PMC8322041/

Comparison Point	Cariprazine (Vraylar)[40]	Lumateperone (Caplyta)[41]
Adjunct for MDD	Proven efficacy	Not approved

Table 13 Side effect profile

Side Effect	Cariprazine (Vraylar)[47]	Lumateperone (Caplyta)[48]
Weight gain	Moderate	Low
EPS (extrapyramidal symptoms)	Low	Very low
Akathisia	Common (up to 20%)	Rare
Metabolic risk	Mild	Very low risk

Table 14 Dosing & tolerability

Factor	Cariprazine (Vraylar)[33]	Lumateperone (Caplyta)[34]
Starting Dose	1.5 mg	42 mg (fixed dose)
Titration Needed	Yes (up to 6 mg)	No (single dose formulation)
Food Requirement	No	No
Half-life	~2–4 days	~13–20 hours
Onset of effect	Slower onset (weeks)	Faster onset (~1 week

[47] U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf

[48] U.S. Food & Drug Administration. Caplyta (lumateperone) Prescribing Information. Intra-Cellular Therapies, Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209500s011lbl.pdf

Input from specified stakeholders

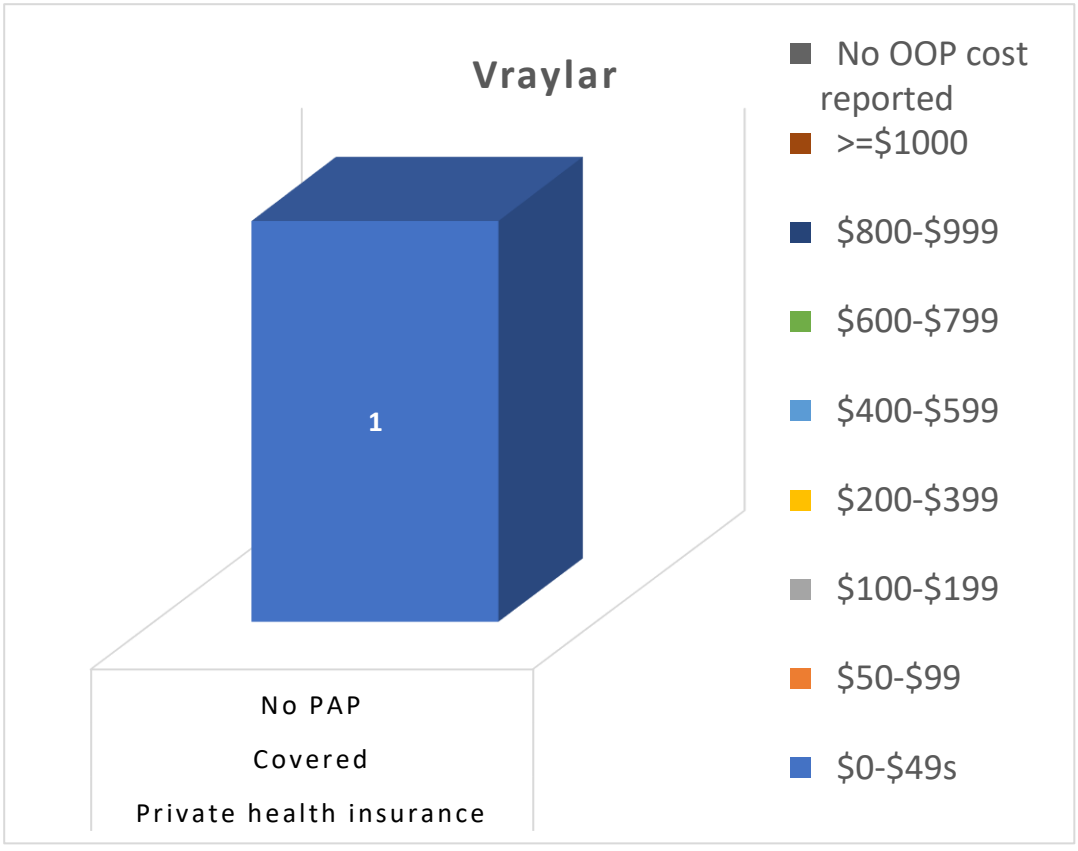
ORS 646A.694(3) and OAR 925-200-0020(2)(k)(A-D)

Patients and caregivers:

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

Survey information was received from one individual taking or having an association with Vraylar. According to Table 10, the survey respondence showed Vraylar was covered under the private insurance with no program assistance provided, and the patient's monthly out-of-pocket cost was between $0-$49.

Table 15 Patient survey responses by reported for out-of-pocket costs impact based on insurance type



Below is a written answer from an Oregon patient who responded to the PDAB survey in April 2025. Survey responses have been edited for readability, length and to protect patient privacy.

” Vraylar ”

- Vraylar was prescribed for bipolar disorder. I have taken it for eight years. It helps regulate depression and mania. My most recent, monthly, out-of-pocket expense was $35. I have tried so many things. I am sticking with Vraylar because it works better than anything else I've tried.

Individuals with scientific or medical training

This section summarizes information reported by healthcare professionals with scientific or medical training identified key barriers for patients in accessing medications. A main obstacle reported was the need for prior authorization for insurance approval before prescriptions can be provided. Other challenges include step therapy protocols, restrictive insurance formularies, and mediation costs. Few respondents viewed prescription quality limits as a barrier to accessing drugs.

There was one healthcare professional that reported the prior authorization process of Vraylar was an administrative burden and laborious for patients to access the medication.

Table 16 Reported administration burden of the drug for patient to access

Drug	Prior Authorization	Step Therapy	Quantity Limit	Cost	PBM/ formulary issues	Considered first line of therapy
Vraylar	Yes	-	-	-	-	-

Safety net providers

This section summarizes information reported by safety-net providers regarding their experience dispensing Vraylar, particularly in relation to the federal 340B Drug Pricing Program. The survey collected information on utilization of the drug, the extent to which it was eligible for 340B discounts, dispensing arrangements, and payment and reimbursement levels.

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

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

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

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

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

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

Table 17 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	7
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between $0-$100,000	27%
Reported total amount paid for drug under 340B was between $100,001-$300-000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between $0-$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between $100-001-$500,000	9%

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

Table 18 Amounts paid for drug under 340B discount program

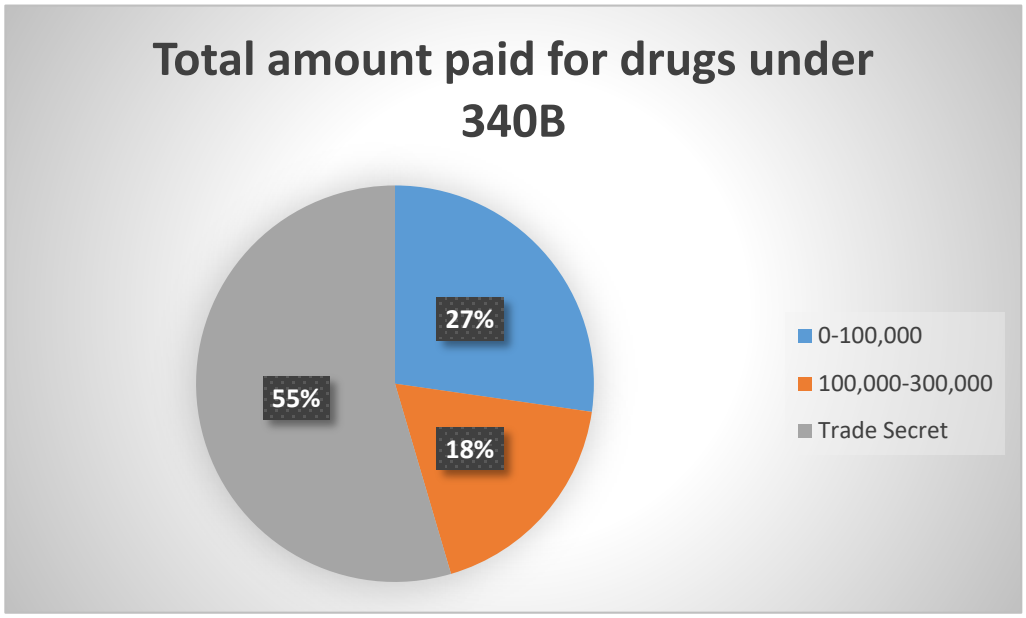
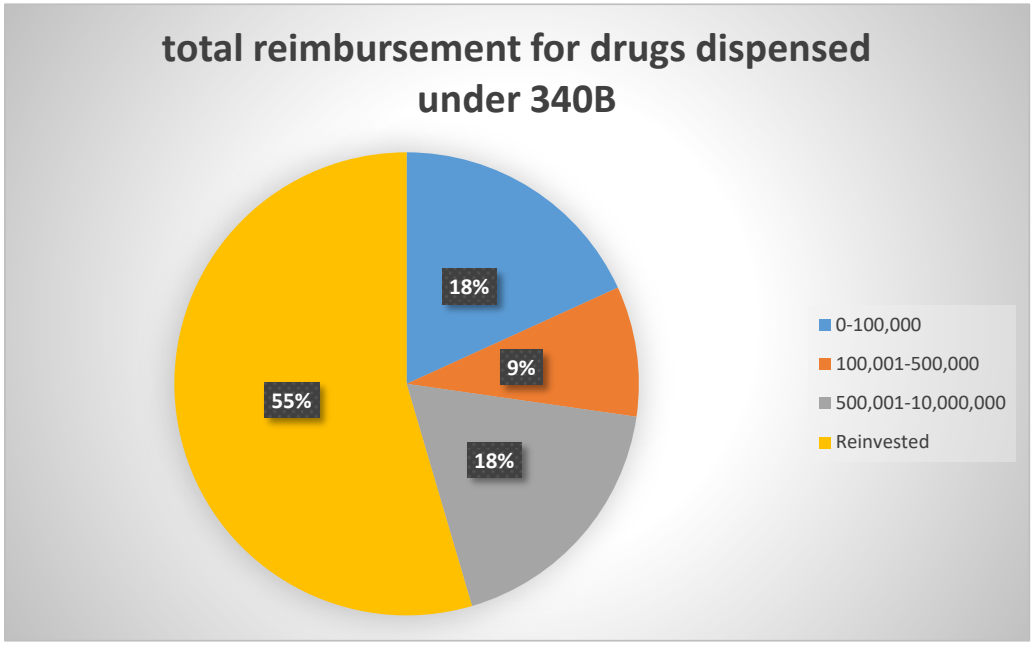


Table 19 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program



Payers

Feedback from health insurance payers was not collected individually for this review. Relevant information from payers is incorporated throughout the material packed based on the data submitted through the formal data call process. This includes details on the total cost of care for the disease, the cost and utilization of the prescription drug, the availability and formulary placement, therapeutic alternatives, as well as reported impacts to member costs.

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

Oregon Prescription Drug
Affordability Board

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

Entresto®
(*sacubitril/valsartan*)[1]

Version 2.0

[1] https://mms.mckesson.com/product/1017676/Novartis-00078077720

Table of Contents

Document version history

Version	Date	Description
v1.0	7/9/2025	Original Release
v2.0		Updated gross spend amounts in the “Cost to the healthcare system” section; added a “Cost to payers” section; updated table 3 to reflect costs to the healthcare system; added table 4 for payer paid amounts; updated sections referencing patients to reference enrollees; added the drug name to the footer; Table 2 removed Total for paid/enrollee & claims and indicated the number as an average.

Review summary

Price history

Entresto® (*sacubitril/valsartan*) was first approved by the FDA in 2015. Since entering the market, the wholesale acquisition cost **(WAC) has risen at an average annual rate of 6 percent**, **exceeding inflation in several years**, including 2018, 2020, 2022, and 2023.[2] By late 2024, the **WAC reached approximately $10.93 per unit**. Pharmacy acquisition costs for **Medicaid also increased by 27 percent** over the same period, reflecting broader trends in pricing escalation.

Cost to the healthcare system

In 2023, Oregon's All Payers All Claims **(APAC) database reported approximately $51 million in gross spending for Entresto, based on 53,866 claims across 10,016 enrollees**.[3] This equated to an **average gross spend of $4,931 per enrollee and $889 per claim**. Among payer types, Medicare accounted for the largest share of utilization and expenditures, followed by commercial and Medicaid plans.

According to 2023 data from commercial payers showed an approximate total annual net spend of **$6.1 million** across **1,711 enrollees** and **5,387 claims**. The net average spend was **$3,625 per enrollee** and **$1,146 per claim**.

Cost to payers

APAC data for payer spend across all lines of business indicated the gross spending for Entresto is **approximately $47 million, with 53,866 claims across 10,016 enrollees**. This resulted in the average **gross annual payer spend to be $4,589 per enrollee and $823 per claim**.[4]

According to the data from **commercial payers**, the net spending for Entresto is **approximately $5.4 million, spread across 5,387 claims and 1,711 enrollees**. The net spend **per enrollee was $3,156 and the net spend per claim was $998**.[5]

Cost to enrollee

Average enrollee out-of-pocket (OOP) costs in 2023 were moderate compared to similar high-cost therapies. APAC data showed **average OOP costs per enrollee of $500 for commercial and $526 for Medicare, with $0 reported for Medicaid enrollees**.

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[2] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span

[3] Based on Oregon's 2023 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 visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

[4] Ibid.

[5] 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.

Carrier-submitted data reflected similar variation by market segment, with **OOP costs ranging from $308 (large group) to $740 (individual group) per enrollee**.[6] One patient survey respondent reported a monthly OOP cost of $181.14, though most reported full insurance coverage.

Price concessions

Carrier-reported data indicates that **81.9 percent of Entresto claims in the commercial market received some form of price concession** in 2023. Manufacturer rebates accounted for the majority of these discounts, followed by pharmacy benefit managers (PBM) price concessions and other negotiated reductions. **Average gross cost per enrollee was $3,544, with net costs reduced to $3,136 after applying concessions**—an average discount of approximately 11.5 percent. In total, **$698,205 in price concessions** were reported across all market segments.

Therapeutic alternatives

No therapeutic alternatives were identified that meet the clinical equivalence criteria required for comparison. Entresto uniquely combines a neprilysin inhibitor with an angiotensin receptor blocker, and no other FDA-approved drugs currently offer this dual mechanism of action. As a result, comparative analyses of alternative treatments were not conducted.

Access and equity considerations

Access to Entresto is shaped by a combination of cost barriers and formulary placement. In 2023, **40.3 percent of health plans required prior authorization**, though step therapy was not applied. Most plans **(93.9%) listed Entresto as a preferred drug**.

[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.

Review background

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

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

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

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

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

Drug information[7]

Drug proprietary name(s): Entresto®

Non-proprietary name (active ingredients): Sacubitril and valsartan

Manufacturer: Novartis Pharmaceuticals Corp.

Treatment:

- To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.
- For the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto reduces NT-proBNP, an established biomarker used to assess the severity and determine the prognosis of heart failure, and is expected to improve cardiovascular outcomes.[8]

Dosage and strength:

- Tablets: 24/26 mg; 49/51 mg; 97/103 mg
- Capsule, sprinkles: 6/6 mg; 15/16 mg

Indication	Titration step dose (twice daily)	
	Starting	Final
Adult Heart Failure	49/51 mg	97/103 mg
Pediatric Heart Failure Patients less than 40 kg	1.6 mg/kg*	72/78 mg
Pediatric Heart Failure Patients at least 40 kg, less than 50 kg	24/26 mg	72/78 mg
Pediatric Heart Failure Patients at least 50 kg	49/51 mg	97/103 mg

*the mg/kg dose is for the oral suspension that has to be compounded from tablets. Different dosing for sprinkle capsules.

- Adjust adult doses every two to four weeks and pediatric doses every two weeks to the target maintenance dose, as tolerated by the patient.
- Reduce starting dose to half the usually recommended starting dosage for:
    - patients not currently taking an angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) or previously taking a low dose of these agents

[7] U.S. Food & Drug Administration. Entresto (sacubitril and valsartan) Prescribing Information. Novartis Pharmaceuticals Corp., Revised 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/207620s018lbl.pdf

[8] "New Novartis study supports Entresto as foundational HFrEF therapy and in-hospital initiation in appropriate stabilized heart failure patients." Novartis, Nov 11, 2018. https://www.novartis.com/us-en/news/media-releases/new-novartis-study-supports-entresto-foundational-hfref-therapy-and-hospital-initiation-appropriate-stabilized-heart-failure-patients

- patients with severe renal impairment
- patients with moderate hepatic impairment

Rought of administration: By mouth

Physician administered: No

FDA approval

Entresto (*sacubitril and valsartan)* was first approved by the FDA on July 7, 2015.[9]

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

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

Health inequities

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

Entresto is recognized as a recommended therapy for heart failure. A study utilizing Optum de-identified Clinformatics Data Mart, which included over 135,000 Medicare and commercially insured patients, revealed that individuals in the lowest income bracket (< $40,000/year) had a 30 percent lower likelihood of receiving Entresto within six months of diagnosis compared to higher-income counterparts (odds ratio (OR) 0.70; adjusted OR 0.83), even after adjusting for clinical factors.[10] Additionally, adherence—defined as covering ≥80 percent of days—was markedly lower among Black (OR 0.64) and Hispanic patients (OR 0.62), compared with white patients.[11]

Cost-related barriers also impact patients' ability to initiate or continue using Entresto. In a study, while 92 percent of heart failure patients expressed willingness to switch to Entresto if their copay increased by just five dollars per month, that number dropped dramatically to 43 percent when faced with a $100 increase.[12] Notably, the impact of cost was not limited to low-income individuals; even among higher-income groups, around 40 percent were unwilling to switch when confronted with the higher copay threshold.[13]

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[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.

[10] Johnson AE, et al. "Relation of Household Income to Access and Adherence to Combination Sacubitril/Valsartan in Heart Failure: A Retrospective Analysis of Commercially Insured Patients." Circ Cardiovasc Qual Outcomes, 2022 Jul;15(7):e009179. https://pubmed.ncbi.nlm.nih.gov/35549378/

[11] Ibid.

[12] Smith, G. H., et al. (2019). Discussing Out-of-Pocket Costs With Patients: Shared Decision Making for Sacubitril-Valsartan in Heart Failure. Journal of the American Heart Association, 8(1), e010635. https://doi.org/10.1161/JAHA.118.010635

[13] Rao, B. R., et al. (2020). Heart Failure and Shared Decision-Making: Patients Open to Medication-Related Cost Discussions. *Circulation. Heart failure*, *13*(11), e007094. https://doi.org/10.1161/CIRCHEARTFAILURE.120.007094

During a CMS forum in Nov. 2023[14] for Entresto, speakers addressed the pressing concerns related to patients access to the essential medication through appropriate formulary positioning and spoke out against the high cost of a life-saving cardiac medication. They specifically highlighted how marginalized groups, particularly Black and Indigenous communities—who suffer disproportionately from heart failure—would face further burdens in terms of mortality and hospitalization risk factors if the cost of the drug continues to rise.[15]

Residents prescribed

ORS 646A.694(1)(b) and OAR 925-200-0020(1)(b) & (2)(b). Data source from APAC. Data sources: Oregon All Payers All Claims (APAC) database and commercial carrier data call.

In 2023, the Oregon APAC database recorded **9,081 unique individuals** with at least one filled prescription for Entresto.[16] In contrast, the **commercial health benefit plan data call**, which included submissions from 11 reporting carriers, identified **1,711 enrollees** with a Entresto prescription fill during the same period.[17]

The substantial variance between the two figures is attributable to differences in data scope and reporting mandates. APAC is a comprehensive claims repository that aggregates utilization data across all payer types, including Medicaid, Medicare, and commercial lines of business. In contrast, the data call process captures a limited subset of commercially insured enrollees and is restricted to the reporting obligations of participating health plans. As a result, APAC offers a more inclusive estimate of statewide utilization, while the carrier-submitted data reflects only a narrow segment of the insured population.

Price for the drug

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

This section examines the pricing dynamics of Entresto, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of the wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), as well as the impact of negotiated price concessions which include discounts, rebates, and other price reduction negotiations. Together, the data provides a comprehensive view of

[14] Transcript: Entresto, November 1, 2023 Medicare Drug Price Negotiation Program Patient-Focused Listening Session. Centers for Medicare & Medicaid Services (CMS), Nov. 1, 2023. https://www.cms.gov/files/document/entresto-transcript-110123.pdf

[15] Ibid.

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

[17] Based on 2023 data collected by DCBS under authorities granted in ORS 731.296 and OES 646A.963 through ORS 646A.697 from Oregon health insurance plans. Cost information from the data call is the cost of the drug after price concessions.

Entresto's list price trajectory, pharmacy acquisition costs, and the degree to which price reductions are realized in practice by payers in Oregon.

Price history

The wholesale acquisition cost (WAC) of Entresto, averaged across 7 NDC's reported national drug codes (NDCs), was approximately **$10.65 per unit** at the end of 2024.[18] Between 2018 and 2024, the package WAC increased at an average annual rate of **6.0 percent** exceeding the general inflation rate of the consumer price index (CPI-U).[19] See Figures 1 and 2.

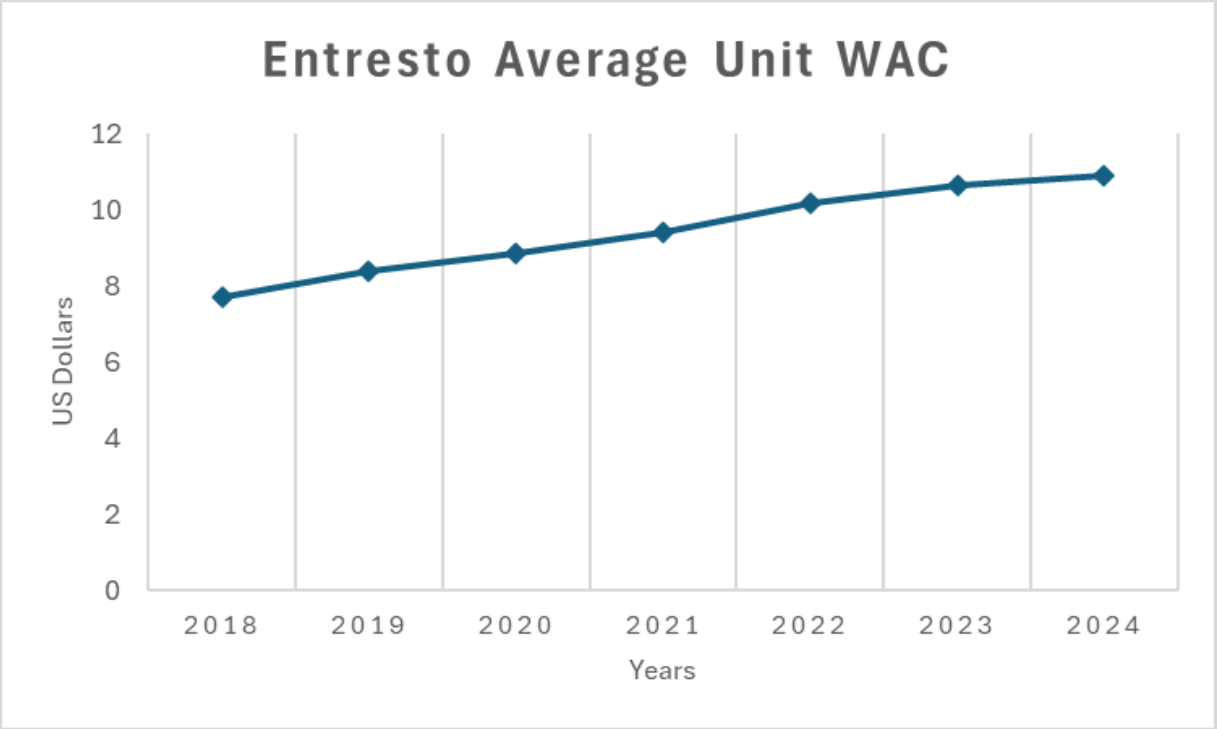

Figure 1 Entresto WAC from 2018-2024

[18] To determine which NDC to use for the WAC price history, the available 2023 utilization data was analyzed and the NDC with the highest volume of claims in 2023 was used.

[19] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/

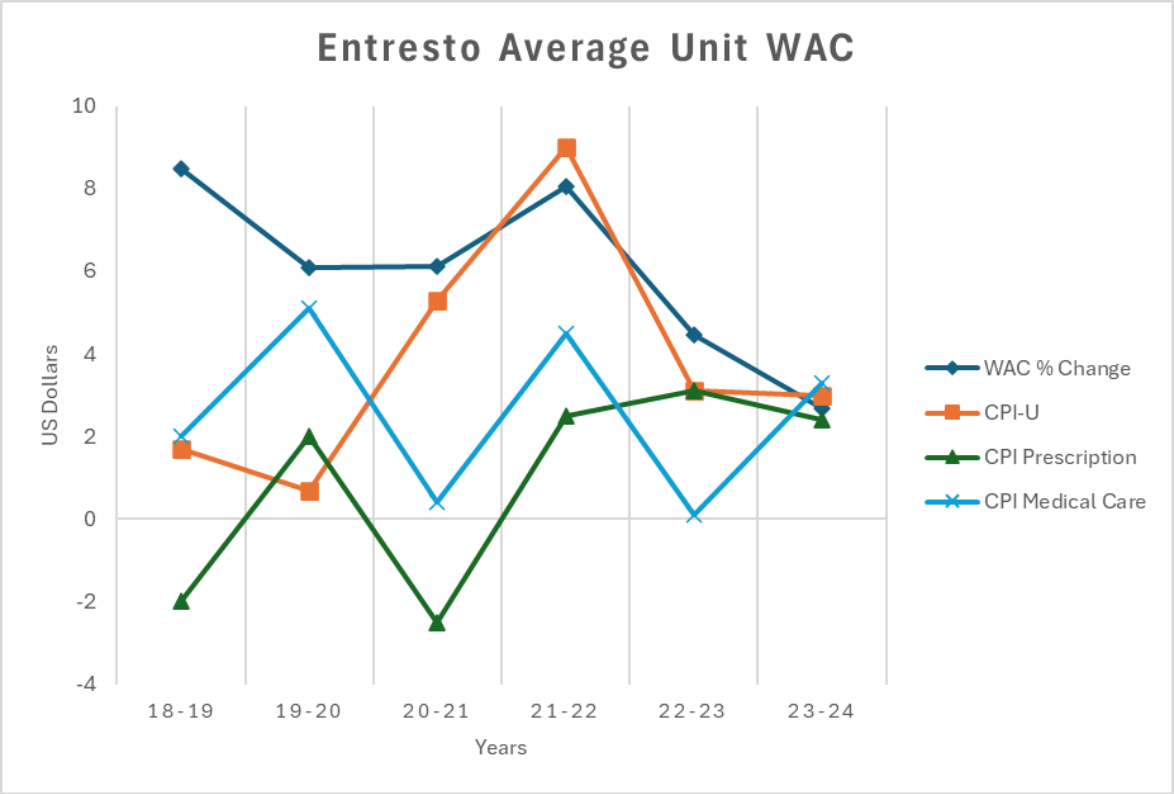

Figure 2 Year over year change in WAC compared to inflation rates[20]

Unit 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. This increase outpaced inflation in 2018-2019, 2019-2020, and 2022-2023.[21]

Pharmacy acquisition costs

The Oregon Actual Average Acquisition Cost (AAAC), which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$8.65 per unit in Q1 2020 to $10.99 per unit in Q4 2024**, an approximate **27 percent increase** over the period (see Figure 3).[22] Relative to the $10.93 WAC in end-of-year 2024, a AAAC increase of 0.55 % percent is indicated.

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

[20] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/
[21] Ibid.
[22] Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2024. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. https://myersandstauffer.com/client-portal/oregon/

trajectory relative to inflation and informs the assessment of its affordability for public and private payers.

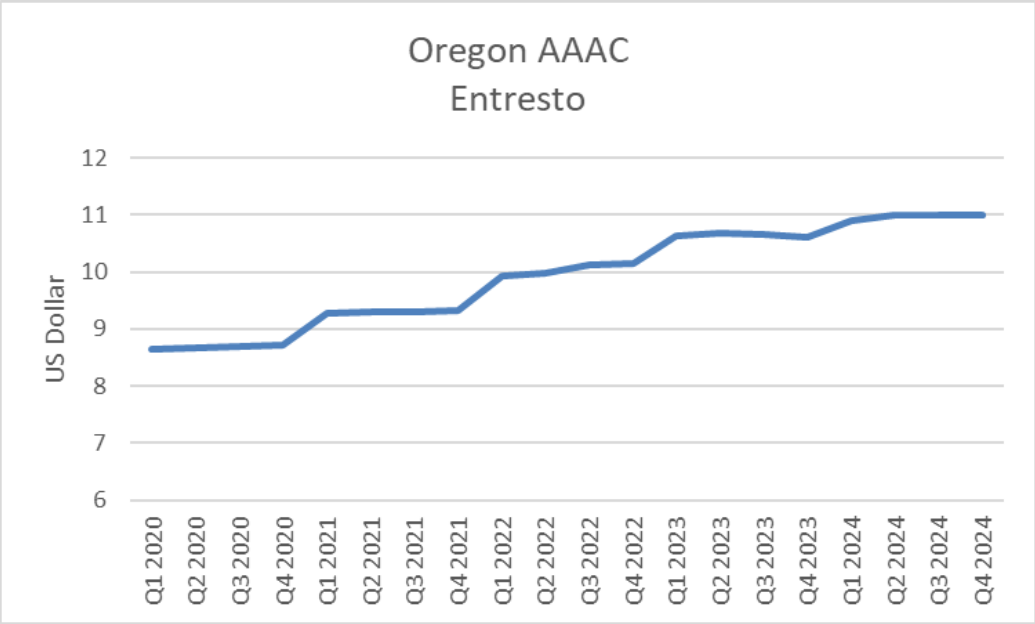

Figure 3 AAAC for Entresto from Q1 2020 to Q4 2024

Estimated average monetary price concession

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

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

Based on carrier-submitted data for 2023, the **average gross cost of Entresto per enrollee in the commercial market was approximately $3,544**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $3,136**, reflecting an **estimated mean discount of 11.5 percent** relative to gross costs.

Across all reporting carriers and market segments, the total cost of Entresto before concessions was **$6,063,238**, with total reported price concessions amounting to approximately **$698,205**, as detailed in Table 1. Notably, **81.9 percent of claims benefited from some form of price concession**, **leaving 18.1% at full gross cost**. Figure 4 shows manufacturer concessions

comprised the largest share, supplemented by PBM discounts and other adjustments across the payer types.

Table 1 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	1,711
Total number of claims	5,387
Total number of claims with price concessions applied	4,412
Percentage of claims with price concessions applied	81.9%
Percentage of cost remaining after concessions	88.5%
Manufacturer price concessions for all market types	$619,355
PBM price concessions for all market types	$70,097
Other price reductions for all market types	$8,754
Cost before price concessions across all market types	$6,063,238
Total price concessions across all market types	$698,205
Cost of after price concessions across all market types	$5,365,033
Avg. payer spend per enrollee without price concessions	$3,544
Avg. payer spend per enrollee with price concessions	$3,136

Figure 4 Percent of price concession in each market type

Estimated total amount of the price concession

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

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

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

Estimated price for therapeutic alternatives[23]

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

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

No therapeutic alternative was identified for Entresto that meets the clinical equivalence specificity required for comparison. As a result, pricing comparisons to alternative therapies are not available for this review.

Estimated average price concession for therapeutic alternatives

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

This section addresses the estimated average of discounts, rebates, or other price concessions associated with therapeutic alternatives to Entresto, as compared to the subject drug itself. At

[23] 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) PDAB 1-2023: Prescription Drug Affordability Review (oregon.gov).

the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this information as additional data become available through carrier reporting, manufacturer disclosures, or other sources.

Estimated costs to health insurance plans

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

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

In 2023, the Oregon APAC database recorded **53,866 claims for Entresto among 10,016 enrollees**, corresponding to a **total gross expenditure of $51.2 million**. This equates to an average **annual spend of $14,793 per enrollee**, or approximately **$2,668 per claim**.

Table 3 provides gross cost estimates by payer line of business:

- **Medicare** accounted for the largest share of utilization, with 28,432 claims from 5,833 enrollees and a total spend of **$31.5 million**.
- **Medicaid** and **commercial** payers reported smaller but notable expenditures of approximately **$8.8 million** and **$10.8 million**, respectively.

Table 2 Estimated 2023 APAC total gross costs to the healthcare system[24]

Payer line of business	Total enrollees	Total claims	Total gross cost amount to healthcare system	Average cost amount per enrollee	Average cost amount per claim
Commercial	2,181	12,094	$10,852,428	$4,976	$897
Medicaid	2,002	13,340	$8,842,935	$4,417	$663
Medicare	5,833	28,432	$31,496,535	$5,400	$1,108
TOTAL	**10,016**	**53,866**	**$51,191,898**	**$14,793**	**$2,668**

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

Table 3 provides gross APAC cost estimates for **payer spend across all lines of business** with **53,866 total claims for Entresto among 10,016 total enrollees.** The **payers gross expenditure of $47,032,151**, equated to a total of an average **annual cost of $13,766 per enrollee**, or approximately **$2,470 per claim**.

Table 3 Estimated 2023 APAC gross cost to the payers

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	2,181	12,094	$9,762,540	$4,476	$807
Medicaid	2,002	13,340	$8,842,935	$4,417	$663
Medicare	5,833	28,432	$28,426,676	$4,873	$1000
TOTAL	**10,016**	**53,866**	**$47,032,151**	**$13,766**	**$2,470**

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (73% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around $6 million**, with payer paying $5.4 million, and enrollees our-of-pocket estimating to be $698,148. Table 4 includes the average plan costs per enrollee in the commercial market ranged from **$3,456 (large group)** to **$3,710 (individual)** annually.

Table 4 Estimated 2023 data call total net costs to the healthcare system, payers and enrollee OOP [25]

Market	Total annual spending	Payer Paid	Enrollee out-of-pocket cost	Number of claims	Number of enrollees
Individual	$1,343,077	$1,075,318	$267,759	1,166	362
Large Group	$3,636,186	$3,312,565	$323,621	3,287	1,052
Small Group	$1,101,632	$994,863	$106,768	934	297
Total	**$6,080,895**	**$5,382,746**	**$698,148**	**5,387**	**1,711**

Market	Avg. plan spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plan spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Individual	$1,152	$922	$230	$3,710	$2,970	$740
Large Group	$1,106	$1,008	$98	$3,456	$3,149	$308
Small Group	$1,179	$1,065	$114	$3,709	$3,350	$359

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

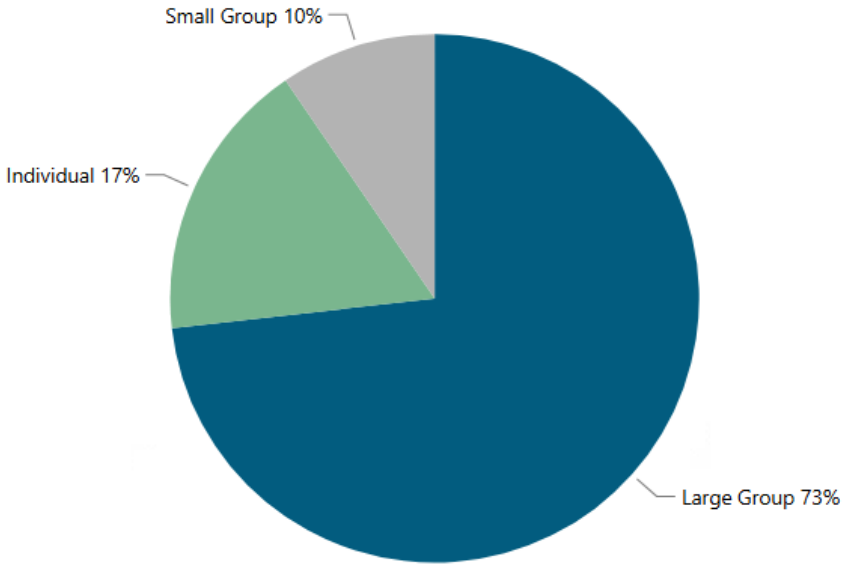

Figure 5 Data call total annual spend (payer paid)

Cost to the state fee-for-service program, represented in Table 5, indicates Entresto was not included on the top 40 quarterly reports. Table 6 shows Oregon's coordinated care organizations (CCOs) paid $8,247,753 for 12,412 claims averaging $664 per paid claim. Table 7 indicates CCOs reported Entresto as having an annual greatest increase from 2022-2023 (rebates not included) with a $2,860,102 year-over-year total cost growth.

Table 5 2023 Gross amount paid for Medicaid/Oregon Health Plan fee for service

Fee for Service[26]							
2023 Quarter	**Drug name on report**	**Amount paid**	**% Total FFS costs**	**Claim count**	**Average paid per claim**	**Preferred drug list (PDL)**	**Prior auth**
Q1	Drug Not on Report						
Q2	Drug Not on Report						
Q3	Drug Not on Report						

[26] Oregon State University Drug Use and Research Management DUR utilization reports 2023. College of Pharmacy, Oregon State University. https://pharmacy.oregonstate.edu/research/pharmacy-practice/drug-use-research-management/dur-reports

Fee for Service[26]							
2023 Quarter	Drug name on report	Amount paid	% Total FFS costs	Claim count	Average paid per claim	Preferred drug list (PDL)	Prior auth
Q4	Drug Not on Report						
Annual Average:							

Drug not indicated in Q1-Q4 of top 40 quarterly reports of the pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Table 6 2023 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	Amount paid	Claim count	Average paid per claim
Entresto	$8,247,753	12,412	$664

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

Table 7 Medicaid CCOs greatest increase in share to total cost from 2022-2023 (rebates not included)

Medicaid CCOs			
2022	2023	YoY change in spending	Percent of total CCO cost 2023
$5,387,651	$8,247,753	$2,860,102	0.2%

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

Impact on patient access to the drug

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

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Entresto, including prior authorization requirements, step therapy protocols, and formulary placement. These data describe how the drug is positioned within insurance benefit designs and the extent to which utilization management processes were applied during the reporting period.

Based on information reported through the carrier data call, the follow plan design features were observed for Entresto. In 2023, approximately **40.3 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **no plans requiring step therapy** before approving its use.

Among the **788 PA requests** recorded during the reporting period, **1,010 were approved (90.8%)** and **102 were denied (9.2%)**.

For formulary placement, **6.1 percent of plans categorized Entresto as a non-preferred drug**, **93.9 percent listed it as preferred**, and **no plans excluded it entirely from the formulary**.

Table 8 Plan design analysis from 2023 data call

Total prior authorizations	1,112
Number of approved prior authorizations	1,010
Number of denied prior authorizations	102
Percentage of approved prior authorizations	90.8%
Percentage of denied prior authorizations	9.2%
Percentage of plans requiring pre-authorization	40.3%
Percentage of plans requiring step therapy	0%
Percentage of plans where drug preferred on formulary	93.9%
Percentage of plans where drug non-preferred on formulary	6.1%
Percentage of plans where drug excluded on formulary	0%

Relative financial impacts to health, medical or social services costs

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

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

The statutory and regulatory criteria contemplate consideration of such impacts to the extent practicable. However, due to limitations in available evidence, data systems, and the challenges inherent in isolating the indirect effects of a single drug on broader healthcare or social service costs, this analysis was not performed.

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

Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Entresto in Oregon, as reported in 2023 by the two data sources: the Oregon All Payers All Claims (APAC) database and the carrier data call.[27] These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type and commercial market segment.

Table 8 presents the average annual enrollee cost-sharing amounts derived from APAC and carrier-submitted data. The APAC data, which includes claims from commercial, Medicaid, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs that varied by payer line of business. For example, **Medicare insured enrollees recorded higher average annual OOP costs** than commercial enrollees, while Medicaid enrollees incurred no OOP costs.

Carrier-submitted data, which captures only commercially insured enrollees in Oregon's individual, small group, and large group markets, also showed variation across segments. On average, enrollees in the **large market paid higher OOP costs per enrollee** compared to those in small group plans, while individual group enrollee costs fell between the two. Copayment, coinsurance, and deductible amounts are delineated separately within each data source, reflecting differences in plan design and reporting requirements.

Differences between the APAC and carrier data sources may reflect methodological and population differences, including the exclusion of health plans with fewer than 5,000 covered lives from the APAC reporting requirement and the effect of price concessions on carrier-reported figures.

Table 9, further describes the distribution of annual enrollee OOP costs, providing measures of central tendency such as minimum, median, and maximum costs observed.

Table 9 Average annual enrollee out-of-pocket costs between APAC and data call

APAC claim line of business	Commercial	Medicaid	Medicare
Number of claims	12,094	13,340	28,432
Number of enrollees	2,181	2,002	5,833
Total copay	$492,419	$0	$1,063,788

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

APAC claim line of business	Commercial	Medicaid	Medicare
Total coinsurance	$225,589	$0	$1,597,764
Total deductible	$373,776	$0	$437,493
Total enrollee paid	$1,089,888	$0	$3,069,859
Average copay per claim	$41	$0	$37
Average coinsurance per claim	$19	$0	$56
Average deductible per claim	$31	$0	$15
Average cost across all claims	$90	$0	$108
Average copay per enrollee	$226	$0	$182
Average coinsurance per enrollee	$103	$0	$274
Average deductible per enrollee	$171	$0	$75
Average cost across all enrollee OOP	$500	$0	$526

Data call market type	Large Group	Small Group	Individual
Number of claims	1166	3287	934
Number of enrollees	362	1052	297
Total copay	$33,412	$171,979	$56,439
Total coinsurance	$85,983	$75,263	$28,907
Total deductible	$148,809	$73,466	$21,422
Total other (i.e. PAP)	($445)	$2,913	$0
Average copay per claim	$29	$52	$60
Average coinsurance per claim	$74	$23	$31
Average deductible per claim	$128	$22	$23
Average cost across all claims	$230	$98	$114
Average copay per enrollee	$92	$163	$190
Average coinsurance per enrollee	$238	$72	$97
Average deductible per enrollee	$411	$70	$72
Average cost across all enrollee OOP	$740	$308	$359

Table 10, further describes the distribution of annual enrollee OOP costs, providing measures of central tendency such as minimum, median, and maximum costs observed.

Table 10 OOP costs central tendency of Entresto costs in 2023

Out of Pocket costs per enrollee per year[28]		
Minimum	*The lowest amount any one enrollee paid*	$0
Average	*Enrollees pay this much on average*	$458
Median	*Half of enrollees pay more than this amount and half pay less*	$0
Max	*The highest amount any one enrollee paid*	$2,752

Clinical information based on manufacturer material[29]

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

Drug indications

- FDA Approved:
  - *Sacubitril and valsartan* is indicated:
    - to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.
    - for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. *Sacubitril and valsartan* reduces NT-proBNP, an established biomarker used to assess the severity and determine the prognosis of heart failure, and is expected to improve cardiovascular outcomes.[30]

[28] For patients who used the drug at least once in the 2023 calendar year.

[29] U.S. Food & Drug Administration. Entresto (sacubitril and valsartan) Prescribing Information. Novartis Pharmaceuticals Corp., Revised 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/207620s018lbl.pdf

[30] "New Novartis study supports Entresto as foundational HFrEF therapy and in-hospital initiation in appropriate stabilized heart failure patients." Novartis, Nov 11, 2018. https://www.novartis.com/us-en/news/media-releases/new-novartis-study-supports-entresto-foundational-hfref-therapy-and-hospital-initiation-appropriate-stabilized-heart-failure-patients

- Off Label Uses: Lowering blood pressure: Studies conducted showed using Entresto to lower blood pressure was well tolerated.[31,32]

Clinical efficacy[33]

Sacubitril and valsartan is a combination of neprilysin inhibitor (sacubitril) and an angiotensin II receptor blocker (valsartan) that is for the treatment of chronic heart failure in adults and pediatric patients aged one and older. Its clinical efficacy in adults with heart failure has been demonstrated in two randomized controlled trials: PARASDGM-HF (vs enalapril) and PARAGON-HF (vs valsartan). The trial supporting pediatric use comes from the PANORAMA-HF study.

- The PARADIGM-HF trial enrolled 8,442 adults with symptomatic chronic heart failure with reduced ejection fraction (HFrEF, LVEF ≤ 40%) and compared sacubitril/valsartan 97/103 mg twice daily to enalapril 10 mg daily. Key findings include:
  - *sacubitril and valsartan* reduced the risk of cardiovascular death or heart failure hospitalization by 20% compared to enalapril (21.8% vs. 26.5%, respectively, hazard ratio [HR] 0.80; 95% CI, 0.73–0.87; $p < 0.0001$) with an absolute risk reduction (ARR) of 4.7% and a number needed to treat (NNT) of 22.
  - *sacubitril and valsartan* also reduced the risk of all-cause mortality compared to enalapril (17% vs. 19.8%; HR 0.84; 95% CI, 0.76–0.93; $p = 0.0009$; ARR 2.8%)).
  - Symptomatic hypotension also occurred more frequently with sacubitril/valsarta n (14.0% vs. 9.2%; p<0.001).

  These results support *sacubitril and valsartan*'s superiority over ACE inhibitors in reducing morbidity and mortality in HFrEF.

- The PARAGON-HF trial compared sacubitril/valsartan 97/103 mg twice daily to valsartan valsartan 160 mg twice daily in 4,796 patients with heart failure and LVEF ≥ 45%, including both heart failure with preserved ejection fraction (HFpEF) and heart failure with mildly reduced EF (HFmrEF). Key findings include:
  - There was a numerical reduction with sacubitril/valsartan, but no significant difference in the primary outcome of total HF hospitalizations and CV death with 12.8 events per 100 patient-yr in the sacubitril/valsartan group and 14.6 per 100 patient-year in the valsartan group (RR 0.87; 95% CI 0.75 to 1.01).
  - The effect was driven by fewer total HF hospitalizations (RR 0.85; 95% CI, 0.72–1.00).

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[31] Xuelin Wang, Feier Song, Lujing Jiang, Ziling Huang, Songyuan Luo, Xin Li, Xuyu He, Efficacy and Safety of Sacubitril/Valsartan in Chronic Type B Aortic Dissection Combined With Mild Hypertension, *American Journal of Hypertension*, Volume 37, Issue 8, August 2024, Pages 612–620, https://doi.org/10.1093/ajh/hpae038

[32] Rakugi, H., Kario, K., Yamaguchi, M. *et al.* Efficacy of sacubitril/valsartan versus olmesartan in Japanese patients with essential hypertension: a randomized, double-blind, multicenter study. Hypertens Res 45, 824–833 (2022). https://doi.org/10.1038/s41440-021-00819-7

[33] U.S. Food & Drug Administration. Entresto (sacubitril and valsartan) Prescribing Information. Novartis Pharmaceuticals Corp., Revised 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/207620s018lbl.pdf

    - Subgroup analyses suggested a possible benefit in patients with LVEF ≤ 57% compared to those with higher baseline LVEF. Benefits are more evident in patients with LVEF before normal.
- The expanded FDA approval in pediatric patients age one year and older was based on the PANORAMA-HF study, a randomized, double-blind study in 110 children aged 1-17 years with chronic HF and LVEF ≤ 40% previously on an ACE or ARB. Sacubitril/valsartan target dose of 3.1 mg/kg BID was compared to enalapril (target dose 0.2 mg/kg) and the primary outcome was reduction in NT-proBNP reduction over 12 weeks:
    At week 12, sacubitril/valsartan (n=54) resulted in a 15.6% greater reduction than enalapril (n=54) (mean ratio 0.84; 95% CI 0.67-1.06) but did not reach superiority over enalapril.
    - While the between-group difference was not statistically significant, the reduction in NT-proBNP was considered clinically meaningful, supporting FDA approval.

Comparative effectiveness

- While there is no therapeutic alternative that includes a neprilysin inhibitor like sacubitril, data supports early and significant absolute risk reduction in all-cause mortality with ACE-inhibitors and substituted ARBs in patients with HFrEF.
- Data from meta-analysis suggests that sacubitril/valsartan is not superior to ACEI and ARB therapy when equivalent doses are utilized in patients with HFrEF and are superior to enalapril at sub-equivalent doses (10 mg daily).
- In patients who cannot tolerate sacubitril/valsartan due to hypotension or cannot access it, therapy with an ACE inhibitor or ARB is recommended.

Clinical safety

- FDA safety warnings and precautions:
    - Fetal toxicity
    - Angioedema
    - Hypotension
    - Impaired renal function
    - Hyperkalemia
- Contraindications:
    - Hypersensitivity to any component.
    - History of angioedema related to previous ACEi or ARB therapy.
    - Concomitant use with ACE inhibitors (and within 36 hours of ACE inhibitor use)
    - Concomitant use with aliskiren in patients with diabetes.
- Common adverse reactions:

- Serious allergic reactions causing swelling of face, lips, tongue, and throat (angioedema) that may cause trouble breathing and death.
- People who are Black and take *sacubitril and valsartan* may have a higher risk of having angioedema than people who are not Black and take *sacubitril and valsartan*.
- People who have had angioedema before taking *sacubitril and valsartan* may have a higher risk of having angioedema than people who have not had angioedema before taking *sacubitril and valsartan*.
- Low blood pressure (hypotension): 18%
- Kidney problem (acute kidney injury): 15%
- Increased amount of potassium in the blood (hyperkalemia): 12%

Input from specified stakeholders

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

See Appendix page for all stakeholder feedback.

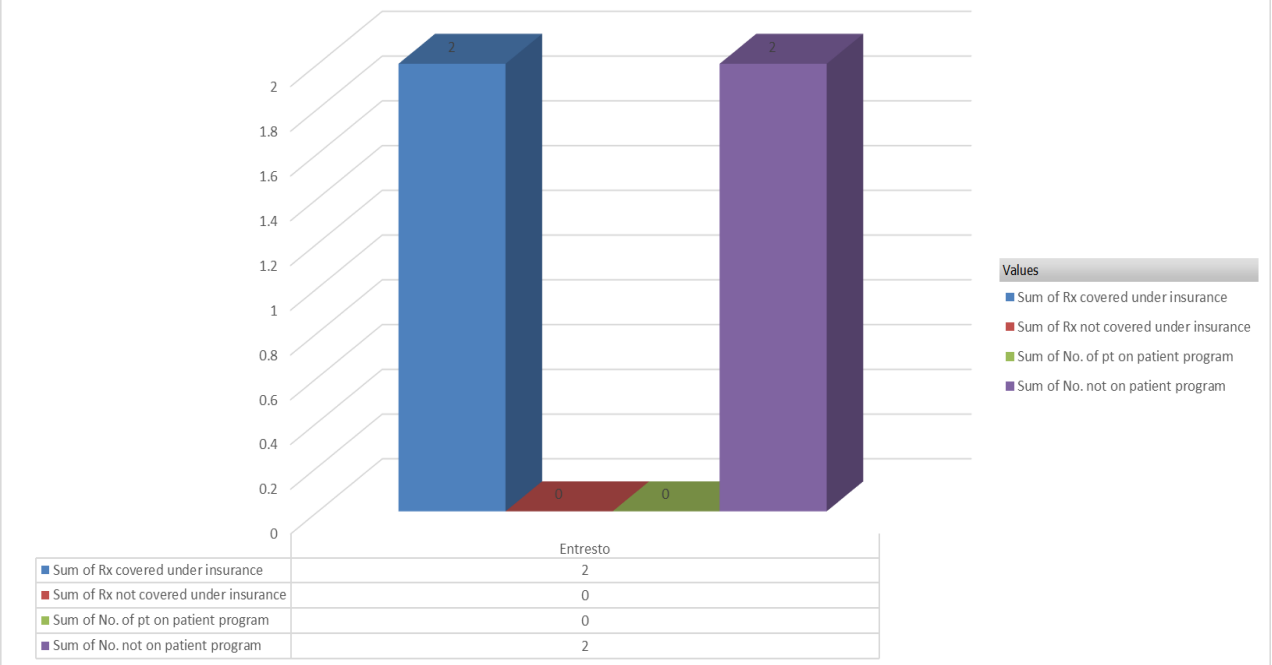
Patients and caregivers:

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

Survey information was received from two individuals taking or having an association with Entresto. For both respondents, their insurance plan covered Entresto.

Table 10 indicated zero patients were on Medicaid, two patients were on Medicare, and zero patients had private health insurance. No patient reported that their prescription was not covered. Zero patients reported being on patient assistance programs.

Table 11 Patient survey responses for out-of-pocket costs impact based on insurance type



	Entresto
Sum of Rx covered under insurance	2
Sum of Rx not covered under insurance	0
Sum of No. of pt on patient program	0
Sum of No. not on patient program	2

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

” Entresto ”

- I take Entresto 24/26mg 2X daily for heart problems and have been taking it since January 2021. The Veterans Administration pays for my medications. Entresto provides better heart function. It is a very expensive med and I'm happy that the VA covers the cost!

- For the past six months, I have been taking Entresto 24-26mg twice a day. My most recent, monthly, out-of-pocket cost was $181.14. In the past, I used losartan to treat the condition.

Individuals with scientific or medical training

This section summarizes information reported by individuals with scientific and medical training. There was no reports for Entresto to determine the impact of the disease, benefits or disadvantages, drug utilization, or input regarding off label usage.

Safety net providers

This section summarizes information reported by safety net providers regarding their experience dispensing Entresto, particularly in relation to the federal 340B Drug Pricing Program. The survey collected information on utilization of the drug, the extent to which it was eligible for 340B discounts, dispensing arrangements, and payment and reimbursement levels.

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

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

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

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

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

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

Table 12 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	9
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%

Survey information	Response
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between $0-$100,000	27%
Reported total amount paid for drug under 340B was between $100,001-$300-000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between $0-$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between $100-001-$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between $500,000-$10,000,000	18%

Table 13 Amounts paid for drug under 340B discount program

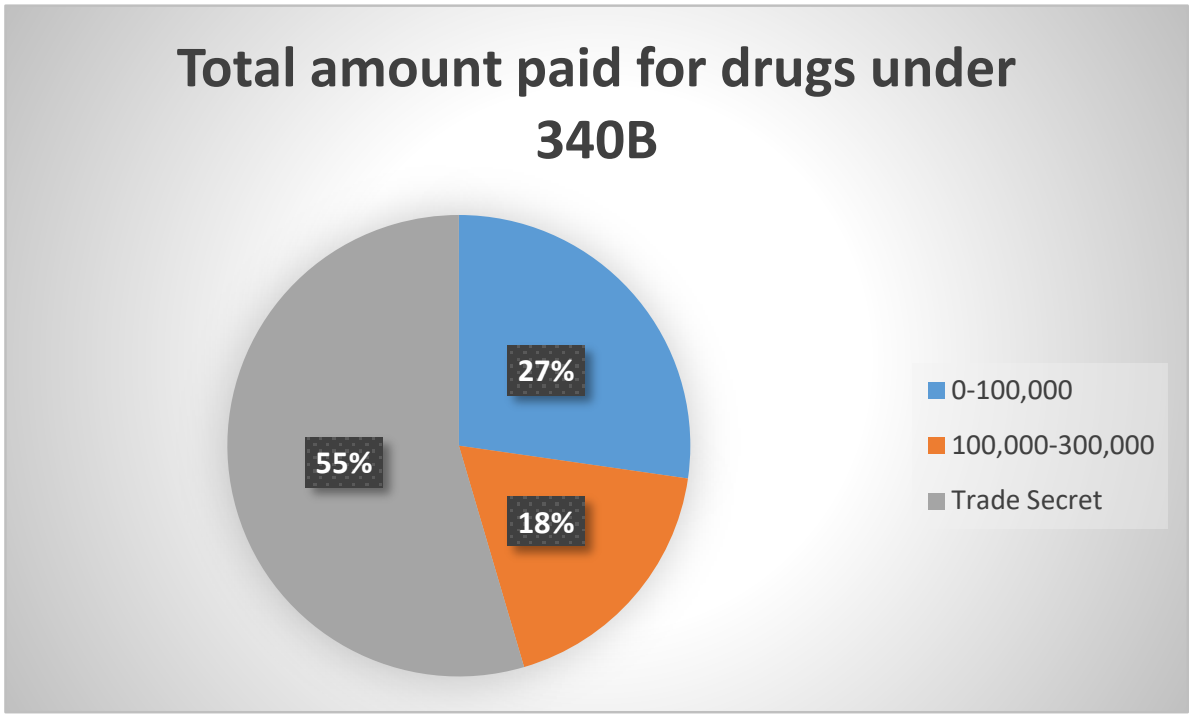
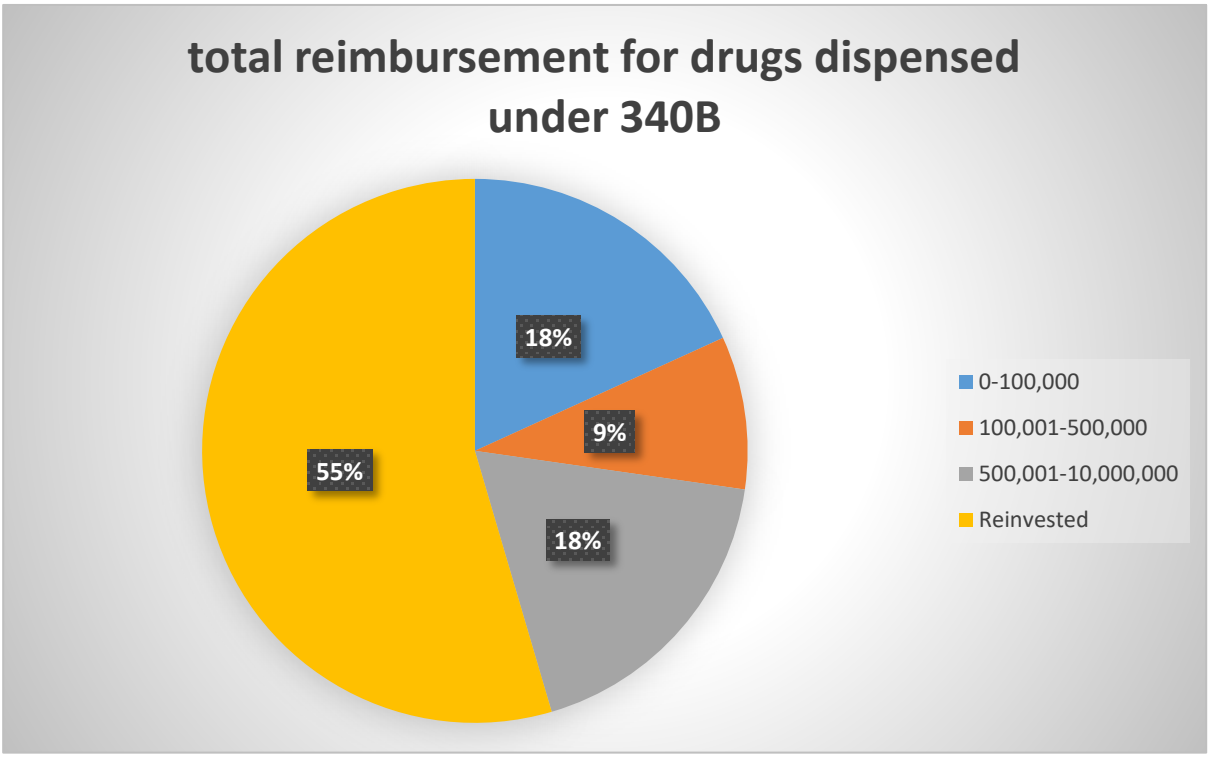


Table 14 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program



Payers

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

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

Appendix

Stakeholder feedback:

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Courtney Piron	Novartis	Entresto	Letter	5/21/2025	**Exhibit A**
Sarah Hoffman	Partnership to Advance Cardiovascular Health	Entresto	Letter	5/21/2025	**Exhibit B**

Oregon Prescription Drug
Affordability Board

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

Ajovy®
(*Fremanezumab-vfrm*)[1]

Version 2.0

[1] https://www.nsmedicaldevices.com/company-news/teva-canada-ajovy-subcutaneous-injection/

Table of Contents

Document version history

Version	Date	Description
v1.0	7/9/2025	Original Release
v2.0		Updated gross spend amounts in the “Cost to the healthcare system” section; added a “Cost to payers” section; updated table 3 to reflect costs to the healthcare system; added table 4 for payer paid amounts; updated sections referencing patients to reference enrollees; added the drug name to the footer; Table 2 removed Total for paid/enrollee & claims and indicated the number as an average; separated rapid and long acting molecule drugs in the clinical review section for consistence with other drug review packets.

Review summary

Price history

Ajovy® (*fremanezumab-vfrm*) was first approved by the FDA in 2018 for the preventive treatment of migraine. Since entering the market, the wholesale acquisition cost **(WAC) has risen at an average annual rate of 4.1 percent, exceeding inflation** in 2020, 2023, and 2024.[2,3] As of late 2024, the **WAC reached $489 per unit**, with **Medicaid acquisition costs (AAAC) tracking 0.7 percent discount**.

Cost to the healthcare system[4,5]

According to Oregon's 2023 APAC data:

- **$7.5 million** in total gross spending for Ajovy, across **1,743 enrollees** and **10,307 claims**.
- The average annual gross spend was **$4,139 per enrollee** and **$2,142 per claim**.

According to data from commercial payers:

- **$3.9 million** in net spending across **1,057 enrollees** and **5,312 claims**.
- The net spend was **$11,205 per enrollee** and **$2,216 per claim**.

Cost to payers[5,6]

According to Oregon's 2023 APAC data:

- **$6,566,874** in payer spending for Ajovy, across **1,743 enrollees** and **10,307 claims**.
- The average annual payer spend was **$11,232 per enrollee** and **$1,940 per claim**.

According to data from commercial payers:

- **$3.4 million** in net spending across **1,057 enrollees** and **5,312 claims**.
- The net spend was **$8,919 per enrollee** and **$1,766 per claim**.

Cost to enrollees[6,7]

Out-of-pocket (OOP) expenses varied across data sources:

- APAC data reported average OOP costs of **$729 per commercial enrollee**, **$455 per Medicare enroll** with **$0 for Medicaid** enrollees.

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[2] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span
[3] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/
[4] Ibid.
[5] 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.
[6] Based on Oregon's 2023 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 visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[7] 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.

- Carrier-submitted data revealed greater variation by market:
    - **Large group plans** averaged **higher** annual OOP costs.
    - **Enrollees under coinsurance plans** face higher annual OOP costs.
- Medicaid enrollees experienced no direct OOP spending due to full coverage under the fee-for-service model.
- The average **OOP cost from the data call was $570 per enrollee** in 2023.

Price concessions[8]

Carrier-reported data indicates that **42.5 percent** of Ajovy claims included some form of price concession based on 2023 data. Manufacturer rebates accounted for the majority of these discounts, followed by pharmacy benefit managers (PBM) price concessions and other negotiated reductions. **Average gross cost per enrollee was $3,772, with net costs reduced to $2,687 after applying concessions**. Total estimated price reductions across carriers amounted to **$1.1 million**, an average **discount of approximately 28.8 percent**.

Therapeutic alternatives[9]

Five CGRP-targeting therapies were reviewed as therapeutic alternatives: **Aimovig, Emgality, Nurtec ODT, Qulipta**, and **Ubrelvy**. Compared to Ajovy:

- **Nurtec ODT** and **Ubrelvy**, used for acute migraine treatment, are not direct preventive alternatives, but may reduce migraine-related healthcare costs.
- **Emgality** and **Aimovig** have comparable efficacy profiles with slightly lower annualized payer costs.
- **Qulipta** presents an oral preventive option, with variable pricing but broader formulary adoption across payers.

Access and equity considerations[10]

- Only **76.4 percent** of formularies list Ajovy as a preferred drug; **99.6 percent** require prior authorization and **3.0 percent** require step therapy.
- Minority participation in Ajovy trials was minimal (<2%), and **Black and Hispanic patients are less likely to receive CGRP-based therapies**, despite similar or greater migraine burden.

[8] 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.
[9] Based on Oregon's 2023 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.
[10] Ibid

Review background

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

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

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

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

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

Drug information[11]

Drug proprietary name(s)	Ajovy®
Non-proprietary name (active ingredients)	*fremanezumab-vfrm*
Manufacturer	Teva Pharmaceuticals USA, Inc.
Pharmacologic category	Calcitonin Gene-Related Peptide (CGRP) Antagonist
Treatment	Migraine prevention in adults
Dosage forms	225 mg/1.5 mL solution in a single-dose prefilled syringe
Route of administration	Subcutaneous
Physician administered	No

FDA approval

Ajovy was first approved by the FDA on 09/14/2018.[12]

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

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

Health inequities

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

Clinical trials for migraine medications—including **Emgality (fremanezumab), Emgality (galcanezumab), Nurtec ODT (rimegepant)**, and **Ubrelvy (ubrogepant)**—have historically underrepresented racial and ethnic minority groups. A review of migraine clinical trials published in *Headache* found that **less than 15 percent** of participants across studies identified as non-white, with **Black Americans comprising less than 2 percent** of study cohorts in many trials—despite experiencing migraine at similar or greater rates than white populations.[13] This lack of diversity limits the generalizability of trial findings and raises concerns about whether these medications perform equally well across all demographic groups.

The **Institute for Clinical and Economic Review (ICER)** highlighted similar concerns in its review of acute migraine treatments, noting that **trial enrollment did not reflect the real-world racial and ethnic diversity of people living with migraine**, particularly underrepresenting Black and

[11] U.S. Food & Drug Administration. *Ajovy (fremanezumab-vfrm) Prescribing Information*. Teva Pharms., Revised 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761089s013lbl.pdf

[12] 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.

[13] Robbins NM, Bernat JL. "Minority Representation in Migraine Treatment Trials." *Headache*. 2017;57(3):525-533. PMID: 28127754

Hispanic patients.[142]. In contrast, the FDA's *Drug Trials Snapshot* for **Nurtec ODT** provides limited but promising subgroup data: pain relief rates were found to be **comparable across racial groups,** with **23.3 percent of Black participants and 21.2 percent of white participants** achieving pain freedom at 2 hours.[15] However, without consistent subgroup analysis across all CGRP-targeting therapies, disparities in both trial design and real-world access remain.

Real-world evidence shows that **Black and Hispanic individuals are less likely to be diagnosed with migraine or prescribed advanced treatments**, even when accounting for socioeconomic status.[16] This reflects broader systemic inequities in pain recognition, access to specialists, and treatment authorization. Compounding these disparities are **structural barriers** such as geographic isolation, lower health literacy, and provider bias[17]—all of which influence medication adherence, proper use of self-injection therapies, and management of side effects.

To ensure equitable care, future clinical research should prioritize diverse enrollment and transparent subgroup reporting, while health systems and payers must address access and affordability gaps for historically underserved populations.

Residents prescribed

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

In 2023, the Oregon APAC database recorded **1,603 unique individuals** with at least one filled prescription for Ajovy.[18] In contrast, the **commercial health benefit plan data call**, which included submissions from 11 reporting carriers, identified **1,057 enrollees** with an Ajovy prescription fill during the same period.[19]

The substantial variance between the two figures is attributable to differences in data scope and reporting mandates. APAC is a comprehensive claims repository that aggregates utilization data across all payer types, including Medicaid, Medicare, and commercial lines of business. In contrast, the data call process captures a limited subset of commercially insured enrollees and

[14] Institute for Clinical and Economic Review (ICER). "Acute Migraine Treatments – Final Evidence Report." January 2020. https://icer.org/wp-content/uploads/2020/10/ICER_Acute-Migraine_Evidence_Report_011020_updated_011320_-2.pdf

[15] FDA. "Drug Trials Snapshot: Nurtec ODT." https://www.fda.gov/drugs/development-approval-process-drugs/drug-trials-snapshots-nurtec-odt

[16] Burch R et al. "The Prevalence and Burden of Migraine Across the U.S. Population." *Headache*. 2021. PMID: 34108270

[17] Williams DR, Mohammed SA. "Discrimination and Racial Disparities in Health: Evidence and Needed Research." *J Behav Med*. 2009;32(1):20–47. PMC2443411

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

[19] Based on 2023 data collected by DCBS under authorities granted in ORS 731.296 and OES 646A.963 through ORS 646A.697 from Oregon health insurance plans. Cost information from the data call is the cost of the drug after price concessions.

is restricted to the reporting obligations of participating health plans. As a result, APAC offers a more inclusive estimate of statewide utilization, while the carrier-submitted data reflects only a narrow segment of the insured population.

Price for the drug

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

This section examines the pricing dynamics of Ajovy, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of the wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), as well as the impact of negotiated prices concessions which include discounts, rebates, and other price reduction negotiations. Together, the data provides a comprehensive view of Ajovy's list price trajectory, pharmacy acquisition costs, and the degree to which price reductions are realized in practice by payers in Oregon.

Price history

The wholesale acquisition cost (WAC) of Ajovy, averaged across three reported national drug codes (NDCs), was approximately **$489 per unit** at the end of 2024.[20] Between 2018 and 2024, the unit WAC increased at an average annual rate of **4.1 percent**, exceeding the general inflation rate (CPI-U) in 2019–2020, 2022–2023, and 2023–2024 (see Figures 1 and 2).[21]

Unit 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.

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

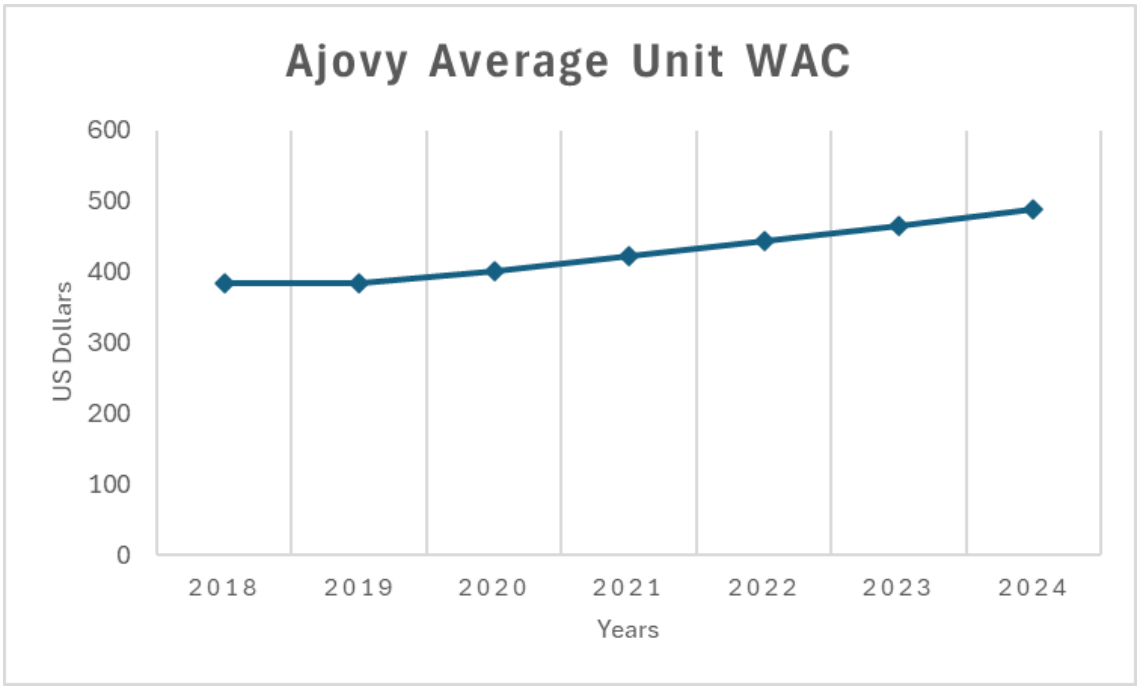


Figure 1 Ajovy average unit WAC from 2018-2024

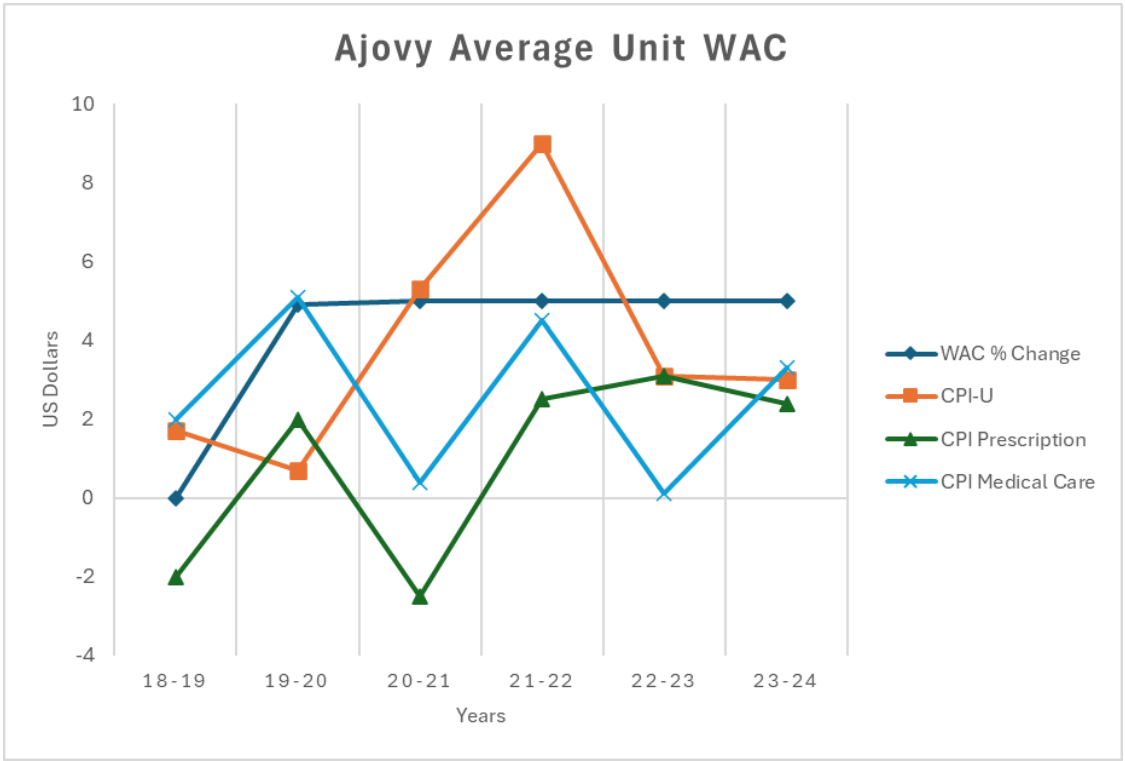


Figure 2 Year over year change in unit WAC compared to inflation rates[22]

[22] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/

Pharmacy acquisition costs

The Oregon Actual Average Acquisition Cost (AAAC), which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$381 per unit in Q1 2020 to $471 per unit in Q4 2024**, **an increase of 23.6 percent** over the period (see Figure 3).[23] Relative to the **$489 WAC in end-of-year** 2024 **a AAAC discount of 0.7 percent** is indicated.

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

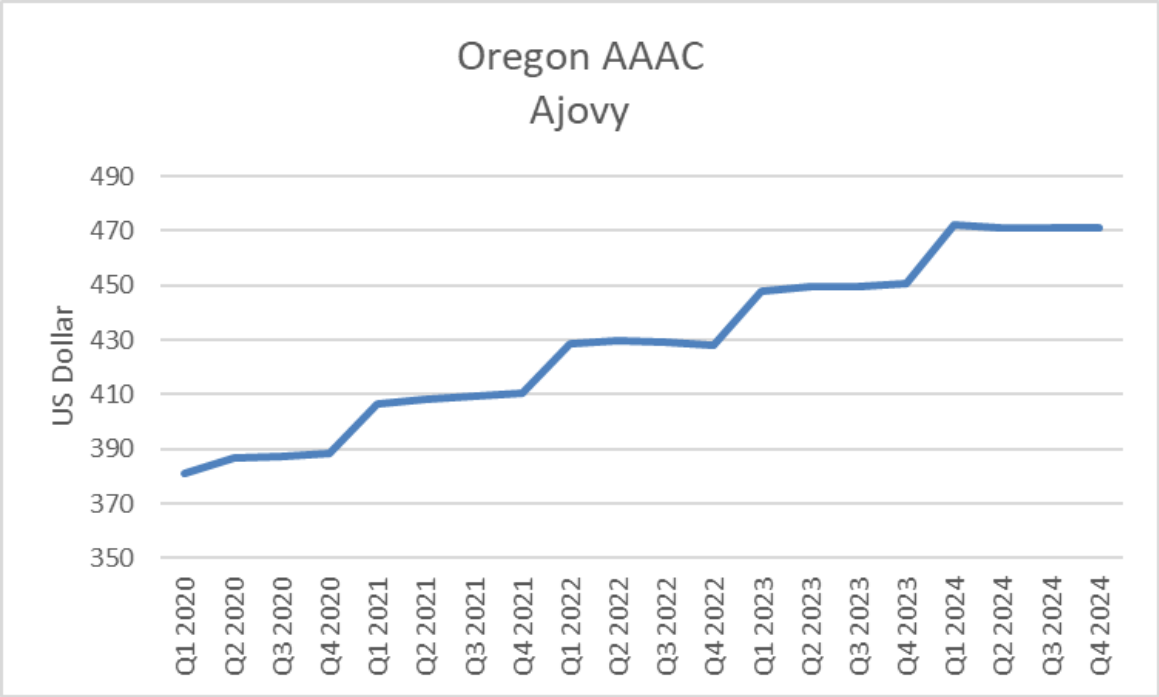


Figure 3 AAAC for Ajovy from Q1 2020 to Q4 2024

Estimated average monetary price concession

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

This section provides an analysis of the average monetary discounts, rebates, and other price concessions applied to Ajovy claims in the commercial market. Drawing on data submitted through the 2023 carrier data call, it evaluates the extent to which these concessions reduced gross drug costs and estimates the average net costs to payers after adjustments. The analysis

[23] This data was compiled using the first weekly AAAC chart of each month from January 2020 to December 2024, available at https://myersandstauffer.com/client-portal/oregon/ as of June 27, 2025.

includes claim-level data on the proportion of claims with applied discounts, and the breakdown of the total concession amounts by type, offering insight into the reduced costs provided through manufacturer, PBM, and other negotiated price reductions.

Based on carrier-submitted data for 2023, the **average gross cost of Ajovy per enrollee in the commercial market was approximately $3,772**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $2,687**, reflecting an **estimated mean discount of 28.8 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Ajovy before concessions was $3,987,390**, with total reported **price concessions amounting to approximately $1,147,200**, as detailed in Table 1. Notably, **42.5 percent of claims benefited from some form of price concession,** leaving **57.5 percent at full gross cost**. Figure 4 shows manufacturer concessions comprised the largest share, supplemented by PBM discounts and other adjustments across the payer types.

Table 1 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	1,057
Total number of claims	5,312
Total number of claims with price concessions applied	2,259
Percentage of claims with price concessions applied	42.5%
Percentage of cost remaining after concessions	71.2%
Manufacturer price concessions for all market types	$1,038,911
PBM price concessions for all market types	$99,504
Other price reductions for all market types	$8,786
Cost before price concessions across all market types	$3,987,390
Total price concessions across all market types	$1,147,200
Cost of after price concessions across all market types	$2,840,190
Avg. payer spend per enrollee without price concessions	$3,772
Avg. payer spend per enrollee with price concessions	$2,687

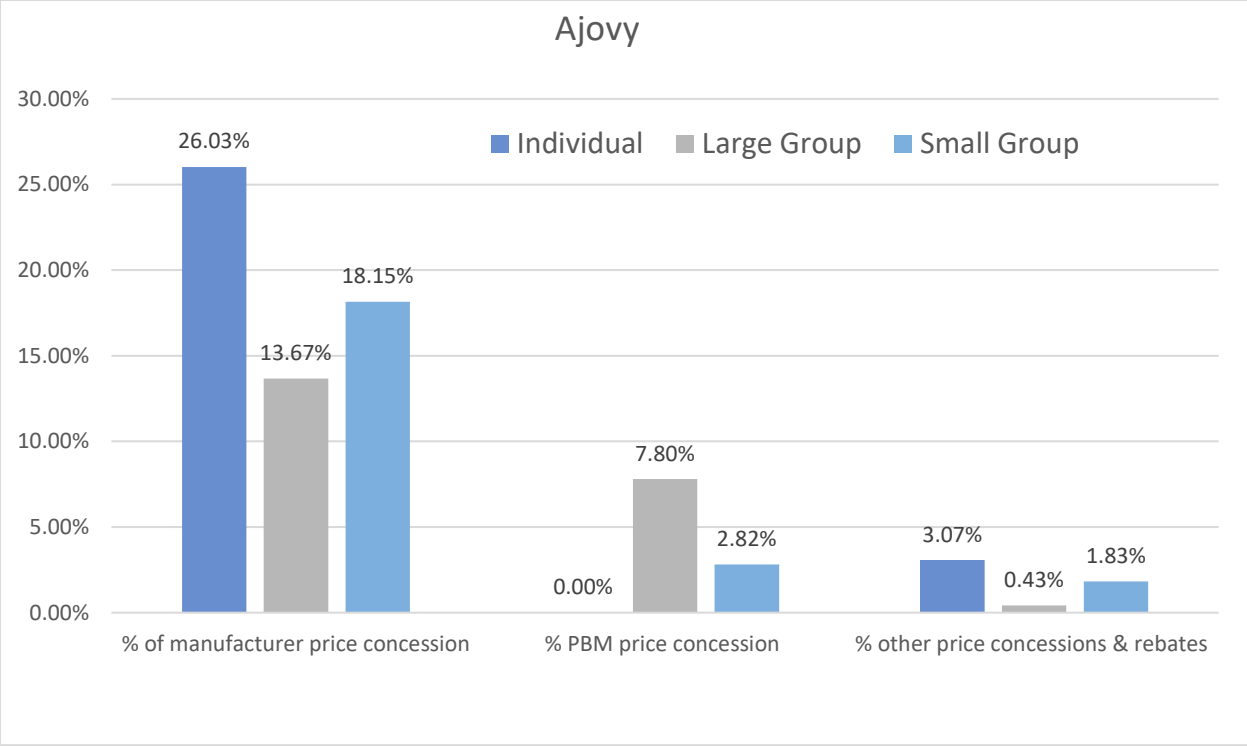


Figure 4 Percent of price concession in each market type

Estimated total amount of the price concession

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

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

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

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.

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

Ajovy's **gross cost per claim, based on APAC data, was $723**, while **net cost data showed a higher per-claim amount of $752**. Compared to Ajovy's gross cost per claim, Emgality had a similar claim cost, while Vyepti showed a higher cost per claim, though a lower paid per enrollee. Vyepti had the lowest enrollee costs at $1,725, while other therapeutic alternatives had higher costs per enrollee as compared to Ajovy. The closest In gross per enrollee costs to Ajovy is Qulipta at $5,679.

Out-of-pocket costs also varied with enrollee payments for Ajovy in **APAC, averaging $86 per claim**. Therapeutic alternative such as Vyepti and Aimovig had lower reported enrollee-paid amounts, ranging from $0 to $58 per claim.

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

Table 2 Average healthcare and average enrollee OOP costs for Ajovy vs therapeutic alternatives

Drug	Total spend	No. of enrollees[25]	No. of claims	Avg. paid/ claim	Avg. paid/ enrollee	Total payer paid	Total enrollees paid	Payer paid/ claim	Enrollee paid/ claim
Subject Drug **Ajovy (data call)**	**$3,993,672**	**1,057**	**5,312**	**$752**	**$3,778**	**$3,391,205**	**$602,467**	**$638**	**$113**
Subject Drug **Ajovy (APAC)**	**$7,451,941**	**1,603**	**10,307**	**$723**	**$4,649**	**$6,566,875**	**$885,066**	**$637**	**$86**
Aimovig	$11,872,686	1,865	15,271	$777	$6,366	$10,990,158	$882,528	$720	$58

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

[25] The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 2, as compared to other totals indicated in this report.

Drug	Total spend	No. of enrollees[25]	No. of claims	Avg. paid/ claim	Avg. paid/ enrollee	Total payer paid	Total enrollees paid	Payer paid/ claim	Enrollee paid/ claim
Emgality	$11,477,154	1,946	15,130	$759	$5,898	$9,896,376	$1,580,777	$654	$104
Nurtec	$14,730,840	2,478	12,335	$1,194	$5,956	$13,227,665	$1,503,175	$1,072	$122
Qulipta	$3,413,298	601	3,037	$1,124	$5,679	$3,012,966	$400,332	$992	$132
Vyepti	$5,175	3	4	$1,294	$1,725	$5,175	$0	$1,294	$0

Estimated average price concession for therapeutic alternatives

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

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

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this information as additional data become available through carrier reporting, manufacturer disclosures, or other sources.

Estimated costs to health insurance plans

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

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

In 2023, the Oregon APAC database recorded **10,307 total claims for Ajovy among 1,743 total enrollees**, corresponding to a **total system gross expenditure of $6,566,874**. This equates to a total of an average **annual cost of $11,232 per enrollee**, or approximately **$1,940 per claim**.

Table 3 provides gross cost estimates by the total APAC system spend across all lines of business:

- **Commercial** accounted for the largest share of utilization, with 6,224 claims from 1,022 enrollees and a total spend of **$4.6 million**.
- **Medicare** and **Medicaid** payers reported smaller but notable expenditures of approximately **$1.3 million** and **$1.5 million**, respectively.

Table 3 Estimated 2023 APAC total gross costs to the healthcare system [26]

Payer line of business	Total enrollees	Total claims	Total gross cost amount to healthcare system	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,022	6,224	$4,647,910	$4,548	$747
Medicaid	413	2,373	$1,497,533	$3,626	$631
Medicare	308	1,710	$1,306,498	$4,242	$764
Totals	**1,743**	**10,307**	**$7,451,941**	**$12,416**	**$2,142**

Table 4 provides gross APAC cost estimates for **payer spend across all lines of business** with **10,307 total claims for Ajovy among 1,743 total enrollees.** The **payers gross expenditure of $6,566,874**, equated to a total of an average **annual cost of $11,232 per enrollee**, or approximately **$1,940 per claim**.

Table 4 Estimated 2023 APAC gross cost to the payers[31]

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,022	6,224	$3,903,055	$3,819	$627
Medicaid	413	2,373	$1,497,533	$3,626	$631
Medicare	308	1,710	$1,166,286	$3,787	$682
Totals	**1,743**	**10,307**	**$6,566,874**	**$11,232**	**$1,940**

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (73% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around $4 million**, with payer paying

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

$3.4 million, and enrollees our-of-pocket estimating to be $602, 467. Table 5 includes the average plan costs per enrollee in the commercial market ranged from **$3,344 (large group)** to **$2,496 (small group)** annually.

Table 5 Estimated 2023 data call total net costs to the healthcare system, payers and enrollee OOP[27]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	860	164	$689,570	$504,899	$184,671
Large Group	3,874	775	$2,923,198	$2,591,771	$331,427
Small Group	578	118	$380,904	$294,535	$86,369
Total	**5,312**	**1057**	**$3,993,672**	**$3,391,205**	**$602,467**

Market	Avg. plan spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plan spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Individual	$802	$587	$215	$4,205	$3,079	$1,126
Large Group	$755	$669	$86	$3,772	$3,344	$428
Small Group	$659	$510	$149	$3,228	$2,496	$732

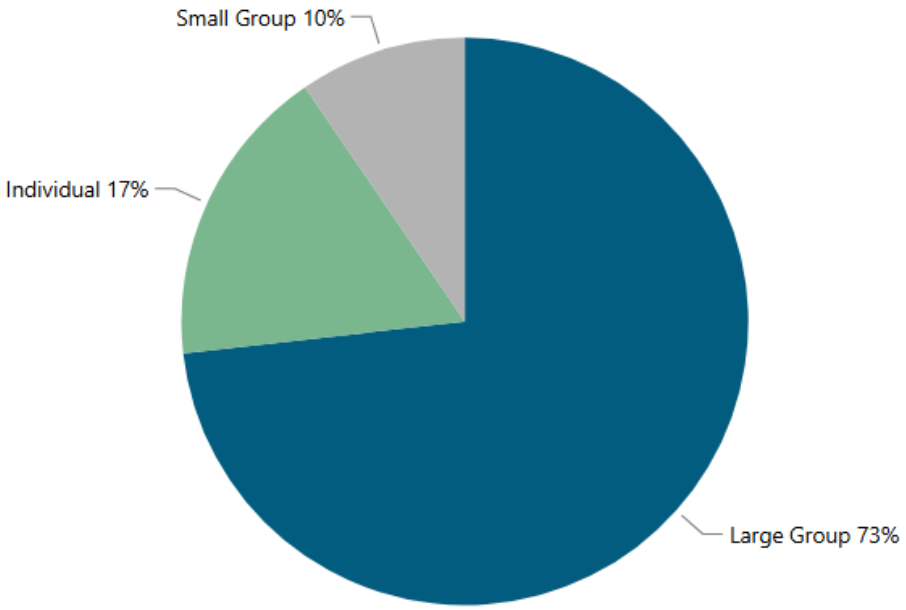


Figure 5 Data call percent of total annual spend (payer paid)

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

Cost to the state fee-for-service program, represented in Table 6, indicates Ajovy was not included on the top 40 quarterly reports. Table 7 reflects Ajovy was not on the Coordinated Care Organization (CCO) top 50 drugs by gross amount paid.

Table 6 2023 Gross amount paid for Medicaid/Oregon Health Plan fee for service

Fee-for-Service[28]							
2023 Quarter	Drug name on report	Amount paid	% Total FFS costs	Claim count	Average paid per claim	Preferred drug list (PDL)	Prior auth
Q1	Drug not on report						
Q2	Drug not on report						
Q3	Drug not on report						
Q4	Drug not on report						
Annual Total:							

Drug not indicated in Q1-Q4 of top 40 quarterly reports of the pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Table 7 2023 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	Amount paid	Claim count	Average paid per claim
Drug not on report			

Pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Impact on patient access to the drug

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

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

[28] Oregon State University Drug Use and Research Management DUR utilization reports 2023. College of Pharmacy, Oregon State University. https://pharmacy.oregonstate.edu/research/pharmacy-practice/drug-use-research-management/dur-reports

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

Based on information reported through the carrier data call, the following plan design features were observed for Ajovy. In 2023, approximately **99.6 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **3.0 percent of plans required step therapy** before approving its use.

Among the **6,024 PA requests** recorded during the reporting period, **4,225 were approved (70.1%)** and **1,799 were denied (29.9%)**.

For formulary placement, **23.6 percent of plans categorized Ajovy as a non-preferred drug**, **76.4 percent listed it as preferred**, and **no plans excluded it entirely from the formulary**.

Table 8 Plan design analysis from 2023 data call

Total prior authorizations	6,024
Number of approved prior authorizations	4,225
Number of denied prior authorizations	1,799
Percentage of approved prior authorizations	70.1%
Percentage of denied prior authorizations	29.9%
Percentage of plans requiring pre-authorization	99.6%
Percentage of plans requiring step therapy	3.0%
Percentage of plans where drug preferred on formulary	76.4%
Percentage of plans where drug non-preferred on formulary	23.6%
Percentage of plans where drug excluded on formulary	0.0%

Relative financial impacts to health, medical or social services costs

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

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

The statutory and regulatory criteria contemplate consideration of such impacts to the extent practicable. However, due to limitations in available evidence, data systems, and the challenges inherent in isolating the indirect effects of a single drug on broader healthcare or social service costs, this analysis was not performed.

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

Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Ajovy in Oregon, as reported in 2023 by the two data sources: the Oregon All Payers All Claims (APAC) database and the carrier data call.[29] These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type and commercial market segment.

Table 8 presents the average annual enrollee cost-sharing amounts derived from APAC and carrier-submitted data. The APAC data, which includes claims from commercial, Medicaid, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs that varied by payer line of business. For example, **commercially insured enrollees recorded higher average annual OOP costs** than Medicare enrollees, while Medicaid enrollees incurred no OOP costs.

Carrier-submitted data, which captures only commercially insured enrollees in Oregon's individual, small group, and large group markets, also showed variation across segments. On average, **enrollees in the large market paid higher OOP costs per enrollee** compared to those in small group plans, while individual group enrollee costs fell between the two. Copayment, coinsurance, and deductible amounts are delineated separately within each data source, reflecting differences in plan design and reporting requirements.

Differences between the APAC and carrier data sources may reflect methodological and population differences, including the exclusion of health plans with fewer than 5,000 covered lives from the APAC reporting requirement and the effect of price concessions on carrier-reported figures.

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

Table 9 Average annual enrollee out-of-pocket costs between APAC and data call

APAC claim line of business	Commercial	Medicaid	Medicare
Number of claims	6224	2373	1710
Number of enrollees	1022	413	308
Total copay	$352,665	$0	$73,514
Total coinsurance	$187,506	$0	$46,614
Total deductible	$204,684	$0	$20,083
Total enrollee paid	$744,855	$0	$140,211
Average copay per claim	$57	$0	$43
Average coinsurance per claim	$30	$0	$27
Average deductible per claim	$33	$0	$12
Average cost across all claims	$120	$0	$82
Average copay per enrollee	$345	$0	$239
Average coinsurance per enrollee	$183	$0	$151
Average deductible per enrollee	$200	$0	$65
Average cost across all enrollee OOP	$729	$0	$455

Data call market type	Large Group	Small Group	Individual
Number of claims	860	3874	578
Number of enrollees	164	775	118
Total copay	$13,844	$174,608	$8,757
Total coinsurance	$117,988	$96,478	$61,662
Total deductible	$50,916	$56,097	$15,413
Total other (i.e. PAP)	$1,923	$4,244	$537
Average copay per claim	$16	$45	$15
Average coinsurance per claim	$137	$25	$107
Average deductible per claim	$59	$14	$27
Average cost across all claims	$212	$84	$149

Data call market type	Large Group	Small Group	Individual
Average copay per enrollee	$84	$225	$74
Average coinsurance per enrollee	$719	$124	$523
Average deductible per enrollee	$310	$72	$131
Average OOP cost per enrollee	$1,113	$421	$728

Table 10, further describes the distribution of annual enrollee OOP costs, providing measures of central tendency such as minimum, median, and maximum costs observed.

Table 10 OOP costs central tendency of Ajovy costs in 2023

Out of pocket costs per enrollee per year[30]		
Average	*Enrollees pay this much on average*	$552
Minimum	*The lowest amount any one enrollee paid*	$0
Median	*Half of enrollees pay more than this amount and half pay less*	$10
Max	*The highest amount any one enrollee paid*	$2,139

Clinical information based on manufacturer material[31]

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

Drug indications

- FDA Approved: preventive treatment of migraine in adults
- Off Label Uses: None

Clinical efficacy

The efficacy of *fremanezumab* (Ajovy) was demonstrated in two randomized, double-blind, placebo-controlled trials, one in patients with episodic migraines (≥ 4 to < 15 migraine headache days/month) and one in patients with chronic migraine (≥ 15 days of headaches per month with ≥ 8 migraine days per month). The primary outcome was mean change in monthly average number of migraine days in episodic migraine and change from baseline in monthly

[30] For patients who used the drug at least once in the 2023 calendar year.
[31] U.S. Food & Drug Administration. *Ajovy (fremanezumab-vfrm) Prescribing Information*. Teva Pharms., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761089s013lbl.pdf

average number of headache days with at least moderate severity in the chronic migraine study.

In both studies, there was a statistically-significant reduction in migraine days from baseline and responder rates (≥50% reduction from baseline) with both monthly and quarterly doses compared to placebo (Table 11 and 12).

Table 11: Key Findings (Study 1) in episodic migraine (n=875) over 3 months:

Endpoint	*fremanezumab* 225 mg monthly	*fremanezumab* 675 mg quarterly	Placebo
Monthly migraine days (MMD) – Baseline	8.9	9.2	9.1
Decreased MMD from baseline	–3.7	–3.4	–2.2
Treatment difference from placebo	-1.5 (95% CI -2.01 to -0.93)*	-1.3 (95% CI -1.79 to -0.72)*	
≥50% MMD Responder Rate	47.7%	44.4%	27.9%
*significantly different than placebo; p<0.0001			

Table 12 Key Findings (Study 2) in chronic migraine (n=1121) over 3 months:

Endpoint	*fremanezumab* 225 mg Monthly	*fremanezumab* 675 mg Quarterly	Placebo
Baseline: Headache days (moderate+)	12.8	13.2	13.3
Decreased Moderate-severity headache days (3-month avg)	–4.6	–4.3	–2.5
Treatment difference from placebo	-2.1 (95% CI -2.76 to -1.45)*	-1.8 (95% CI -2.46 to -1.15)*	
≥50% Response (moderate headache day reduction)	40.8%	37.6%	18.1%
*significantly different than placebo; P<0.0001			

Table 13 Pharmacokinetics

Distribution	6L
Metabolism	Degraded by enzymatic proteolysis
Half-life elimination	31 days
Time to peak	5-7 days

Clinical safety[32]

- FDA safety warnings and precautions:
  - Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria
  - Hypertension
  - Raynaud's Phenomenon
- Contraindications:
  - Ajovy is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients. Reactions have included anaphylaxis and angioedema.
- Common side effects:
  - Injection-site reactions (43 to 45%) can happen within hours and up to one month after receiving Ajovy.
  - Antibody development

[32] U.S. Food & Drug Administration. *Ajovy (fremanezumab-vfrm) Prescribing Information*. Teva Pharms., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761089s013lbl.pdf

Therapeutic alternatives:[33,34,35,36,37,38]

Table 14 FDA Approved Indications

Proprietary name	Non-proprietary name	Manufacturer (year approved)	Episodic migraine prevention	Chronic migraine prevention	Cluster headache prevention	Acute migraine treatment
Monoclonal Antibody CGRP Inhibitors (long acting)						
Ajovy	*fremanezumab*	Teva Pharm. (2018)	Yes	Yes	No	No
Aimovig	*erenumab*	Amgen Inc. (2018)	Yes	Yes	No	No
Emgality	*galcanezumab*	Eli Lilly (2018)	Yes	Yes	Yes (episodic)	No
Vyepti	*eptinezumab-jjmr*	Lundbeck Seattle BioPharmaceuticals, Inc. (2020)	Yes	Yes	No	No
Small molecule CGRP Receptor Antagonists (rapid acting)						
Nurtec ODT	*imegepant*	Pfizer (2020)	Yes	No	No	Yes
Qulipta	*atogepant*	Abbvie (2021)	Yes	Yes	No	No

[33] Ibid
[34] U.S. Food & Drug Administration. *Aimovig (erenumab-aooe) Prescribing Information*. Amgen Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761077s015lbl.pdf
[35] U.S. Food & Drug Administration. *Emgality (galcanezumb-gnlm) Prescribing Information*. Eli Lily, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf
[36] U.S. Food & Drug Administration. *Nurtec ODT (rimegepant) Prescribing Information*. Pfizer, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf
[37] U.S. Food & Drug Administration. *Qulipta (atogepant) Prescribing Information*. Abbvie, Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215206s004lbl.pdf
[38] U.S. Food & Drug Administration. Vyepti (*eptinezumab-jjmr) Prescribing Information*. Lundback Seattle BioPharm, Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215206s004lbl.pdf

Table 15 Efficacy: Migraine days decreased & responder rates

Proprietary name	Non-proprietary name	Change from baseline	Chronic migraine decrease in monthly average	≥50% Responder (episodic)	≥50% Responder (chronic)
Monoclonal Antibody CGRP Inhibitors (long acting)					
Ajovy	*fremanezumab*	–3.4 to –3.7 vs –2.2 placebo	–5.0 vs –3.2 placebo	~45% vs ~28% placebo	~37–41% vs 18% placebo
Aimovig	*erenumab*	–3.2 to –3.7 vs –1.8 placebo	–6 to –7 vs –4 placebo	~41–48%	~40%
Emgality	*galcanezumab*	–4.3 to –4.7 vs –2.3 to –2.8 placebo	–4.8 vs –2.7 placebo	~59–62% vs ~36–39% placebo	28% vs 15% placebo
Vyepti	*eptinezumab-jjmr*	–8 days (episodic & chronic)	Same	~40% ≥75% responders	~40% ≥75%
Small molecule CGRP Receptor Antagonists (rapid acting)					
Nurtec ODT	*imegepant*	~0.8-day decrease; 49% responders	N/A	49%	—
Qulipta	*atogepant*	–1.2 to –1.7; ~30–38% ≥75% responders	–8 days chronic daily	—	—

Comparative effectiveness:

- Overall, all of the CGRP inhibitors result in greater reductions in monthly migraine days, monthly headache days, and acute medication use compared to placebo.
- The magnitude of treatment effect of CGRP inhibitors is modest with approximately 0.4 to 3.7 days reduction in migraine days compared to placebo
- There is insufficient comparative data to conclude any differences in efficacy between CGRP inhibitors

Table 16 Adverse effect profile

Proprietary name	Non-proprietary name	Common AEs	Notable risks
Monoclonal Antibody CGRP Inhibitors (long acting)			
Ajovy	*fremanezumab*	Injection-site rxn (43–45%), <1% hypersensitivity	Low risk overall
Aimovig	*erenumab*	Injection-site rxn (5–6%), constipation, muscle spasms, hypertension	Serious constipation/hospitalization rare
Emgality	*galcanezumab*	Injection-site rxn, mild allergic rxn; no constipation prominent	Generally well tolerated
Vyepti	*eptinezumab-jjmr*	Infusion site rxn, nasopharyngitis, throat irritation	Minimal hypersensitivity
Small molecule CGRP Receptor Antagonists (rapid acting)			
Nurtec ODT	*imegepant*	Nausea (~2.7%), abdominal discomfort, indigestion	Low, mild GI symptoms
Qulipta	*atogepant*	Constipation (14%), nausea (7.7%), fatigue, dizziness	Weight loss possible

Table 17 Route and dosing

Proprietary name	Non-proprietary name	Route / form	Dose and frequency
Monoclonal Antibody CGRP Inhibitors (long acting)			
Subject drug **Ajovy**	*fremanezumab*	SC injection (prefilled syringe/pen)	225 mg monthly or 675 mg quarterly

Proprietary name	Non-proprietary name	Route / form	Dose and frequency
Aimovig	*erenumab*	SC injection (autoinjector/pen)	70 or 140 mg monthly
Emgality	*galcanezumab*	SC injection	240 mg loading, then 120 mg monthly
Vyepti	*eptinezumab-jjmr*	IV infusion	100 mg every 3 months
Small molecule CGRP Receptor Antagonists (rapid acting)			
Nurtec ODT	*imegepant*	Orally disintegrating tablet (ODT)	75 mg every other day (preventive) or as needed (acute)
Qulipta	*atogepant*	Oral tablet	10, 30, or 60 mg once daily

Safety summary:

- The monoclonal antibody CGRP antagonists (fremanezumab, erenumab, eptinezumab, and galcanezumab) are administered parenterally and include common side effects of injection site reactions and hypersensitivity reactions. Hypersensitivity reactions requiring discontinuation or steroid treatment have been reported within hours to one month after fremanezumab administration. There is a theoretical concern for cardiovascular side effects and erenumab has been associated with hypertension.

- The oral CGRP antagonists (rimegepant, atogepant) have common GI side effects associated with them (nausea, abdominal pain, dyspepsia) and atogepant can cause constipation. They should be avoided in severe liver impairment and with strong CYP3A34 inhibitors and inducers.

Input from specified stakeholders

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

Patients and caregivers:

Note: The information presented is based on self-reported survey responses from individuals prescribed certain medications. Participation in the survey was voluntary, and the responses reflect each individual's personal understanding and interpretation of the question asked. As

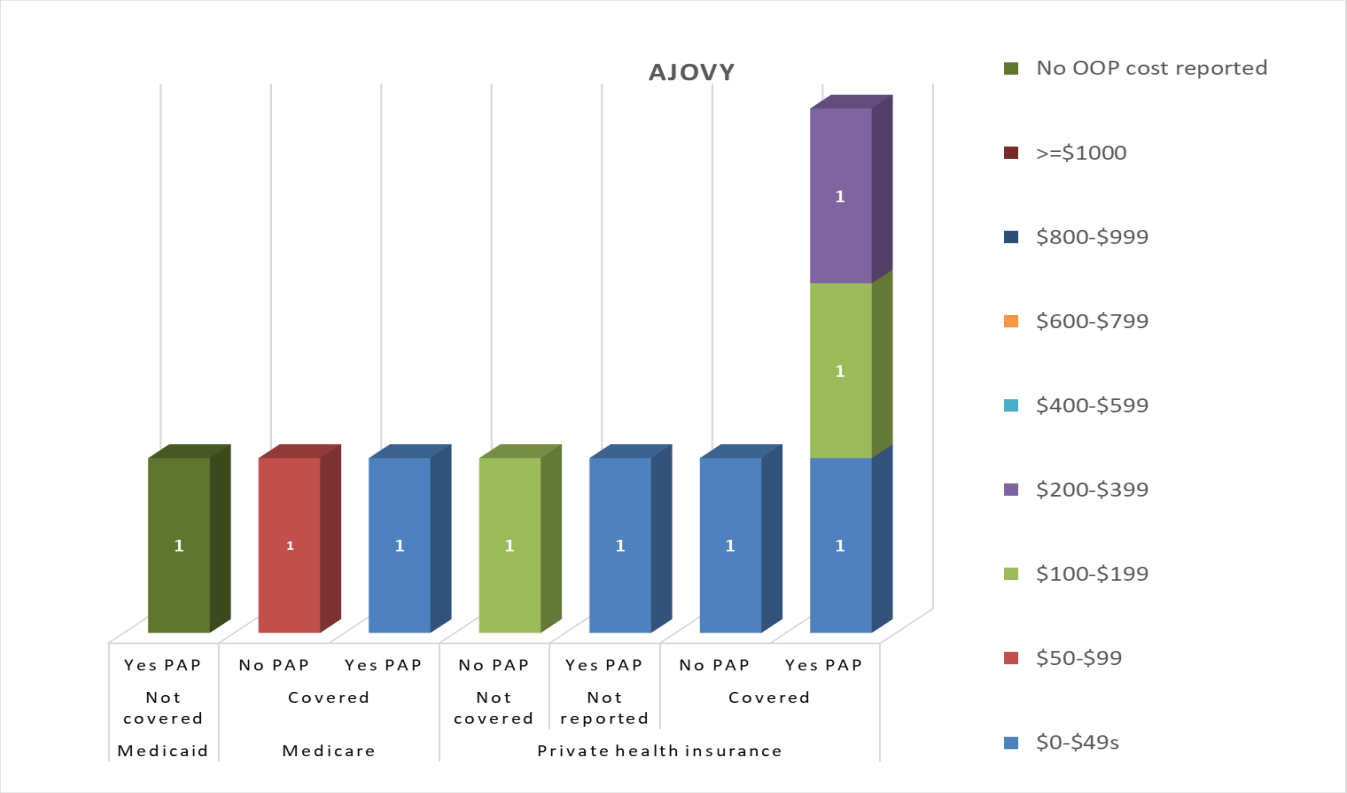
such, the data may contain inconsistencies or inaccuracies due to varying levels of comprehension, recall bias, or misinterpretation of question intent. These limitations should be considered when interpreting the responses.

Survey information was received from nine individuals either currently taking or associated with the use of Ajovy. According to the survey results, **three respondents indicated that Ajovy was not covered by their insurance**. Based on Table 17, one respondent was enrolled in **Medicaid**, two were on **Medicare**, and six had **private health insurance**.

The **Medicaid participant** reported the drug was **not covered** by their plan but was receiving assistance through a **patient assistance program (PAP)**. Among the **two Medicare respondents**, both had the drug covered; one was also enrolled in a PAP. Of the **six private insurance participants**, four had the drug covered, three of whom were on PAP. One respondent did not report coverage status but was receiving PAP support, while another reported **no coverage and no PAP** assistance.

In terms of out-of-pocket (OOP) costs, **four respondents paid less than $49**, another **four reported paying between $50 and $399**, and **one respondent did not report any OOP cost**.

Table 18 Patient survey responses by reported for out-of-pocket costs impact based on insurance type



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

”Ajovy”

- Doctors, neurologist have tried everything and nothing is stopping the migraines. They wanted to try Ajovy but insurance denied it. The medications I take only help with some of the pain but they do not reduce the amount of chronic, complex migraines with aura I am having. Doctors have appealed, but insurance coverage is still denied for Ajovy. I have several other medical conditions, but the migraines, by far, limit by ability to function.
- The doctor prescribed it and it works. I used Emgality, but insurance stopped covering it, so I switched to Ajovy.
- Ajovy decreases the number of migraine days per month. I pay $15 a month with an assistance program. I had a bad reaction to Aimovig with site pain and swelling but it did help decrease the number of migraine days.
- Ajovy has reduced severity and frequency of really bad, 48-hour migraines to 12 hours. I pay $11 per month through the Medicare Part D Extra Help program. I also take several other drugs. Mirtazapine as a preventative has also reduced severity and frequency. Oxycodone and Butalbital at the same time when I have significant pain that is uncontrollable. Maxalt aborts most migraines that I still have.
- Ajovy reduces and lessens migraines. My most recent, monthly, out-of-pocket cost for Ajovy was $91. I have tried many, many other remedies. I tried to get on a patient assistance program but was unsuccessful. At one point they lost all my information and I had to start over. I would send everything in and when I would eventually contact them about the process, they would add something to the list of requirements. Finally they denied me, but gave no reason. When I went on Medicare, the price skyrocketed.
- Ajovy lessens migraines. My most recent monthly, out-of-pocket expense was $150. I have tried other medications that worked, but insurance quit paying for them.
- Ajovy reduces migraines from 25 per month to two per month or less. My most recent, monthly, out-of-pocket cost was $28. I have 75 percent medical financial assistance. I tried Aimovig and Emgality but Ajovy is more effective. Ajovy radically improved my life. I do not want to go back to 25 migraines per month.

- Ajoyv has stopped chronic migraines. I tried multiple medications and they only helped sometimes. Nothing helped as well as Ajovy. It was covered until this year. My most recent, monthly, out-of-pocket cost was $174.26. I now am trying Aimovig 70 ML INJ that is covered by my insurance through Medicare Advantage. The cost is $47 but it is not as effective.

*Here is a patient story that was included in the Drug Price Transparency program's legislative repo*rt for 2024. *The story has been edited for readability, length and to protect patient privacy.*

- We are a low-income family on OHP Medicaid. My 28-year-old has multiple chronic illnesses, so I also buy an ACA Obamacare plan so our long-term psychiatrist can continue providing care. The OHP plan did not cover psychiatry. The OHP mental health program is weak with long, long wait times and we would have to start way back 10 years ago with diagnosis. In spite of these two plans, we struggle with prescription costs. I had to come up with $426 last month for Ajovy and I am on Social Security retirement and work as a low-paid caregiver. This covered a monthly dose of a self-injected antibody (Ajovy) that has given my 28-year-old huge relief from daily migraines, postural orthostatic tachycardia syndrome (POTS), and depression. Last month my 28-year-old was ill, but the Ajovy injection was overdue, and they began having severe migraines. They tried the autoinjector and spilled the medicine. OHP refused to replace it. I had to work extra hours, incurring back pain, and now worry we are over the Medicaid income limits. It is a catch-22 situation. Please help us. Thank you!

Individuals with scientific or medical training

This section summarizes information reported by healthcare professionals with scientific or medical training who identified key barriers for patients in accessing the medications under review. The most commonly cited challenge was the **requirement for prior authorization**, which was viewed as a significant hurdle that delays treatment initiation. **Step therapy protocols**, which require patients to try and fail alternative medications before accessing Ajovy, were also reported as a burden. Additionally, **medication cost** was flagged as an access concern.

Among survey respondents, one healthcare professional cited each of the following as administrative burdens: **prior authorization**, **step therapy**, and **cost**. In contrast, **quantity limits**, PBM/formulary restrictions, and first-line therapy status were not reported as notable barriers to access for this medication.

Table 19 Reported administration burden of the drug for patient to access

Drug name	Prior Authorization	Step Therapy	Quantity Limit	Cost	PBM/ formulary issues	Considered first line of therapy
Ajovy	Yes	Yes	-	Yes	-	-

Safety net providers

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

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

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

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

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

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

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

Table 20 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	3
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between $0-$100,000	27%
Reported total amount paid for drug under 340B was between $100,001-$300-000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between $0-$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between $100-001-$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between $500,000-$10,000,000	18%

Table 21 Amounts paid for drug under 340B discount program

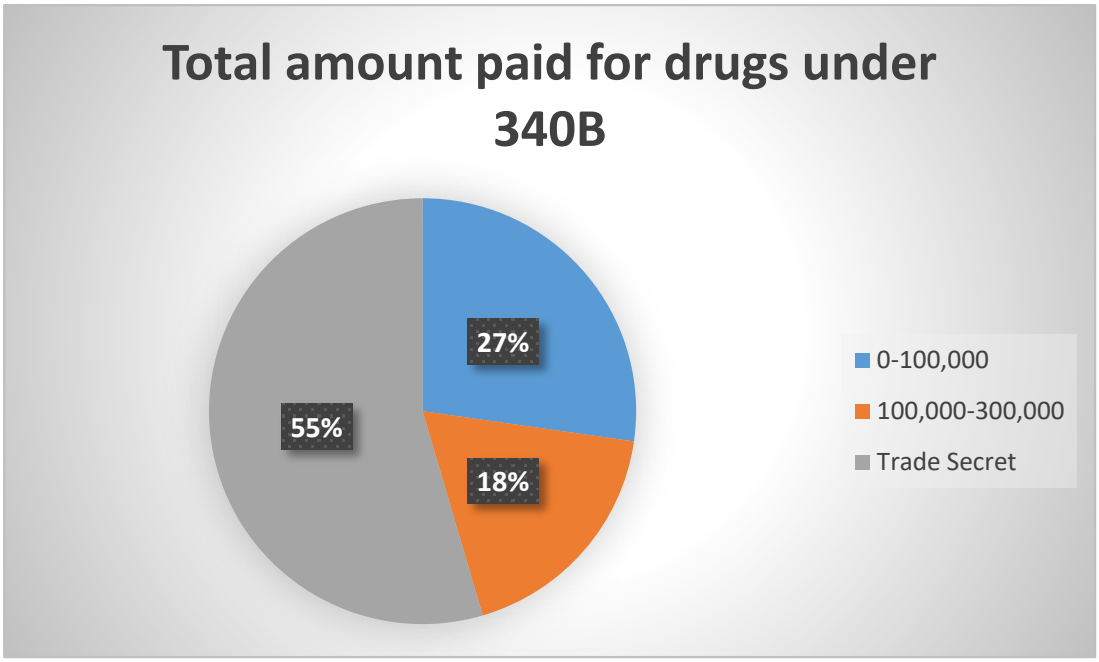
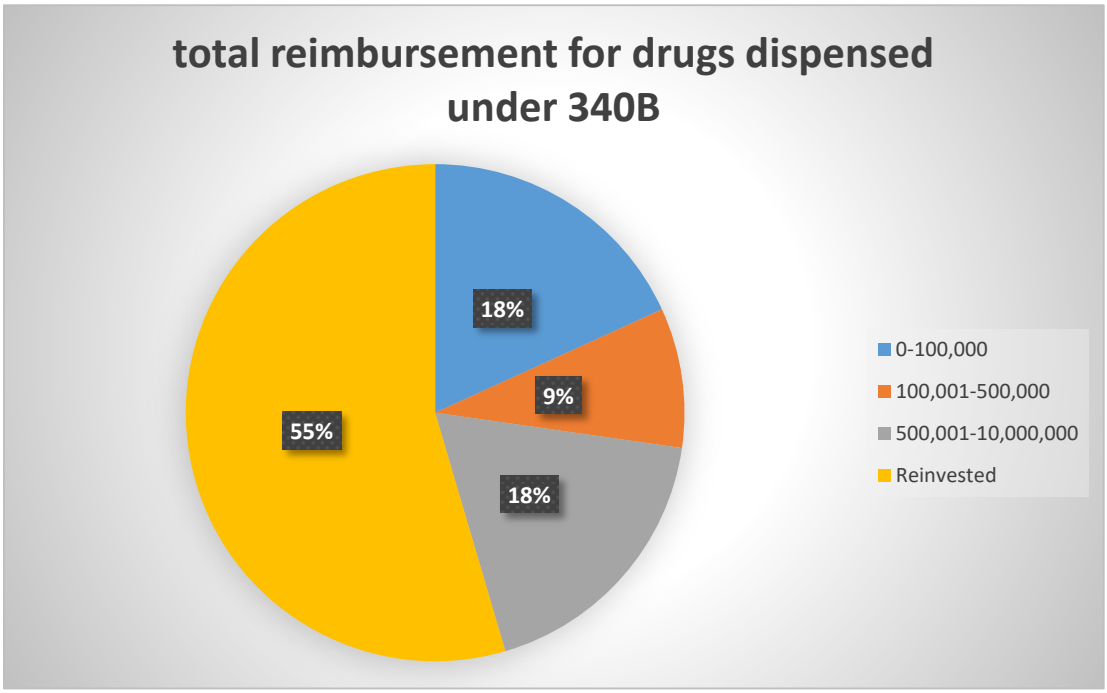


Table 22 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program



Payers

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

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

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

Emgality®
(*Galcanezumab*)[1]

Version 2.0

[1] https://prescriberpoint.com/sample-store/emgality-33a147b?prodId=b1348d25-27bc-4cf4-3370-08dbae3d4c27

Table of Contents

Document version history

Version	Date	Description
v1.0	7/9/2025	Original Release
v2.0		Updated gross spend amounts in the “Cost to the healthcare system” section; added a “Cost to payers” section; updated table 3 with an additional section for payer paid amounts

Review summary

Price history

Emgality® (*galcanezumab-gnlm*) was first approved by the FDA in 2018 for the preventive treatment of migraine. Since entering the market, the wholesale acquisition cost **(WAC) has risen at an average annual rate of 2.8 percent**, **exceeding inflation** in 2020, 2023, and 2024.[2,3] As of late 2024, the **WAC reached approximately $651 per unit,** with **Medicaid acquisition costs (AAAC) tracking 5.45 percent discount**.

Cost to the healthcare system[4,5]

In 2023, Oregon's All Payers All Claims **(APAC) database reported approximately $11.5 million in gross spending for Emgality, based on 15,130 claims across 2,084 enrollees**. This equated to an **average gross spend of $5,507 per enrollee and $759 per claim**. Among payer types, commercial line of business accounted for the largest share of utilization and expenditures, followed by Medicare and Medicaid plans.

Data call information showed the **large group represented the majority of spending at 62 percent**, followed by individual and small group.

Cost to payers[6,7]

APAC data for payer spend indicated the **gross spending for Emgality is approximately $9.9 million, with 15,130 claims across 1,946 enrollees**. This resulted in the **average gross annual payer spend to be $5,085 per enrollee and $654 per claim**.

According to the data from commercial payers, **the net spending for Emgality is approximately $3.1 million, spread across 5,088 claims and 935 enrollees**. The **net spend per enrollee was $3,342 and the net spend per claim was $614**.

[2] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span
[3] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/
[4] Ibid.
[5] 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.
[6] Ibid.
[7] Based on Oregon's 2023 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 visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

Cost to enrollees[8,9]

Average enrollee out-of-pocket (OOP) costs in 2023 were moderate compared to similar high-cost therapies. APAC data showed **average OOP costs per enrollee of $344 for commercial and $292 for Medicare, with $0 reported for Medicaid enrollees**.

Carrier-submitted data reflected similar variation by market segment, with **OOP costs ranging from $544 (small group) to $1,719 (large group) per enrollee**. The average **OOP cost from the data call was $804 per enrollee** in 2023.

Price concessions[10]

Carrier-reported data indicates that **79.01 percent of Emgality claims in the commercial market received some form of price concession** in 2023. Manufacturer rebates accounted for the majority of these discounts, followed by pharmacy benefit managers (PBM) price concessions and other negotiated reductions. **Average gross cost per enrollee was $4,301, with net costs reduced to $2,531 after applying concessions**. In total, **$1.7 million in price concessions** were reported across all market segments, an average **discount of approximately 41.2 percent.**

Therapeutic alternatives[11]

Five CGRP-targeting therapies were reviewed as therapeutic alternatives: **Aimovig, Ajovy, Nurtec ODT, Qulipta, and Vyepti**. Compared to Emgality:

- **Ajovy** and **Aimovig** are injectable preventives with similar efficacy and cost profiles.
- **Nurtec ODT** is used for acute migraine treatment.
- **Qulipta** presents an oral preventive, offers an alternative formulation route.
- **Vyepti** is an IV infusion that requires a clinic visit and is taken every three months.

Access and equity considerations[12]

Access to Emgality is shaped by a combination of cost barriers and formulary placement. In 2023, **73.3 percent of health plans required prior authorization**, with **step therapy required by 0.4 percent**. Most plans **(81.8%) listed Emgality as a non-preferred drug**.

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[8] [8] Based on Oregon's 2023 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

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

[10] Ibid

[11] Based on Oregon's 2023 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.

[12] Ibid

Review background

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

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

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

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

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

Drug Information

Drug proprietary name	Emgality®
Non-proprietary name (active ingredient)	*galcanezumab-gnlm*
Manufacturer	Eli Lilly and Company
Pharmacologic Category	Calcitonin Gene-Related Peptide (CGRP) Antagonist
Treatment	• preventive treatment of migraine • treatment of episodic cluster headache in adults
Dosage forms and strengths	• Injection: 100 mg/mL solution in a single-dose prefilled syringe • Injection: 120 mg/mL solution in a single-dose prefilled pen

	• Injection: 120 mg/mL solution in a single-dose prefilled syringe
Dosing	• Cluster headache: 300 mg SUBQ at the onset of the cluster and then once monthly until the end of the cluster period • Migraine prevention: 240 mg SUBQ once, followed by 120 mg once monthly
Route of administration:	Subcutaneous
Physician administered:	No

FDA approval

Emgality was first approved by the FDA on 09/27/2018 for the preventive treatment of migraines.[13] In 2019, it was approved for the treatment of episodic cluster headache.

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.

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.

Clinical trials for migraine medications—including **Emgality (fremanezumab), Emgality (galcanezumab), Nurtec ODT (rimegepant)**, and **Ubrelvy (ubrogepant)**—have historically underrepresented racial and ethnic minority groups. A review of migraine clinical trials published in *Headache* found that **less than 15 percent** of participants across studies identified as non-white, with **Black Americans comprising less than 2 percent** of study cohorts in many trials—despite experiencing migraine at similar or greater rates than white populations.[14] This lack of diversity limits the generalizability of trial findings and raises concerns about whether these medications perform equally well across all demographic groups.

The **Institute for Clinical and Economic Review (ICER)** highlighted similar concerns in its review of acute migraine treatments, noting that **trial enrollment did not reflect the real-world racial and ethnic diversity of people living with migraine**, particularly underrepresenting Black and

[13] 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.
[14] Robbins NM, Bernat JL. "Minority Representation in Migraine Treatment Trials." *Headache*. 2017;57(3):525-533. PMID: 28127754

Hispanic patients.[15][2]. In contrast, the FDA's *Drug Trials Snapshot* for **Emgality** provides limited but promising subgroup data: pain relief rates were found to be **comparable across racial groups,** with **23.3 percent of Black participants and 21.2 percent of white participants** achieving pain freedom at 2 hours.[16] However, without consistent subgroup analysis across all CGRP-targeting therapies, disparities in both trial design and real-world access remain.

R**eal-world evidence** shows that **Black and Hispanic individuals are less likely to be diagnosed with migraine or prescribed advanced treatments**, even when accounting for socioeconomic status.[17] This reflects broader systemic inequities in pain recognition, access to specialists, and treatment authorization. Compounding these disparities are **structural barriers** such as geographic isolation, lower health literacy, and provider bias[18]—all of which influence medication adherence, proper use of self-injection therapies, and management of side effects.

To ensure equitable care, future clinical research should prioritize diverse enrollment and transparent subgroup reporting, while health systems and payers must address access and affordability gaps for historically underserved populations.

Residents prescribed

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

In 2023, the Oregon APAC database recorded **1,946 unique individuals** with at least one filled prescription for Emgality.[19] In contrast, the **commercial health benefit plan data call**, which included submissions from 11 reporting carriers, identified **935 enrollees** with a Emgality fill during the same period.[20]

The substantial variance between the two figures is attributable to differences in data scope and reporting mandates. APAC is a comprehensive claims repository that aggregates utilization data across all payer types, including Medicaid, Medicare, and commercial lines of business. In contrast, the data call process captures a limited subset of commercially insured enrollees and is restricted to the reporting obligations of participating health plans. As a result, APAC offers a

[15] Institute for Clinical and Economic Review (ICER). "Acute Migraine Treatments – Final Evidence Report." January 2020. https://icer.org/wp-content/uploads/2020/10/ICER_Acute-Migraine_Evidence_Report_011020_updated_011320_-2.pdf

[16] FDA. "Drug Trials Snapshot: Nurtec ODT." https://www.fda.gov/drugs/development-approval-process-drugs/drug-trials-snapshots-nurtec-odt

[17] Burch R et al. "The Prevalence and Burden of Migraine Across the U.S. Population." *Headache*. 2021. PMID: 34108270

[18] Williams DR, Mohammed SA. "Discrimination and Racial Disparities in Health: Evidence and Needed Research." *J Behav Med*. 2009;32(1):20–47. PMC2443411

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

[20] Based on 2023 data collected by DCBS under authorities granted in ORS 731.296 and OES 646A.963 through ORS 646A.697 from Oregon health insurance plans. Cost information from the data call is the cost of the drug after price concessions.

more inclusive estimate of statewide utilization, while the carrier-submitted data reflect only a narrow segment of the insured population.

Price for the drug

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

This section examines the pricing dynamics of Emgality, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of the wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), as well as the impact of negotiated prices concessions which include discounts, rebates, and other price reduction negotiations. Together, these data provide a comprehensive view of Emgality's list price trajectory, pharmacy acquisition costs, and the degree to which price reductions are realized in practice by payers in Oregon.

Price history

The wholesale acquisition cost (WAC) of Emgality, averaged across four reported national drug codes (NDCs), was approximately **$651 per unit** as of end-of-year 2024.[21] Between 2018 and 2024, the package WAC increased at an average annual rate of **2.8 percent**, exceeding the general inflation rate (CPI-U) in 2019–2020, 2022–2023, and 2023–2024 (see Figures 1 and 2).[22]

Unit 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.

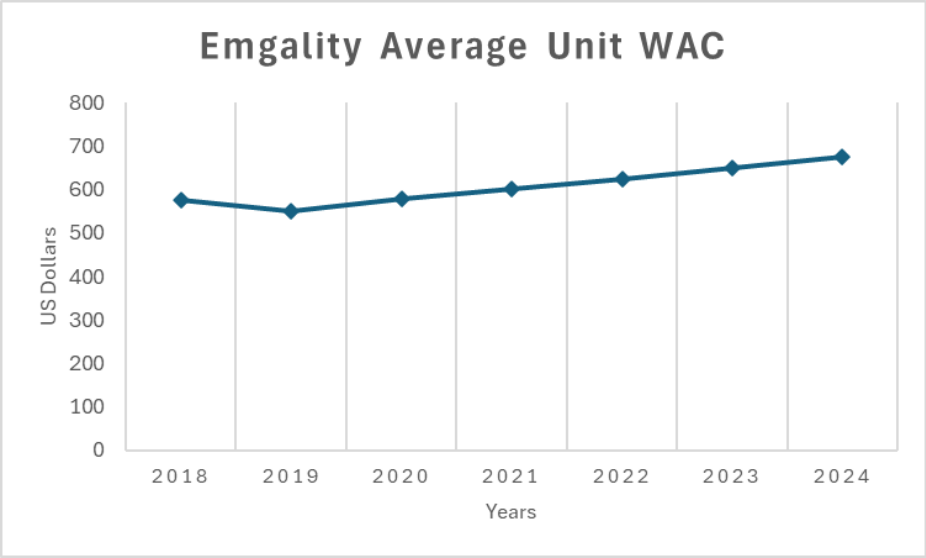


Figure 1 Emgality average unit WAC from 2018-2024

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

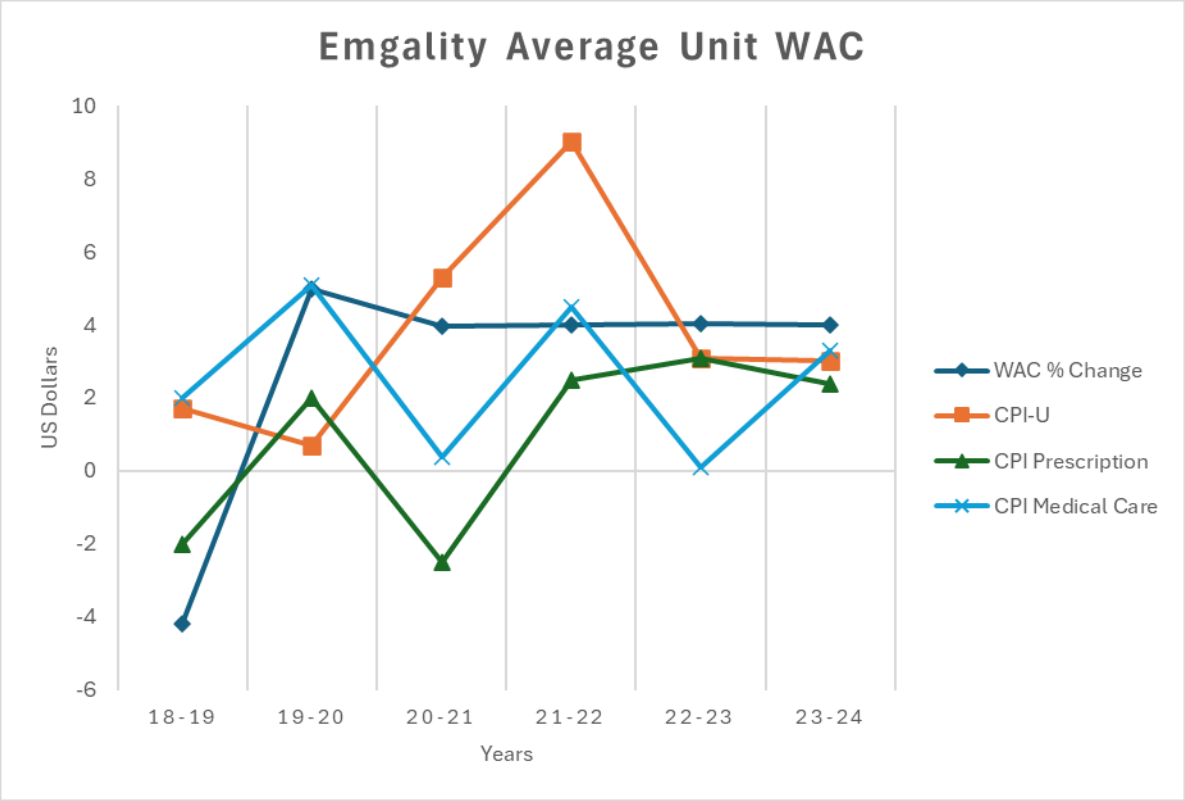


Figure 2 Year over year change in unit WAC compared to inflation rates[23]

Pharmacy acquisition costs

The Oregon actual average acquisition cost (AAAC) for Emgality from Quarter 1 of 2020 to Quarter 4 of 2024. The AAAC for Emgality **rose from $572 in Quarter 1 of 2020, to $642 in Quarter 4 of 2024, an increase of 14 percent** (see Figure 3).[24] Relative to the **$677 WAC in end-of-year** 2024 a **AAAC discount of 5.45 percent** is indicated.

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

[23] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/
[24] Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2024. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. https://myersandstauffer.com/client-portal/oregon/

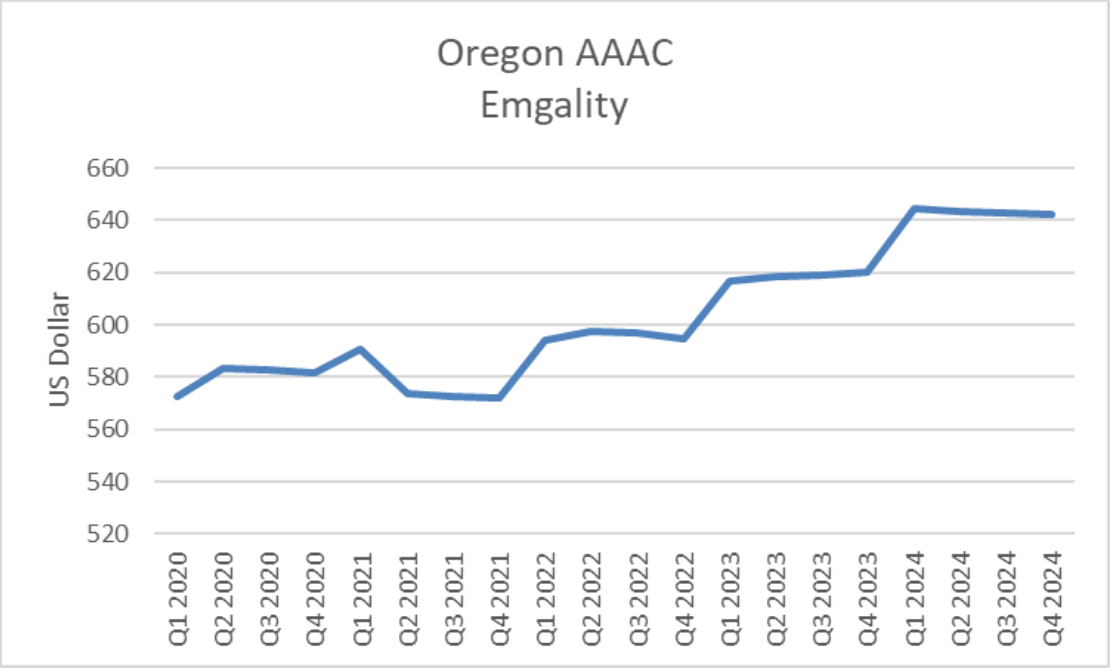


Figure 3 AAAC for Emgality from Q1 2020 to Q4 2024

Estimated average monetary price concession

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

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

Based on carrier-submitted data for 2023, the **average gross cost of Emgality per enrollee in the commercial market was approximately $4,301**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $2,531**, reflecting an **estimated mean discount of 41.2 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Emgality before concessions was $4,021,432**, with total reported **price concessions amounting to approximately $1,655,143**, as detailed in Table 1. Notably, **79 percent of claims benefited from some form of price concession**, leaving **20 percent at full gross cost**. Figure 3 shows manufacturer concessions comprised the largest share, supplemented by PBM discounts and other adjustments across the payer types.

Table 1 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	935
Total number of claims	5,088
Total number of claims with price concessions applied	4,020

Percentage of claims with price concessions applied	79.01%
Percentage of cost remaining after concessions	58.8%

Manufacturer price concessions for all market types	$1,389,500
PBM price concessions for all market types	$252,373
Other price reductions for all market types	$13,271

Cost before price concessions across all market types	$4,021,432
Total price concessions across all market types	$1,655,143
Cost of after price concessions across all market types	$2,366,289

Avg. payer spend per enrollee without price concessions	$4,301
Avg. payer spend per enrollee with price concessions	$2,531

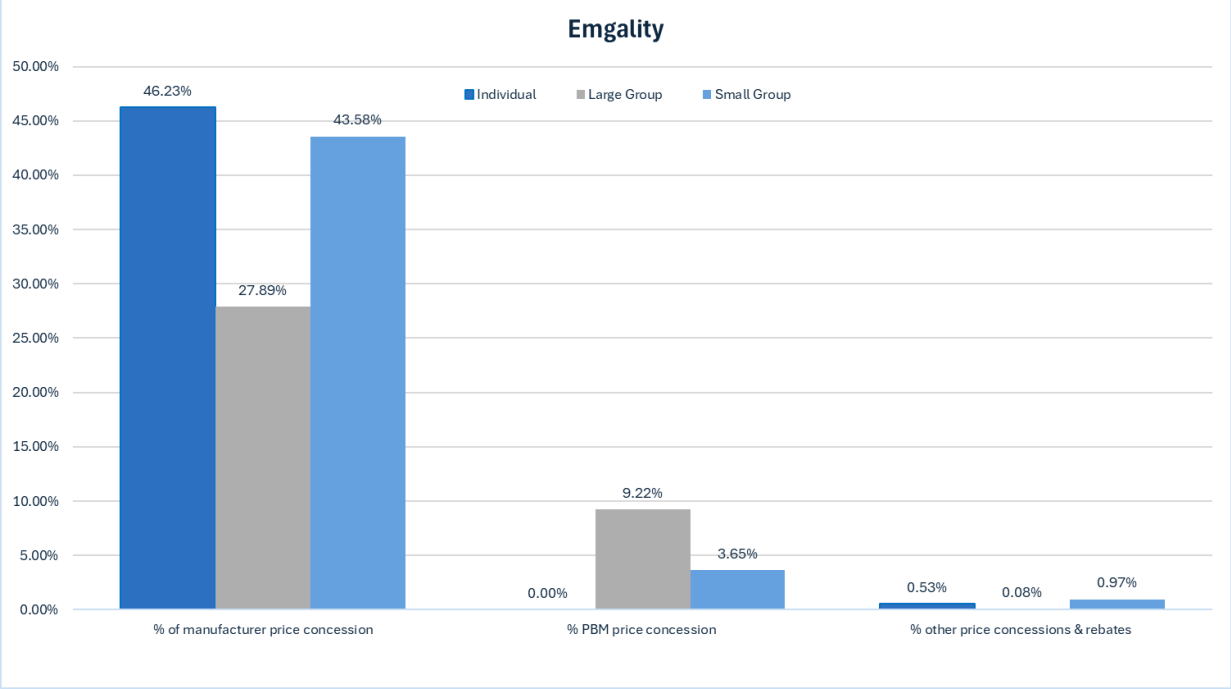


Figure 4 Percent of price concession in each market type

Estimated total amount of the price concession

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

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

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

Estimated price for therapeutic alternatives[25]

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

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

Emgality's **gross cost per claim, based on APAC data, was $759**, while **net cost data showed a higher per-claim amount of $762**. Compared to Emgality's gross cost per claim, Aimovig and Ajovy have similar claim costs, while Nurtec showed a higher cost per claim and per enrollee, though it shows to have fewer claims than Emgality APAC claims. Qulipta and Vyepti show lower numbers of enrollees and claims, but have with elevated costs for payers in respect to the number of claims paid.

Out-of-pocket costs also varied with enrollee payments for Emgality in **APAC averaging $104 per claim**. Therapeutic alternative such as Aimovig and Ajovy had lower reported enrollee-paid amounts ranging from $58 and $86 per claim.

[25] Therapeutic alternative to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. ORS 925-200-0020(2)(c) PDAB 1-2023: Prescription Drug Affordability Review (oregon.gov). Accessed 01/09/2024.

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

Table 2 Average healthcare and average enrollee OOP costs for Emgality vs therapeutic alternatives

Drug	Total spend	No. of enrollees [26]	No. of claims	Avg. paid/ claim	Avg. Paid/ enrollee	Total payer paid	Total enrollees paid	Payer paid/ claim	Enrollee paid/ claim
Subject drug **Emgality (data call)**	**$3,876,846**	**935**	**5,088**	**$762**	**$4,146**	**$3,124,793**	**$752,054**	**$614**	**$148**
Subject drug **Emgality (APAC)**	**$11,477,154**	**1,946**	**15,130**	**$759**	**$5,898**	**$9,896,376**	**$1,580,777**	**$654**	**$104**
Aimovig	$11,872,686	1,865	15,271	$777	$6,366	$10,990,158	$882,528	$720	$58
Ajovy	$7,451,775	1,603	10,307	$723	$4,649	$6,566,875	$885,066	$637	$86
Nurtec	$14,730,840	2,478	12,335	$1,194	$5,945	$13,227,665	$1,503,175	$1,072	$122
Qulipta	$3,413,298	601	3,037	$1,124	$5,679	$3,012,966	$400,332	$992	$132
Vyepti	$5,175	3	4	$1,294	$1,725	$5,175	$0	$1,294	$0

Estimated average price concession for therapeutic alternatives

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

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

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this information as additional data become available through carrier reporting, manufacturer disclosures, or other sources.

[26] The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 2, as compared to other totals indicated in this report.

Estimated costs to health insurance plans

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

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

In 2023, the Oregon APAC database recorded **15,130 total claims for Emgality among 2,084 total enrollees**, corresponding to a **total system gross expenditure of $11,477,154**. This equates to a total of an average **annual cost of $15,818 per enrollee**, or approximately **$2,259 per claim**.

Table 3 provides gross cost estimates by the total APAC system spend across all lines of business:

- **Commercial** accounted for the largest share of utilization, with 8,715 claims from 1,112 enrollees and a total spend of **$6.4 million**.
- **Medicare** and **Medicaid** payers reported smaller but notable expenditures of approximately **$3.6 million** and **$1.5 million**, respectively.

Table 3 Estimated 2023 APAC total gross costs to the healthcare system[27]

Payer line of business	Total enrollees	Total claims	Total gross cost amount	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,112	8,715	$6,412,751	$5,767	$736
Medicaid	331	2,187	$1,471,650	$4,446	$673
Medicare	641	4,228	$3,592,753	$5,605	$850
Totals	**2,084**	**15,130**	**$11,477,154**	**$15,818**	**$2,259**

Table 4 provides gross APAC cost estimates for **payer spend across all lines of business** with **15,130 total claims for Emgality among 2,084 total enrollees.** The **payers gross expenditure of $9,896,376**, equated to a total of an average **annual cost of $14,153 per enrollee**, or approximately **$2,033 per claim**.

[27] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC is based off gross cost information prior to any price concessions such as discounts or coupons.

Table 4 Estimated 2023 APAC gross cost to the payers[28]

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,112	8,715	$5,200,738	$4,677	$597
Medicaid	331	2,187	$1,471,650	$4,446	$673
Medicare	641	4,228	$3,223,988	$5,605	$850
Totals	**2,084**	**15,130**	**$9,896,376**	**$14,153**	**$2,033**

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (62% of total), followed by small group and individual markets. The **collected total net cost to the healthcare system was around $3.9 million**, with payer paying $3.1 million, and enrollees out-of-pocket estimating to be $752,054. Table 5 includes the average plan costs per enrollee in the commercial market ranged from **$4,850 (individual)** to **$3,723 (small group)** annually.

Table 5 Estimated 2023 data call total net costs to the healthcare system, payers and enrollee OOP[29]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	1,053	164	$795,397	$513,520	$281,877
Large Group	3,091	592	$2,415,092	$2,093,225	$321,868
Small Group	944	179	$666,357	$518,048	$148,309
Total	**5,088**	**935**	**$3,876,846**	**$3,124,793**	**$752,054**

Market	Avg. plan spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plan spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Individual	$755	$3,131	$268	$4,850	$488	$1,719
Large Group	$781	$3,536	$104	$4,080	$677	$544
Small Group	$706	$2,894	$157	$3,723	$549	$829

[28] Ibid.
[29] Cost information from the data call is the net cost of the drug after price concessions.

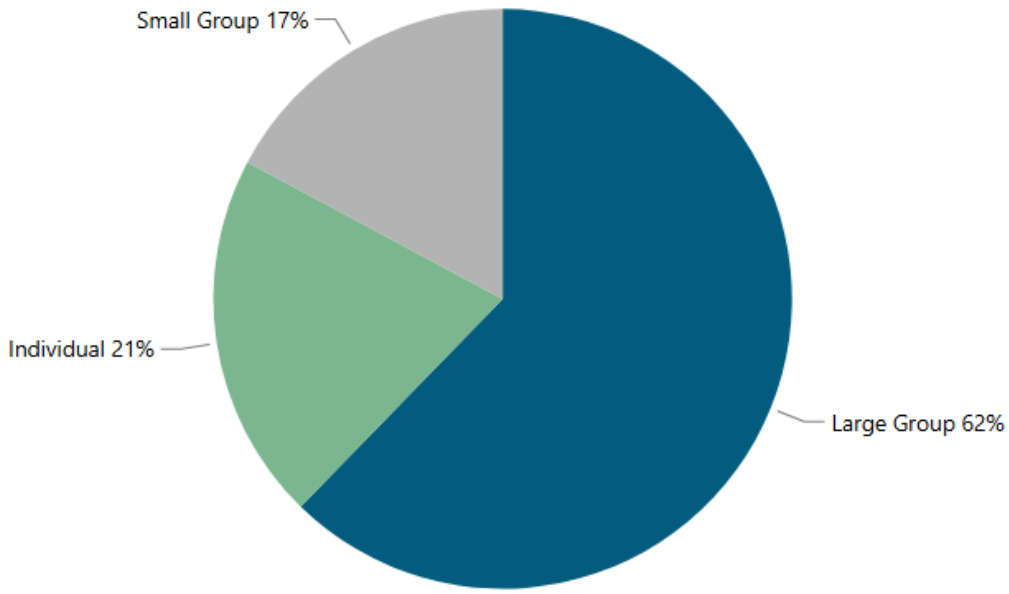


Figure 5 Data call percent of total annual spend (payer paid)

Cost to the state fee-for-service program, represented in Table 6, indicates Emgality was not included on the top 40 quarterly reports. Table 7 reflects Emgality was not on the Coordinated Care Organization (CCO) top 50 drugs by gross amount paid.

Table 6 2023 Gross amount paid for Medicaid/Oregon Health Plan fee for service

Fee-for-Service[30]							
2023 Quarter	**Drug name on report**	**Amount paid**	**% Total FFS costs**	**Claim count**	**Average paid per claim**	**Preferred drug list (PDL)**	**Prior auth**
Q1	Drug not on report						
Q2	Drug not on report						
Q3	Drug not on report						

[30] Oregon State University Drug Use and Research Management DUR utilization reports 2023. College of Pharmacy, Oregon State University. https://pharmacy.oregonstate.edu/research/pharmacy-practice/drug-use-research-management/dur-reports

Fee-for-Service[30]							
2023 Quarter	Drug name on report	Amount paid	% Total FFS costs	Claim count	Average paid per claim	Preferred drug list (PDL)	Prior auth
Q4	Drug not on report						
Annual Total:							

Drug not indicated in Q1-Q4 of top 40 quarterly reports of the pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Table 7 2023 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	Amount paid	Claim count	Average paid per claim
Drug not on report			

Pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Impact on patient access to the drug

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

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Emgality, including prior authorization requirements, step therapy protocols, and formulary placement. These data describe how the drug is positioned within insurance benefit designs and the extent to which utilization management processes were applied during the reporting period.

Based on information reported through the carrier data call, the follow plan design features were observed for Emgality. In 2023, approximately **99.6 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **0.4 percent of plans required step therapy** before approving its use.

Among the **3,787 PA requests** recorded during the reporting period, **2,775 were approved (73.3%)** and **1,012 were denied (26.7%)**.

For formulary placement, **81.8 percent of plans categorized Emgality as a non-preferred drug**, **18.2 percent listed it as preferred**, and **no plans excluded it entirely from the formulary**.

Table 8 Plan design analysis from 2023 data call

Total prior authorizations	3,787
Number of approved prior authorizations	2,775
Number of denied prior authorizations	1,012
Percentage of approved prior authorizations	73.3%
Percentage of denied prior authorizations	26.7%
Percentage of plans requiring pre-authorization	99.6%
Percentage of plans requiring step therapy	0.4%
Percentage of plans where drug preferred on formulary	18.2%
Percentage of plans where drug non-preferred on formulary	81.8%
Percentage of plans where drug excluded on formulary	0.0%

Relative financial impacts to health, medical or social services costs

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

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

The statutory and regulatory criteria contemplate consideration of such impacts to the extent practicable. However, due to limitations in available evidence, data systems, and the challenges inherent in isolating the indirect effects of a single drug on broader healthcare or social service costs, this analysis was not performed.

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

Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Emgality in Oregon, as reported in 2023 by the two data sources: the Oregon All Payers All Claims (APAC) database and the carrier data call.[31] These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type and commercial market segment.

Table 9 presents the average annual enrollee cost-sharing amounts derived from APAC and carrier-submitted data. The APAC data, which includes claims from commercial, Medicaid, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs that varied by payer line of business. For example, **commercially insured enrollees recorded higher average annual OOP costs** than Medicare enrollees, while Medicaid enrollees incurred no OOP costs.

Carrier-submitted data, which capture only commercially insured enrollees in Oregon's individual, small group, and large group markets, also showed variation across segments. On average, **enrollees in the large market paid higher OOP costs per enrollee** compared to those in small group plans, while individual group enrollee costs fell between the two. Copayment, coinsurance, and deductible amounts are delineated separately within each data source, reflecting differences in plan design and reporting requirements.

Differences between the APAC and carrier data sources may reflect methodological and population differences, including the exclusion of health plans with fewer than 5,000 covered lives from the APAC reporting requirement and the effect of price concessions on carrier-reported figures.

Table 9 *Average annual enrollee out-of-pocket costs between APAC and data call*

APAC claim line of business	Commercial	Medicaid	Medicare
Number of claims	8,715	2,187	4,228
Number of enrollees	1,112	331	641
Total copay	$376,041	$0	$128,399
Total coinsurance	$382,204	$0	$187,331
Total deductible	$453,767	$0	$62,659

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

APAC claim line of business	Commercial	Medicaid	Medicare
Total enrollee paid	$1,212,013	$0	$368,765
Average copay per claim	$8,715	$2,187	$4,228
Average coinsurance per claim	$1,112	$331	$641
Average deductible per claim	$43	$0	$30
Average cost across all claims	$44	$0	$44
Average copay per enrollee	$52	$0	$15
Average coinsurance per enrollee	$139	$0	$87
Average deductible per enrollee	$338	$0	$200
Average cost across all enrollee OOP	$344	$0	$292

Data call market type	Large Group	Small Group	Individual
Number of claims	1053	3091	944
Number of enrollees	164	592	179
Total copay	$14,111	$118,754	$14,865
Total coinsurance	$119,576	$119,518	$123,445
Total deductible	$146,614	$80,895	$10,591
Total other (i.e. PAP)	$1,576	$2,700	($592)
Average copay per claim	$13	$38	$16
Average coinsurance per claim	$114	$39	$131
Average deductible per claim	$139	$26	$11
Average cost across all claims	$268	$104	$157
Average copay per enrollee	$86	$201	$83
Average coinsurance per enrollee	$729	$202	$690
Average deductible per enrollee	$894	$137	$59
Average OOP cost per enrollee	$1,719	$544	$829

Table 10, further describes the distribution of annual enrollee OOP costs, providing measures of central tendency such as minimum, median, and maximum costs observed.

Table 10 OOP costs central tendency of Emgality costs in 2023

Out of pocket costs per enrollee per year[32]		
Average	*Enrollees pay this much on average*	$812
Minimum	*The lowest amount any one enrollee paid*	$0
Median	*Half of enrollees pay more than this amount and half pay less*	$30
Max	*The highest amount any one enrollee paid*	$2,081

Clinical information based on manufacturer material[33]

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

Drug indications

- FDA Approved:
  - Emgality is a CGRP antagonist indicated in adults for the:
    - preventive treatment of migraine.
    - treatment of episodic cluster headache.

- Off Label Uses: None

Clinical efficacy

Efficacy in Episodic Migraine Prevention

Clinical efficacy of galcanezumab for the prevention of episodic migraine was evaluated in two 6-month, double-blind, placebo-controlled trials involving patients with 4–14 monthly migraine days (Table 10). Patients were randomized to galcanezumab 120 mg monthly, 250 mg monthly, or placebo over 6 months. The primary endpoint was mean change from baseline in the monthly average number of migraine headache days. Results were similar between the two doses and therefore only the 120 mg dose was FDA approved and will be included here. In both studies, galcanezumab resulted in statistically significant decreases in migraine days per month of about 2 days per month.

[32] For patients who used the drug at least once in the 2023 calendar year.
[33] U.S. Food & Drug Administration. *Emgality (galcanezumb-gnlm) Prescribing Information*. Eli Lily, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf

Table 11 Clinical Efficacy in Prevention of Episodic Migraine

Endpoint	galcanezumab 120 mg	Placebo	Mean difference (95% CI)	p-value
Study 1				
Change from Baseline in Monthly Migraine Days	–4.7	–2.8,	–1.9 (-2.48 to -1.37)	<0.001
Proportion of patients with ≥50% reduction from baseline in migraine days	62%	39%,	+23% NNT 5	<0.001
Study 2				
Change from Baseline in Monthly Migraine Days	-4.3	-2.3	-2.02 (-2.6 to -1.5)	<0.001
Proportion of patients with ≥50% reduction from baseline in migraine days	59%	36%	23% NNT 5	<0.001
NNT: number needed to treat				

Efficacy in Chronic Migraine Prevention

The efficacy of galcanezumab for the prevention of chronic migraine (≥15 headache days/month) was studied in one 3-month randomized, double-blind, placebo-controlled trial (Table 11). The primary endpoint was identical to the episodic migraine trials. Galcanezumab 120 mg monthly resulted in a reduction of monthly migraine days by about 2 days per month compared to placebo.

Table 12 Efficacy in Chronic Migraine Prevention

Endpoint	galcanezumab 120 mg	Placebo	Mean difference (95%CI)	p-value
Change from Baseline in Monthly Migraine Days	–4.8	–2.7	–2.1 (-2.9 to –1.3)	p<0.001
Proportion of patients with ≥50% reduction from baseline in migraine days	28%	15%	+13% NNT 4	p<0.001
NNT: number needed to treat				

Efficacy in Episodic Cluster Headache

Galcanezumab was studied for the use of cluster headaches in one 8-week randomized controlled trial (n=106) comparing galcanezumab 300 mg SUBQ at baseline and at 1 month compared to placebo in patients with episodic cluster headaches (Table 12). The primary endpoint was the mean change from baseline in weekly frequency of cluster headache attacks in weeks 1 to 3.

Table 13 Clinical Efficacy in Cluster Headache

Endpoint	galcanezumab 300 mg	Placebo	Mean difference (95% CI)	p-value
Decrease Weekly Cluster Attack Frequency (Weeks 1–3)	–8.7	–5.2	-3.5 (0.2 to 6.7)	0.036
Percentage of patients with a reduction in weekly cluster headaches from baseline of ≥50% at Week 3	71.4%	52.6%		0.046

Compared to placebo, galcanezumab was more effective in the short term (1 to 3 weeks) in the prevention of cluster headaches (2.2 to 3.5 fewer attacks) but there no difference at weeks 8 to 12.

Clinical safety

- FDA safety warnings and precautions:
  - Hypersensitivity reactions: Hypersensitivity reactions can occur days after administration, and may be prolonged.
  - Hypertension
  - Raynaud's Phenomenon

- Contraindications:
  - Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

- Common side effects:
  - Injection-site reactions (18%)
  - Antibody development (5-13%)

Therapeutic alternatives:[34,35,36,37]

Table 14 FDA Approved Indications

Drug	Acute Migraine	Episodic Migraine Prevention	Chronic Migraine Prevention	Cluster Headache Prevention
Monoclonal Antibody CGRP Inhibitors (long acting)				
Subject drug: ***galcanezumab* (Emgality)**	No	Yes	Yes	Yes (episodic)
***Erenumab* (Aimovig)**	No	Yes	Yes	No
***Fremanezumab* (Ajovy)**	No	Yes	Yes	No
Eptinezumab Vyepti	No	Yes	Yes	No

Table 15 Efficacy for Chronic or Episodic Migraine Prevention

Drug	Migraine days per month (mean difference from placebo) in Episodic	Migraine days per month (mean difference from placebo) in Chronic	Percentage with at least 50% reduction in number of migraine days per month
Monoclonal Antibody CGRP Inhibitors (long acting)			
Subject drug: ***galcanezumb* (Emgality)**	–-1.0 to -2.0	–-2.0	~28%
***Erenumab* (Aimovig)**	-1.0 to -2.3	-2.5	~25%
***Fremanezumab* (Ajovy)**	-1.5 to -3.0	-1.7 to -2.0	16-22%
***Eptinezumab* (Vypeti)**	-1.0	-2.0 to 2.6	14%-22%

[34] U.S. Food & Drug Administration. *Emgality (galcanezumb-gnlm) Prescribing Information*. Eli Lily, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf

[35] U.S. Food & Drug Administration. *Aimovig (erenumab-aooe) Prescribing Information*. Amgen Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761077s015lbl.pdf

[36] U.S. Food & Drug Administration. *Ajovy (fremanezumab-vfrm) Prescribing Information*. Teva Pharms., Revised 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761089s013lbl.pdf

[37] U.S. Food & Drug Administration. Vyepti (*eptinezumab-jjmr) Prescribing Information*. Lundback Seattle BioPharm, Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215206s004lbl.pdf

Table 16 Adverse Effects (AEs)

Drug	Common AEs	Notable Risks
Monoclonal Antibody CGRP Inhibitors		
Subject drug: ***galcanezumb*** **(Emgality)**	Injection-site rxn, mild allergic rxn; no constipation prominent	Generally well tolerated
Erenumab **(Aimovig)**	Injection site reactions constipation (3–5%)	Rare serious constipation, hypertension
fremanezumab **(Ajovy)**	Injection site reactions	Hypersensitivity reactions requiring discontinuation and corticosteroid treatment have been reported within hours to one month after administration
eptinezumab **(Vyepti)**	Infusion site rxn, nasopharyngitis, throat irritation	Minimal hypersensitivity

Table 17 Route and dosing

Drug	Route / form	Dose and frequency
Monoclonal Antibody CGRP Inhibitors (long acting)		
Subject drug ***galcanezumb*** **(Emgality)**	SC injection	240 mg loading, then 120 mg monthly
Erenumab **(Aimovig)**	SC injection (autoinjector/pen)	70 or 140 mg monthly
fremanezumab **(Ajovy)**	SC injection (prefilled syringe/pen)	225 mg monthly or 675 mg quarterly
eptinezumab **(Vyepti)**	IV infusion	100 mg every 3 months

Input from specified stakeholders

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

See Appendix page for all stakeholder feedback.

Patients and caregivers:

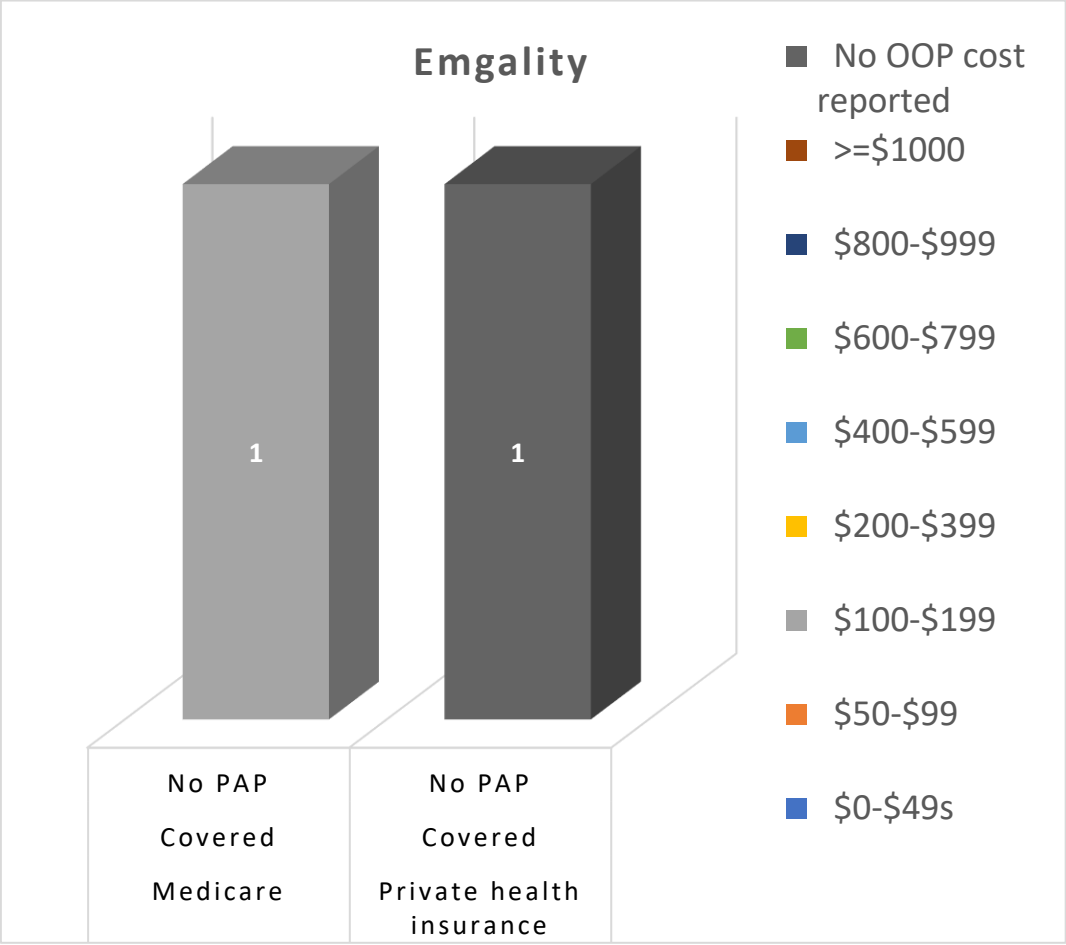
Note: The information presented is based on self-reported survey responses from individuals prescribed certain medications. Participation in the survey was voluntary, and the responses reflect each individual's personal understanding and interpretation of the question asked. As such, the data may contain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

Survey information was received from two individuals taking or having an association with Emgality. For both respondents, insurance covered Emgality.

Table 10 indicated one patient had the drug covered under Medicare, was not on a patient assistant program (PAP), and paid between $100-$199 monthly for Emgality.

One patient with private health insurance did not report an out-of-pocket cost or help from a PAP.

Table 18 Patient survey responses by reported for out-of-pocket costs impact based on insurance type



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

"Emgality"

- For the past three years, I take Emgality, 120mg, every 28 days to prevents migraines. I have tried many other drugs and they are not effective and/or have bad side effects. I'm fortunate to have private health insurance.
- I take Emgality, 120 mg, once a month and it prevents 80 percent of my migraines. I was having them four times a week from long covid. I have been taking Emgality 18 months and pay $127 for out-of-pocket per month. Botox worked best but my out of pocket cost

was $650 every 90 days. I had fewer breakthrough migraines with Botox. I didn't like getting 30 injections all over my head but it sure worked. I don't qualify for patient assistance because I'm on Medicare. My Medicare plan this month said I didn't qualify anymore. I'm fighting it. It's truly messed up that since the age of 9, I have worked, paid into Social Security and Medicare, yet I pay about $520 a month for my advantage plan and co-pays. Medical dental and behavioral health coverage should be free for people making less than $100,000/year. Below are written answers from Oregon patients who responded to the PDAB survey in April 2025. Survey responses have been edited for readability, length and to protect patient privacy.

Individuals with scientific or medical training

This section summarizes information reported by healthcare professionals with scientific or medical training who identified key barriers for patients in accessing the medications under review. The most commonly cited challenge was the **requirement for prior authorization,** which was viewed as a significant hurdle that delays treatment initiation. Other challenges included **step therapy protocols, restrictive insurance formularies, and mediation costs**. Few respondents viewed prescription quality limits as a barrier to accessing drugs.

There was one healthcare professional that reported the prior authorization process, step therapy, and cost of Emgality as burdens for patients to access the medication.

Table 19 Reported administration burden of the drug for patient to access

Drug	Prior Authorization	Step Therapy	Quantity Limit	Cost	PBM/ formulary issues	Considered first line of therapy
Emgality	Yes	Yes	-	Yes	-	-

Reported benefits of the prescription drug compared to therapeutic alternatives:

- Extended dosing: monthly dosing vs. daily dosing (for oral medications)
- Less potential for DDIs: not metabolized by CYP450 enzymes, thus, there is less potential for interactions with concomitant medications
- Dose adjustments: not needed for those with impaired hepatic or renal function
- Additional indication: episodic cluster headache
- Side effect profile: generally well tolerated and does not have the additional effects non-CGRP medications may exhibit such as lowering blood pressure or cognitive effects.
- Administration: compared to Botox, this can be self-administered

Reported disadvantages of the prescription drug compared to therapeutic alternatives:

- Administration: may be unfavorable (i.e., subcutaneous injection vs. oral)
- Cost: newer medication such as Emgality (FDA approved in 2018) will cost more than those that have been on the market for a long time
- Potential increased medication burden: non-CGRP therapeutic alternatives have different FDA-approved indications that could potentially benefit a patient treating a comorbid condition
- Storage: requires refrigeration
- Long term data: there is not as much data available for the long term safety and efficacy of CGRPs compared to the non-CGRP medications, which have been widely used for many years.

Safety net providers

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

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

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

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

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

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

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

Table 20 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	4
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between $0-$100,000	27%
Reported total amount paid for drug under 340B was between $100,001-$300-000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between $0-$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between $100-001-$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between $500,000-$10,000,000	18%

Table 21 Amounts paid for drug under 340B discount program

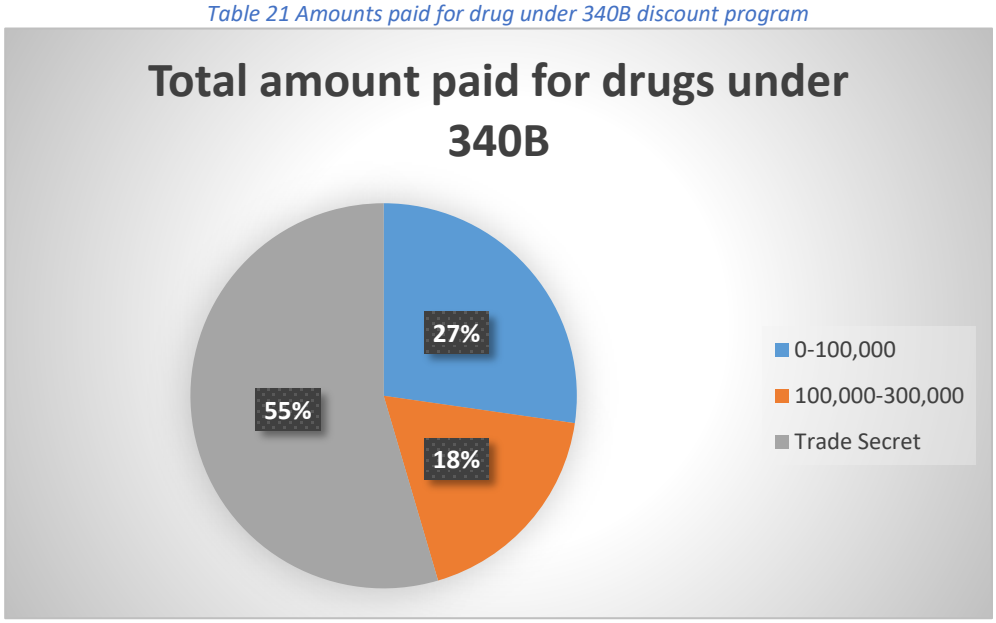
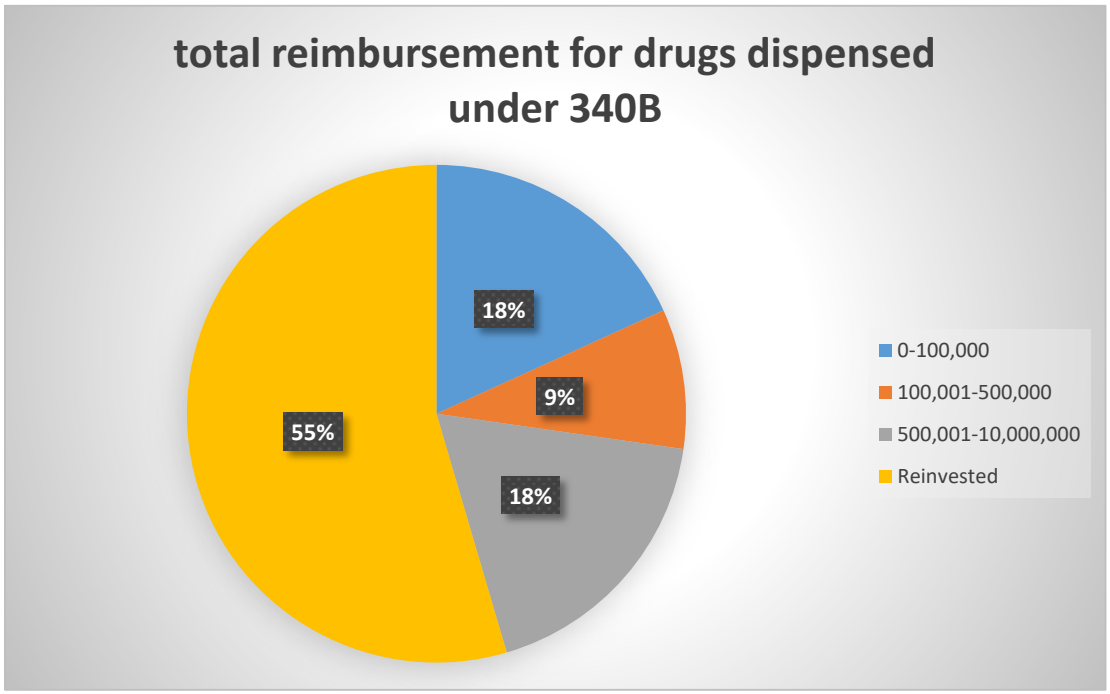


Table 22 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program



Payers

Relevant information from payers is incorporated throughout the material packed based on the data submitted through the formal data call process. This includes details on the total cost of

care for the disease, the cost and utilization of the prescription drug, the availability and formulary placement, therapeutic alternatives, as well as reported impacts to member costs.

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

Appendix

Stakeholder feedback:

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Cynthia Ransom	Eli Lilly	Emgality	Letter	5/21/2025	**Exhibit A**

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

Nurtec ODT® (*rimegepant/rimegepant sulfate*)[1]

Version 2.0

[1] https://www.mims.com/malaysia/drug/info/nurtec?type=full

Table of Contents

Document version history

Version	Date	Description
v1.0	7/9/2025	Original Release
v2.0		Updated gross spend amounts in the “Cost to the healthcare system” section; added a “Cost to payers” section; updated table 3 to reflect costs to the healthcare system; added table 4 for payer paid amounts; updated sections referencing patients to reference enrollees; added the drug name to the footer; Table 2 removed Total for paid/enrollee & claims and indicated the number as an average; updated summary page

Review summary

Price history

Nurtec ODT® (*rimegepant sulfate*) was first approved by the FDA in 2020 for the preventive treatment of migraine. Since entering the market, the wholesale acquisition cost **(WAC) has risen at an average annual rate of 4.1 percent**, **exceeding inflation** in 2020 to 2023.[2,3] As of late 2024, the **WAC reached approximately $119 per unit,** with **Medicaid acquisition costs (AAAC) tracking 17 percent discount**.

Cost to the healthcare system[4,5]

In 2023, Oregon's All Payers All Claims **(APAC) database reported approximately $14.7 million in gross spending for Nurtec ODT, based on 12,335 claims across 2,638 enrollees**. This equated to an **average gross spend of $5,584 per enrollee and $1,194 per claim**. Among payer types, Medicare accounted for the largest share of utilization and expenditures, followed by commercial and Medicaid plans.

According to data from commercial payers:

- **$5.6 million** in net spending across **1,103 enrollees** and **4,654 claims**.
- The average net spend was **$5,050 per enrollee** and **$1,197 per claim**.

Cost to payers[6,7]

APAC data for payer spend indicated the gross spending for Nurtec ODT is approximately $13.2 million, with 12,335 claims across 2,478 enrollees. This resulted in the average gross annual payer spend to be $5,338 per enrollee and $1,072 per claim. According to the data from commercial payers, the net spending for Nurtec ODT is approximately $4.7 million, spread across 4,654 claims and 1,103 enrollees. The net spend per enrollee was $4,224 and the net spend per claim was $1,006.

[2] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span
[3] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/
[4] Ibid.
[5] 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.
[6] Ibid.
[7] Based on Oregon's 2023 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.

Cost to enrollees[8,9]

Average enrollee out-of-pocket (OOP) costs in 2023 were moderate compared to similar high-cost therapies. APAC data showed **average OOP costs per enrollee of $797 for commercial and $471 for Medicare, with $0 reported for Medicaid enrollees**. Carrier-submitted data reflected similar variation by market segment, with **OOP costs ranging from $1,890 (individual group) to $399 (large group) per enrollee**.

Price concessions[10]

Carrier-reported data indicates that **59.7 percent of Nurtec ODT claims in the commercial market received some form of price concession** in 2023. Manufacturer rebates accounted for the majority of these discounts, followed by pharmacy benefit managers (PBM) price concession and other negotiated reductions. **Average gross cost per enrollee was $5,172, with net costs reduced to $3,813 after applying concessions**—an average discount of approximately **26.3 percent**. In total, **$1.5 million in price concessions** were reported across all market segments.

Therapeutic alternatives[11]

Six CGRP-targeting therapies were reviewed as therapeutic alternatives: **Aimovig, Ajovy, Emgality, Qulipta, Vyepti,** and **Zavzpret**. Compared to Nurtec ODT:

- **Ubrelvy**, is used for acute migraine treatment, is not direct preventive alternatives, but may reduce migraine-related healthcare costs.
- **Emgality** and **Aimovig** have comparable efficacy profiles with slightly lower annualized payer costs, and are subcutaneous (SC) options.
- **Qulipta** and **Ubrelvy** presents an oral preventive option.
- **Vyrepti** presents as an IV infusion option, and **Zavzpret** is a intranasal spray.

Cost information was provided through APAC for all therapeutic alternatives. **Nurtec ODT had the highest reported APAC claims (2,478) with the highest gross total of $14,730840**. Aimovig, Emgality, and Ubrelvy had similar amounts of total spend and claims reported.

[8] Based on Oregon's 2023 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 visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[9] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.
[10] Ibid.
[11] Based on Oregon's 2023 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.

Access and equity considerations[12]

Access to Nurtec ODT is shaped by a combination of cost barriers and formulary placement. In 2023, **99.6 percent of health plans required prior authorization**, with **0.4 percent requiring step therapy**. Most plans **(86.1%) listed Nurtec ODT as a non-preferred drug**.

Review background

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

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

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

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

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

[12] Ibid

Drug information[13]

Drug proprietary name	Nurtec®
Non-proprietary name (active ingredient)	*rimegepant sulfate*
Manufacturer	Biohaven Pharmaceuticals
Pharmacologic Category	Calcitonin Gene-Related Peptide (CGRP) Antagonist
Treatment	Episodic migraine prevention and acute treatment of migraine in adults
Dosage	75 mg orally disintegrating tablets
Dosing	• Acute migraine treatment: 75 mg orally as needed • Preventive treatment of episodic migraine: 75 mg orally every other day
Route of administration	Oral
Physician administered	No

FDA approval

Nurtec was first approved for acute migraine treatment by the FDA on 02/27/2020.[14] In 2021, it was FDA approved for preventive treatment of episodic migraine.

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

At time of the review, the drug had no designation indications under the Orphan Drug Act.

Health inequities

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

Clinical trials for migraine medications—including **Emgality (fremanezumab), Emgality (galcanezumab), Nurtec ODT (rimegepant)**, and **Ubrelvy (ubrogepant)**—have historically underrepresented racial and ethnic minority groups. A review of migraine clinical trials published in *Headache* found that **less than 15 percent** of participants across studies identified as non-white, with **Black Americans comprising less than 2 percent** of study cohorts in many trials—despite experiencing migraine at similar or greater rates than white populations.[15] This

[13] U.S. Food & Drug Administration. Nurtec ODT (rimegepant) Prescribing Information. Pfizer, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf

[14] FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, the earliest approval date across all related FDA applications was used.

[15] Robbins NM, Bernat JL. "Minority Representation in Migraine Treatment Trials." *Headache*. 2017;57(3):525-533. PMID: 28127754

lack of diversity limits the generalizability of trial findings and raises concerns about whether these medications perform equally well across all demographic groups.

The **Institute for Clinical and Economic Review (ICER)** highlighted similar concerns in its review of acute migraine treatments, noting that **trial enrollment did not reflect the real-world racial and ethnic diversity of people living with migraine**, particularly underrepresenting Black and Hispanic patients.[16] In contrast, the FDA's *Drug Trials Snapshot* for **Nurtec ODT** provides limited but promising subgroup data: pain relief rates were found to be **comparable across racial groups,** with **23.3 percent of Black participants and 21.2 percent of white participants** achieving pain freedom at two hours.[17] However, without consistent subgroup analysis across all CGRP-targeting therapies, disparities in both trial design and real-world access remain.

R**eal-world evidence** shows that **Black and Hispanic individuals are less likely to be diagnosed with migraine or prescribed advanced treatments**, even when accounting for socioeconomic status. This reflects broader systemic inequities in pain recognition, access to specialists, and treatment authorization. Compounding these disparities are **structural barriers** such as geographic isolation, lower health literacy, and provider bias[18]—all of which influence medication adherence, proper use of self-injection therapies, and management of side effects.

To ensure equitable care, future clinical research should prioritize diverse enrollment and transparent subgroup reporting, while health systems and payers must address access and affordability gaps for historically underserved populations.

Residents prescribed

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

In 2023, the Oregon APAC database recorded **2,478 unique individuals** with at least one filled prescription for Nurtec ODT.[19] In contrast, the **commercial health benefit plan data call**, which included submissions from 11 reporting carriers, identified **1,103 enrollees** with a Nurtec ODT fill during the same period.[20]

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[16] Institute for Clinical and Economic Review (ICER). "Acute Migraine Treatments – Final Evidence Report." January 2020. https://icer.org/wp-content/uploads/2020/10/ICER_Acute-Migraine_Evidence_Report_011020_updated_011320_-2.pdf

[17] FDA. "Drug Trials Snapshot: Nurtec ODT." https://www.fda.gov/drugs/development-approval-process-drugs/drug-trials-snapshots-nurtec-odt

[18] Williams DR, Mohammed SA. "Discrimination and Racial Disparities in Health: Evidence and Needed Research." *J Behav Med*. 2009;32(1):20–47. PMC2443411

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

[20] Based on 2023 data collected by DCBS under authorities granted in ORS 731.296 and OES 646A.963 through ORS 646A.697 from Oregon health insurance plans. Cost information from the data call is the cost of the drug after price concessions.

The substantial variance between the two figures is attributable to differences in data scope and reporting mandates. APAC is a comprehensive claims repository that aggregates utilization data across all payer types, including Medicaid, Medicare, and commercial lines of business. In contrast, the data call process captures a limited subset of commercially insured enrollees and is restricted to the reporting obligations of participating health plans. As a result, APAC offers a more inclusive estimate of statewide utilization, while the carrier-submitted data reflect only a narrow segment of the insured population.

Price for the drug

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

This section examines the pricing dynamics of Nurtec ODT, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of the wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), as well as the impact of negotiated prices concessions which include discounts, rebates, and other price reduction negotiations. Together, these data provide a comprehensive view of Nurtec ODT's list price trajectory, pharmacy acquisition costs, and the degree to which price reductions are realized in practice by payers in Oregon.

Price history

The wholesale acquisition cost (WAC) of Nurtec ODT, was provided by one reported national drug codes (NDCs), and was approximately **$119 per unit** at the end of 2024.[21] Between 2018 and 2024, the unit WAC increased at an average annual rate of **4.1 percent**, exceeding the general inflation rate (CPI-U) in 2020 to 2024 (see Figures 1 and 2).[22]

Unit 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.

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

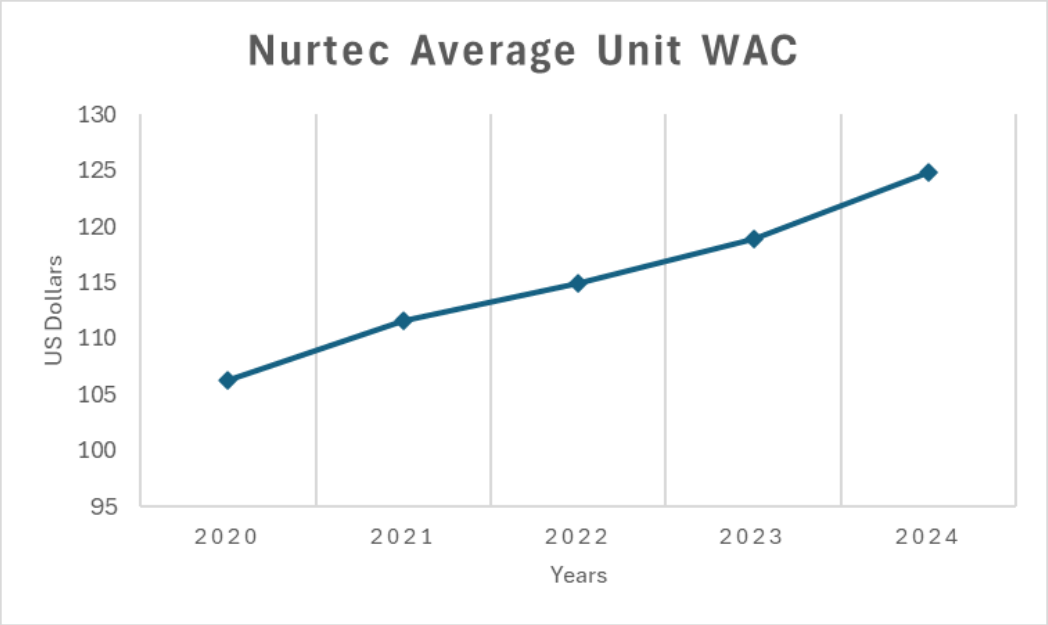


Figure 1 Nurtec average unit WAC from 2020-2024

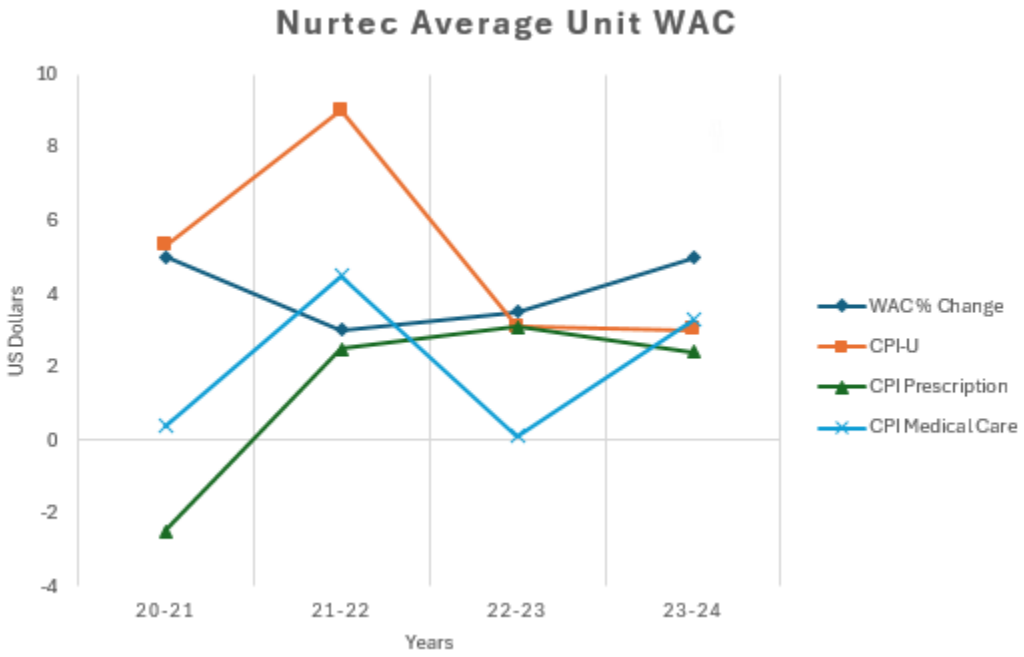


Figure 2 Year over year change in unit WAC compared to inflation rates[23]

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

Pharmacy acquisition costs

The Oregon Actual Average Acquisition Cost (AAAC), which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$102 per unit in Q3 2020 to $102 per unit in Q4 2024**, an approximate **17 percent increase** over the period (see Figure 3).[24] Relative to the $119 WAC in end-of-year 2024 a **AAAC discount of 0.7 percent** is indicated.

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

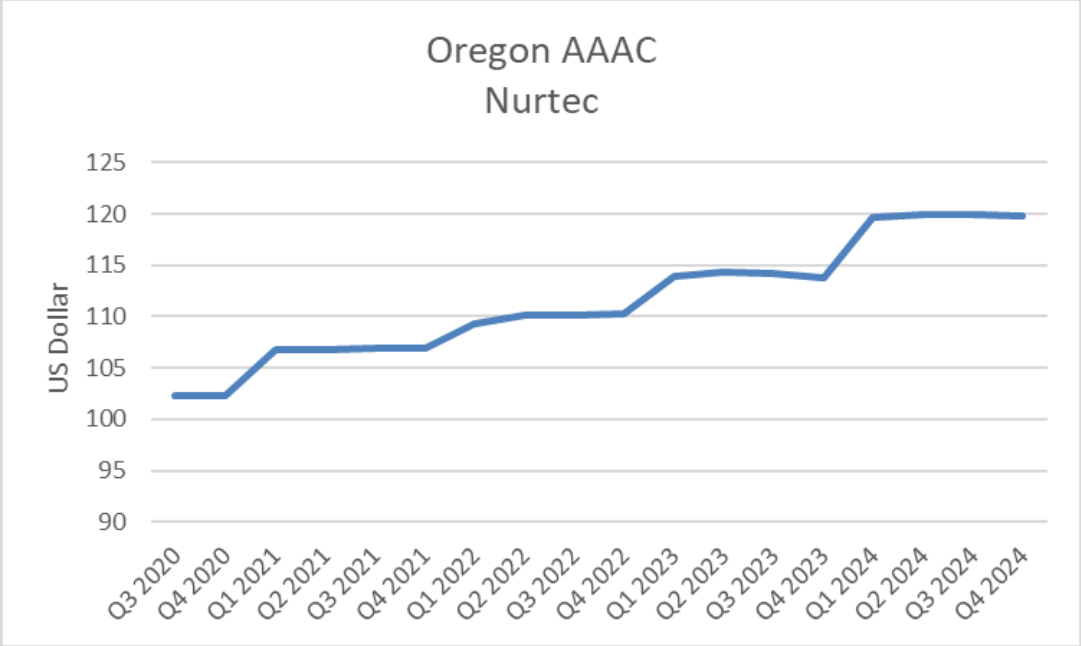


Figure 3 AAAC for Nurtec from Q3 2020 to Q4 2024

Estimated average monetary price concession

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

This section provides an analysis of the average monetary discounts, rebates, and other price concessions applied to Nurtec ODT claims in the commercial market. Drawing on data submitted through the 2023 carrier data call, it evaluates the extent to which these concessions

[24] Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2023. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. https://myersandstauffer.com/client-portal/oregon/

reduced gross drug costs and estimates the average net costs to payers after adjustments. The analysis includes claim-level data on the proportion of claims with applied discounts and the breakdown of the total concession amounts by type, offering insight into the reduced costs provided through manufacturer, PBM, and other negotiated price reductions.

Based on carrier-submitted data for 2023, the **average gross cost of Nurtec ODT per enrollee in the commercial market was approximately $5,172**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $3,813**, reflecting an **estimated mean discount of 26.3 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Nurtec ODT before concessions was $5,705,207**, with total reported **price concessions amounting to approximately $1,499,588**, as detailed in Table 1. Notably, **59.7 percent of claims benefited from some form of price concession**, leaving **40.3 percent at full gross cost**. Figure 3 shows manufacturer concessions comprised the largest share, supplemented by PBM discounts and other adjustments across the payer types.

Table 1 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	1,103
Total number of claims	4,654
Total number of claims with price concessions applied	2778
Percentage of claims with price concessions applied	59.7%
Percentage of cost remaining after concessions	73.7%
Manufacturer price concessions for all market types	$982,138
PBM price concessions for all market types	$512,312
Other price reductions for all market types	$5,137
Cost before price concessions across all market types	$5,705,207
Total price concessions across all market types	$1,499,588
Cost of after price concessions across all market types	$4,205,619
Avg. payer spend per enrollee without price concessions	$5,172
Avg. payer spend per enrollee with price concessions	$3,813

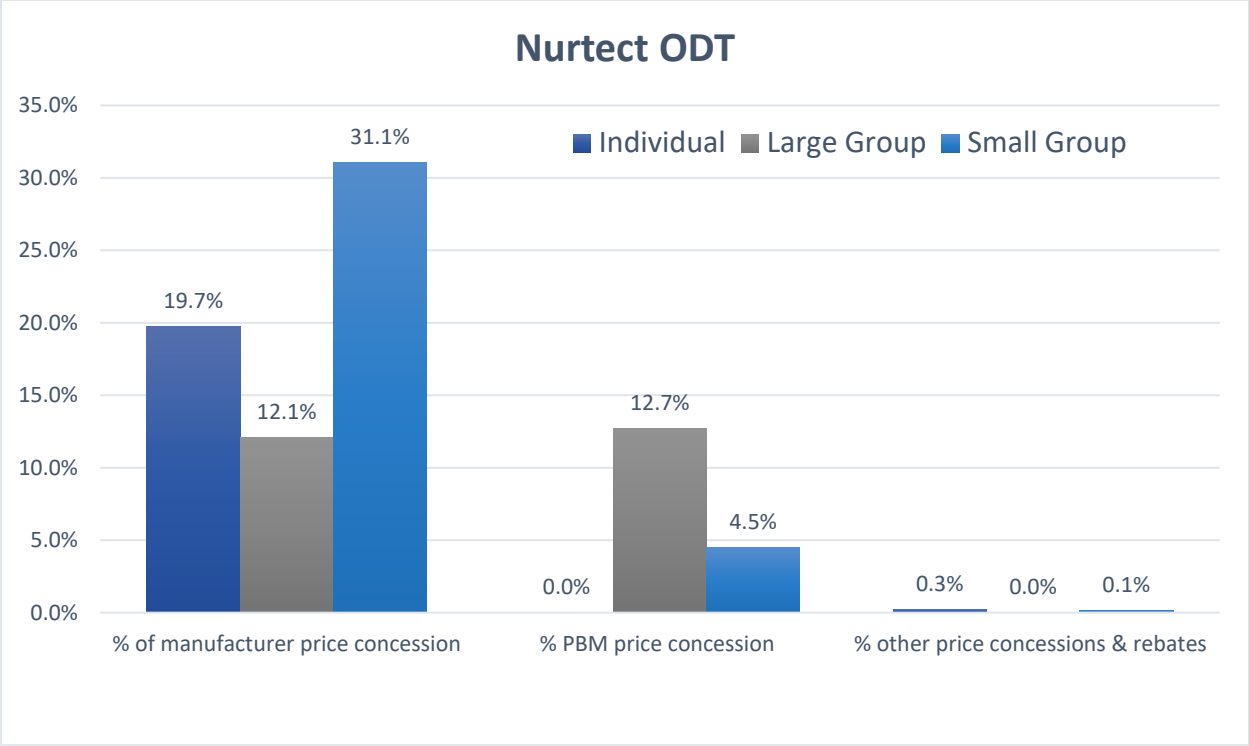


Figure 4 Percent of price concession in each market type

Estimated total amount of the price concession

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

This section is intended to quantify the total discounts, rebates, or other price concessions provided by the manufacturer of Nurtec ODT to each pharmacy benefit managers, expressed as a percentage of the drug's price. At the time of this review, there was no specific data available to PDAB to determine the total amount of such price concessions in the Oregon market. The statutory and regulatory criteria call for consideration of such information to the extent practicable; however, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate the data as they become available through improved reporting or additional disclosures from manufacturers, PBMs, and payers.

Estimated price for therapeutic alternatives[25]

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

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

Nurtec ODT's **gross cost per claim, based on APAC data, was $1,194**, while **net cost data showed a higher per-claim amount of $1,197**. Compared to Nurtec's gross cost per claim, Qulipta had a similar claim cost, while Vyepti showed a higher cost per claim, yet with the lowest cost per enrollee across all therapeutic alternatives, though it shows to have four claims. Aimovig, Ajovy, Emgality, and Ubrelvy show lower per-claim, with Ajovy having an average of $723 per claim compared to Nurtec ODT.

Out-of-pocket costs also varied with enrollee payments for Nurtec ODT in **APAC averaging $122 per claim**. Therapeutic alternative such as Vyepti and Emgality had lower reported enrollee-paid amounts ranging from $0 to $104 per claim.

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

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

Table 2 Average healthcare and average Enrollee OOP costs for Nurtec ODT vs therapeutic alternatives

Drug	Total spend	No. of enrollees [26]	No. of claims	Avg, paid/ claim	Avg, Paid/ enrollee	Total payer paid	Total enrollees paid	Payer paid/ claim	Enrollee paid/ claim
Subject Drug **Nurtec ODT (Data Call)**	**$5,570,441**	**1,106**	**4,654**	**$1,197**	**$5,050**	**$4,680,613**	**$889,828**	**$1,006**	**$191**
Subject Drug **Nurtec ODT (APAC)**	**$14,730,840**	**2,478**	**12,335**	**$1,194**	**$5,945**	**$13,227,665**	**$1,503,175**	**$1,072**	**$122**
Aimovig	$11,872,686	1,865	15,271	$777	$6,366	$10,990,158	$882,528	$720	$58
Ajovy	$7,451,941	1,603	10,307	$723	$4,649	$6,566,875	$885,066	$637	$86
Emgality	$11,477,154	1,946	15,130	$759	$5,898	$9,896,376	$1,580,777	$654	$104
Qulipta	$3,413,298	601	3,037	$1,124	$5,679	$3,012,966	$400,332	$992	$132
Ubrelvy	$11,813,998	2,288	11,854	$997	$5,163	$10,583,552	$1,230,446	$893	$104
Vyepti	$5,175	3	4	$1,294	$1,725	$5,175	$0	$1,294	$0
Zavzpret	$43,807	18	41	$1,068	$2,434	$41,360	$2,447	$1,009	$60

Estimated average price concession for therapeutic alternatives

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

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

The statutory and regulatory criteria call for consideration of such information to the extent practicable; however, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this information as additional data become available through carrier reporting, manufacturer disclosures, or other sources.

[26] The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 2, as compared to other totals indicated in this report.

Estimated costs to health insurance plans

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

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

In 2023, the Oregon APAC database recorded **12,335 total claims for Nurtec ODT among 2,638 total enrollees**, corresponding to a **total system gross expenditure of $13,227,665**. This equates to a total of an average **annual cost of $15,279 per enrollee**, or approximately **$3,293 per claim**.

Table 3 provides gross cost estimates by the total APAC system spend across all lines of business:

- **Commercial** accounted for the largest share of utilization, with 6,541 claims from 1,388 enrollees and a total spend of **$7.5 million**.
- **Medicare** and **Medicaid** payers reported smaller but notable expenditures of approximately **$5.2 million** and **$2.0 million**, respectively.

Table 3 Estimated 2023 APAC total gross costs to the healthcare system[27]

Payer line of business	Total enrollees	Total claims	Total gross cost amount	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,388	6,541	$7,502,604	$5,405	$1,147
Medicaid	408	1,842	$2,024,678	$4,962	$1,099
Medicare	842	3,952	$5,203,559	$6,180	$1,317
Totals	**2,638**	**12,335**	**$14,730,840**	**$16,547**	**$3,563**

Table 4 provides gross APAC cost estimates for **payer spend across all lines of business** with **12,335 total claims for Nurtec ODT among 2,638 total enrollees.** The **payers gross expenditure of $13,227,665**, equated to a total of an average **annual cost of $15,279 per enrollee**, or approximately **$3,293 per claim**.

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

Table 4 Estimated 2023 APAC gross cost to the payers[28]

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,388	6,541	$6,396,257	$4,608	$978
Medicaid	408	1,842	$2,024,678	$4,962	$1,099
Medicare	842	3,952	$4,806,730	$5,709	$1,216
Totals	**2,638**	**12,335**	**$13,227,665**	**$15,279**	**$3,293**

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the **large market segment** represented the majority of commercial spending (63% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around $5.6 million**, with payer paying $4.7 million, and enrollees out-of-pocket estimating to be $889,828. Table 5 includes the average plan costs per enrollee in the commercial market ranged from **$6,153 (individual)**, **$4,668 (large group)**, and **$5,693 (small group)** annually.

Table 5 Estimated 2023 data call total net costs to the healthcare system, payers and enrollee OOP[29]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of-pocket cost
Individual	708	146	$898,374	$622,456	$275,918
Large Group	3,086	757	$3,533,543	$3,231,183	$302,359
Small Group	860	200	$1,138,525	$826,974	$311,551
Total	**4,654**	**1103**	**5,570,442**	**4,680,613**	**889,828**

Market	Avg. plan spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plan spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Individual	$1,269	$4,263	$390	$6,153	$879	$1,890
Large Group	$1,145	$4,268	$98	$4,668	$1,047	$399
Small Group	$1,324	$4,135	$362	$5,693	$962	$1,558

[28] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[29] Cost information from the data call is the cost of the drug after price concessions.

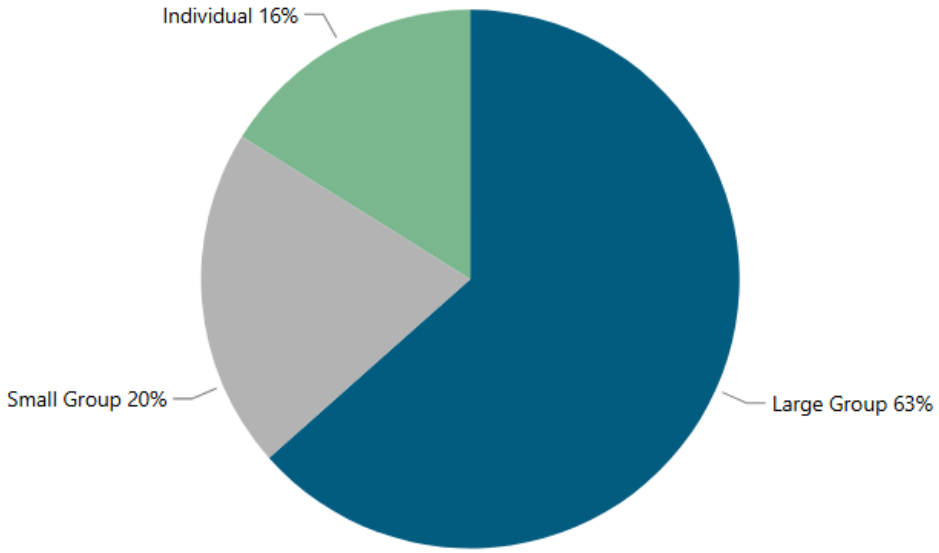


Figure 5 Data call percent of total annual spend (payer paid)

Cost to the state fee-for-service program, represented in Table 6, indicates Nurtec ODT was not included on the top 40 quarterly reports. Table 7 reflects Nurtec ODT was not on the Coordinated Care Organization (CCO) top 50 drugs by gross amount paid.

Table 6 2023 Gross amount paid for Medicaid/Oregon Health Plan fee for service

Fee-for-Service[30]							
2023 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	Drug not reported						
Q2	Drug not reported						
Q3	Drug not reported						
Q4	Drug not reported						

[30] Source: Oregon State University Drug Use and Research Management DUR utilization reports 2022. DUR Reports | College of Pharmacy | Oregon State University

Fee-for-Service[30]							
2023 Quarter	Drug name on report	Amount paid	% Total fee for service costs	Claim count	Average paid per claim	Preferred drug list (PDL)	Prior auth
Annual Average:							

Drug not indicated in Q1-Q4 of top 40 quarterly reports of the pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Table 7 2023 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	Amount paid	Claim count	Average paid per claim
Drug not reported			

Pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Impact on patient access to the drug

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

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Nurtec ODT, including prior authorization requirements, step therapy protocols, and formulary placement. These data describe how the drug is positioned within insurance benefit designs and the extent to which utilization management processes were applied during the reporting period.

Based on information reported through the carrier data call, the follow plan design features were observed for Nurtec ODT. In 2023, approximately **58.8 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **0.4 percent of plans required step therapy** before approving its use.

Among the **3,606 PA requests** recorded during the reporting period, **2,121 were approved (58.8%)** and **1,485 were denied (41.2%)**.

For formulary placement, **86.1 percent of plans categorized Nurtec ODT as a non-preferred drug**, **12.3 percent listed it as preferred**, and **1.6 percent plans excluded it entirely from the formulary**.

Table 8 Plan design analysis from 2023 data call

Total prior authorizations	3,606
Number of approved prior authorizations	2,121
Number of denied prior authorizations	1,485
Percentage of approved prior authorizations	58.8%
Percentage of denied prior authorizations	41.2%
Percentage of plans requiring pre-authorization	99.6%
Percentage of plans requiring step therapy	0.4%
Percentage of plans where drug preferred on formulary	12.3%
Percentage of plans where drug non-preferred on formulary	86.1%
Percentage of plans where drug excluded on formulary	1.6%

Relative financial impacts to health, medical or social services costs

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

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

The statutory and regulatory criteria contemplate consideration of such impacts to the extent practicable. However, due to limitations in available evidence, data systems, and the challenges inherent in isolating the indirect effects of a single drug on broader healthcare or social service costs, this analysis was not performed.

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

Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Nurtec ODT in Oregon, as reported in 2023 by the two data sources: the Oregon All Payers All Claims (APAC) database and the carrier data call.[31] These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type and commercial market segment.

Table 9 presents the average annual enrollee cost-sharing amounts derived from APAC and carrier-submitted data. The APAC data, which includes claims from commercial, Medicaid, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs that varied by payer line of business. For example, **commercial insured enrollees recorded higher average annual OOP costs** than Medicare enrollees, while Medicaid enrollees incurred no OOP costs.

Carrier-submitted data, which capture only commercially insured enrollees in Oregon's individual, small group, and large group markets, also showed variation across segments. On average, **enrollees in the large group market paid higher OOP costs per enrollee** compared to those in small group plans, while individual group enrollee costs fell between the two. Copayment, coinsurance, and deductible amounts are delineated separately within each data source, reflecting differences in plan design and reporting requirements.

Differences between the APAC and carrier data sources may reflect methodological and population differences, including the exclusion of health plans with fewer than 5,000 covered lives from the APAC reporting requirement and the effect of price concessions on carrier-reported figures.

Table 9 Average annual enrollee out-of-pocket costs between APAC and data call

APAC claim line of business	Commercial	Medicaid	Medicare
Number of claims	6,541	1,842	3,952
Number of enrollees	1,388	408	842
Total copay	$358,655	$0	$149,306
Total coinsurance	$398,557	$0	$164,057

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

APAC claim line of business	Commercial	Medicaid	Medicare
Total deductible	$349,169	$0	$111,920
Total enrollee paid	$1,106,346	$0	$396,829
Average copay per claim	$6,541	$1,842	$3,952
Average coinsurance per claim	$1,388	$408	$842
Average deductible per claim	$55	$0	$38
Average cost across all claims	$61	$0	$42
Average copay per enrollee	$53	$0	$28
Average coinsurance per enrollee	$169	$0	$100
Average deductible per enrollee	$258	$0	$177
Average cost across all enrollee OOP	$287	$0	$195

Data call market type	Large Group	Small Group	Individual
Number of claims	708	3086	860
Number of enrollees	146	757	200
Total copay	$20,196	$141,898	$22,199
Total coinsurance	$133,098	$85,087	$235,790
Total deductible	$121,169	$73,945	$53,562
Total other (i.e. PAP)	$1,454	$1,430	$0
Average copay per claim	$29	$46	$26
Average coinsurance per claim	$188	$28	$274
Average deductible per claim	$171	$24	$62
Average cost across all claims	$390	$98	$362
Average copay per enrollee	$138	$187	$111
Average coinsurance per enrollee	$912	$112	$1,179
Average deductible per enrollee	$830	$98	$268
Average OOP cost per enrollee	$1,890	$399	$1,558

Table 10, further describes the distribution of annual enrollee OOP costs, providing measures of central tendency such as minimum, median, and maximum costs observed.

Table 10 OOP costs central tendency of Nurtec ODT costs in 2023

Out-of-pocket costs per-enrollee-per-year[32]		
Average	*Enrollees pay this much on average*	$607
Minimum	*The lowest amount any one enrollee paid*	$0
Median	*Half of enrollees pay more than this amount and half pay less*	$15
Max	*The highest amount any one enrollee paid*	$3,665

Clinical information based on manufacturer material[33]

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

Drug indications

- FDA Approved:
  - acute treatment of migraine with or without aura in adults
  - preventive treatment of episodic migraine in adults

- Off Label Uses: None

Clinical efficacy

Acute Treatment of Migraine

The efficacy of Rimegepant ODT in the acute treatment of moderate-to-severe migraine was studied in one randomized, double-blind, placebo-controlled trial (N=1,466). The co-primary endpoints were pain freedom at 2 hours and freedom from most bothersome symptoms (MBS) (Table 10). In addition to the primary endpoints, Rimegepant demonstrated a statistically significant reduction in sustained pain freedom in up to 48 hours and use of rescue medication.

Table 11 Clinical Efficacy in Acute Treatment of Migraine

Endpoint	Rimegepant ODT	Placebo	p-value	Mean difference (95% CI)
Pain freedom	21.2%	10.9%	<0.001	10.4% (6.5% to 14.2%)

[32] For patients who used the drug at least once in the 2023 calendar year.
[33] U.S. Food & Drug Administration. Nurtec ODT (rimegepant) Prescribing Information. Pfizer, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf

Endpoint	Rimegepant ODT	Placebo	p-value	Mean difference (95% CI)
Freedom from most bothersome symptom (MBS)*	35.1%	26.8%	0.001	8.3% (3.4% to 13.2%)

*MBS commonly included photophobia, nausea, or phonophobia.

Preventive Treatment of Episodic Migraine

The efficacy of Rimegepant ODT in the prevention of episodic migraines was shown in one 12-week, randomized, double-blind trial (N=747) comparing Rimegepant ODT 75 mg orally every other day to placebo in patients with ~10 monthly migraine days. The primary outcome was change in migraine days per month (Table 11). Rimegepant modestly reduced decreased monthly migraine days compared to placebo by about 1 migraine day/month.

Table 12 Clinical Efficacy in Preventive Treatment of Episodic Migraine

Endpoint	Rimegepant ODT	Placebo	Difference (95% CI)	p-value
Decrease Monthly migraine days (Weeks 9–12)	–4.3	–3.5	–0.8 (–1·46 to –0·20)	0.010
≥50% reduction in migraine days	49.1%	41.5%	7.6% (0 to 15)	0.044

Clinical safety

- FDA safety warnings and precautions:
  - Hypersensitivity Reactions: Severe hypersensitivity reactions have included dyspnea and rash, and can occur days after administration.
  - Hypertension
  - Raynaud's Phenomenon
- Contraindications:
  - Patients with a history of hypersensitivity reaction to rimegepant
- Common adverse effects:
  - Gastrointestinal: abdominal pain (≤2%), dyspepsia (≤ 2%), nausea (2-3%)

Therapeutic alternatives:[34,35,3637,38,39,40,41]

Table 13 FDA Approved Indications

Drug	Acute Migraine	Episodic Migraine Prevention	Chronic Migraine Prevention	Cluster Headache Prevention
Small molecule CGRP Receptor Antagonists (rapid acting)				
Subject Drug ***Rimegepant*** **(Nurtec ODT)**	Yes	Yes	N/A	N/A
Ubrogepant **(Ubrelvy)**	Yes	No	No	No
Atogepant **Qulipta**	No	Yes	Yes	No
Zavegepant **(Zavzpret)**	Yes	No	No	No
Monoclonal Antibody CGRP Inhibitors (long acting)				
Erenumab **(Aimovig)**	No	Yes	Yes	No
Fremanezumab **(Ajovy)**				
galcanezumab **(Emgality)**	No	Yes	Yes	Yes (episodic)
Eptinezumab **(Vyepti)**	No	Yes	Yes	No

[34] U.S. Food & Drug Administration. *Nurtec ODT (rimegepant) Prescribing Information*. Pfizer, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf
[35] U.S. Food & Drug Administration. *Aimovig (erenumab-aooe) Prescribing Information*. Amgen Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761077s015lbl.pdf
[36] U.S. Food & Drug Administration. *Ajovy (fremanezumab-vfrm) Prescribing Information*. Teva Pharms., Revised 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761089s013lbl.pdf
[37] U.S. Food & Drug Administration. *Emgality (galcanezumb-gnlm) Prescribing Information*. Eli Lily, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf
[38] U.S. Food & Drug Administration. *Qulipta (atogepant) Prescribing Information*. Abbvie, Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215206s004lbl.pdf
[39] U.S. Food & Drug Administration. *Ubrelvy (ubrogepant) Prescribing Information*. AbbVie Inc., Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/211765s007lbl.pdf
[40] U.S. Food & Drug Administration. *Zavzpret (zavegepant hydrochloride) Prescribing Information*. Pfizer, Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/211765s007lbl.pdf
[41] U.S. Food & Drug Administration. Vyepti (*eptinezumab-jjmr) Prescribing Information*. Lundback Seattle BioPharm, Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215206s004lbl.pdf

Table 14 Efficacy for Chronic or Episodic Migraine Prevention

Drug	Migraine days per month (mean difference from placebo) in Episodic	Migraine days per month (mean difference from placebo) in Chronic	Percentage with at least 50% reduction in number of migraine days per month
Small Molecule CGRP Receptor Antagonists (rapid acting)			
Subject drug ***Rimegepant*** **(Nurtec ODT)**	-0.8	N/A	49%
Atogepant **(Qulipta)**	-0.7 to -1.7	N/A	N/A
Monoclonal Antibody CGRP Inhibitors (long acting)			
Erenumab **(Aimovig)**	-1.0 to -2.3	-2.5	~25%
Fremanezumab **(Ajovy)**	-1.5 to -3.0	-1.7 to -2.0	16-22%
Galcanezumab **(Emgality)**	–-1.0 to -2.0	–-2.0	~28%
Eptinezumab **(Vypeti)**	-1.0	-2.0 to 2.6	14%-22%

Table 15 Efficacy in acute migraine treatment

Drug	Freedom from pain at 2 hours (mean difference from placebo)/number needed to treat (NNT)	Freedom from most bothersome symptoms at 2 hours (mean difference from placebo)/number needed to treat (NNT)
Small Molecule CGRP Receptor Antagonists (rapid acting)		
Subject drug ***Rimegepant*** **(Nurtec ODT)**	~10-16% NNT 10-14	~8-12% NNT 9-13
Urbrogepant **(Ubrelvy)**	~7.5-16% NNT 9-14	10% NNT 10
Zavegepant **(Zavzpret)**	~7% NNT 14	8-9% NNT 12-13

Table 16 Adverse Effects (AEs)

Drug	Common AEs	Notable Risks
Small Molecule CGRP Receptor Antagonists (rapid acting)		
Subject drug ***Rimegepant* (Nurtec ODT)**	Nausea (~2%), indigestion	Hypersensitivity (rare)
***Urbrogepant* (Ubrelvy)**	Nausea, somnolence (≥2%)	Minimal serious risks; contraindicated with strong CYP4A inhibitors
***Atogepant* (Qulipta)**	Nausea, constipation, fatigue/somnolence	Generally mild GI effects
***Zavegepant* (Zavzpret)**	Nasal discomfort, dysgeusia, nausea	Rare anaphylaxis; avoid with severe liver impairment
Monoclonal Antibody CGRP Inhibitors (long acting)		
***Erenumab* (Aimovig)**	Injection site reactions constipation (3–5%)	Rare serious constipation, hypertension
***Fremanezumab* (Ajovy)**	Injection site reactions	Hypersensitivity reactions requiring discontinuation and corticosteroid treatment have been reported within hours to one month after administration
***Galcanezumab* (Emgality)**	Injection site reactions, mild rash	Low incidence of hypersensitivity
***Eptinezumab* (Vypeti)**	Infusion site rxn, nasopharyngitis, throat irritation	Minimal hypersensitivity

Input from specified stakeholders

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

See Appendix page for all stakeholder feedback.

Patients and caregivers:

Note: The information presented is based on self-reported survey responses from individuals prescribed certain medications. Participation in the survey was voluntary, and the responses

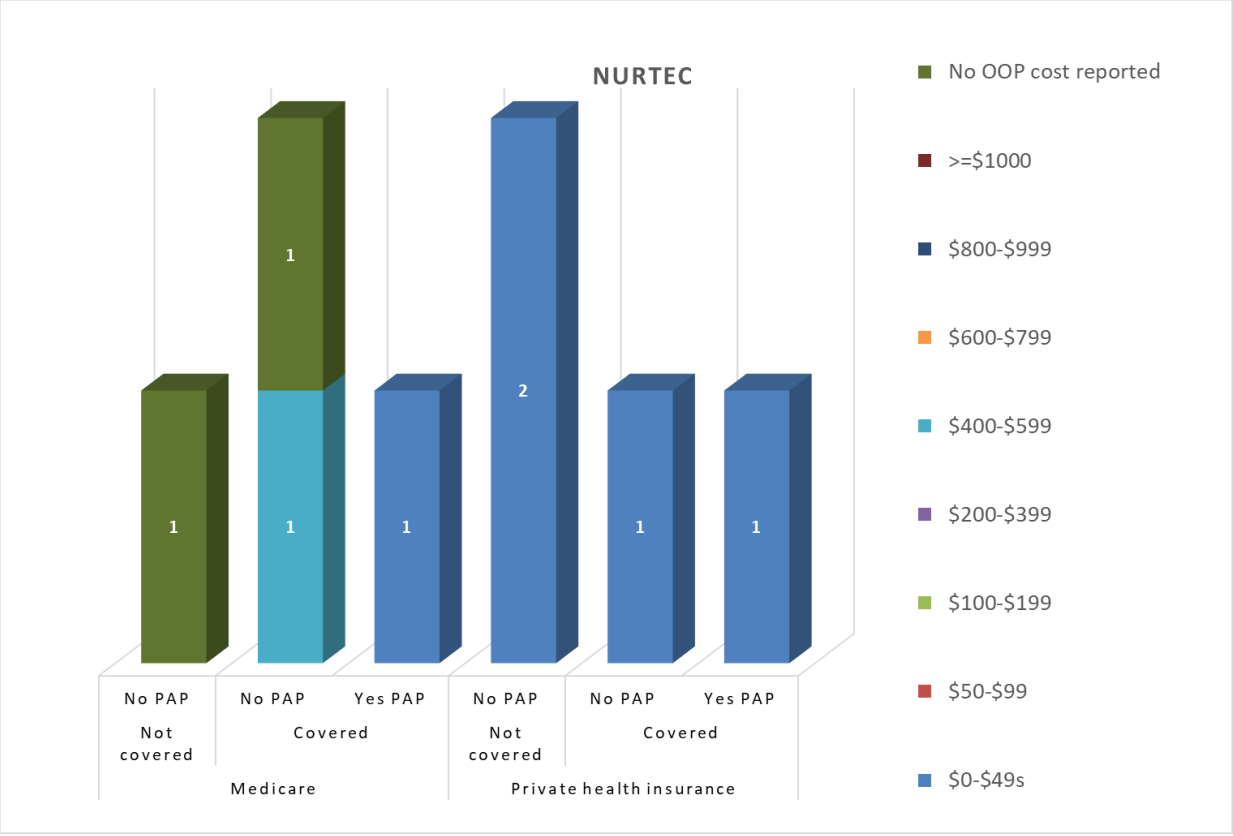
reflect each individual's personal understanding and interpretation of the question asked. As such, the data may contain inconsistencies or inaccuracies due to varying levels of comprehension, recall bias, or misinterpretation of question intent. These limitations should be considered when interpreting the responses.

Survey information was received from eight individuals taking or having an association with Nurtec. According to the survey results, five respondence had Nurtec covered under the insurance, regardless of the type of insurance used.

Table 10 indicated two patient had the drug covered under Medicare, one was on a patient assistant program (PAP) and one was not, and paid between $0-$49 or $400-$599 monthly for Nurtec.

Four patients with private health insurance did report an out-of-pocket cost between $0-$49 and one was on a PAP.

Table 17 Patient survey responses by reported for out-of-pocket costs impact based on insurance type



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

” Nurtec ”

- Nurtec helps reduce pain. My most recent, monthly, out-of-pocket cost was $442.86. I tried another medication but can no longer take the other drug due to heart problems.
- I only took a two-pill sample from my doctor. I chose not to purchase Nurtec because the out-of-pocket cost was $1,100 for eight doses. I could not afford it nor did insurance cover any of it. Nurtec blocks pain receptors during a migraine. It was the most effective medication I've taken for my migraines and it worked within 30-90 minutes to significantly reduce pain and other symptoms. I have typically used ibuprofen or acetaminophen to manage migraine pain but they often are ineffective. My insurance company denied approval for Nurtec and suggested I try other step-one meds. But they were vasoconstrictors rather than neuroreceptor blocks and I have concerns about taking vasoconstrictors because of my health history so I have not tried any. It's possible they may have covered some of the cost, but only after I tried two to five other preferred step-one drugs and proved they failed. I was extremely frustrated by the fact that my doctor could hand out a sample of this medication and for the first time, I was able to experience an extremely effective remedy for my pain without side effects. After following up on the results of the sample, my doctor wrote a prescription. But due to the lack of insurance coverage and prohibitively high out-of-pocket cost, I could not have this medication to treat what has been a nearly life-long condition. Once I realized I was not going to be able to afford this prescription, I wished my doctor had never offered me a sample. Knowing there's a drug out there that truly helps but I can't have is more painful than operating under the assumption that there is no remedy and I must make due the best I can with the management strategies I've developed throughout my lifetime.
- Nurtec has provided the most relief of any drug I've tried over the last twenty years. I have tried Sumatriptan (Imitrex), Rizatriptan (Maxalt), Naproxen Sodium, Ibuprofen, Excedrin Migraine, Ubrogepant (Ubrelvy), Topiramate (Topamax), Amitriptyline (Elavil – tricyclic), Nortriptyline, Erenumab (Aimovig), Galcanezumab (Emgality), Botulinum toxin, Magnesium, Ganglion blocks (SPG block), Ketorolac (Toradol) IV, Ketorolac once it was available in pill form, Metoclopramide (Reglan) IV, Diphenhydramine (Benadryl) IV, Diphenhydramine OTC, Saline IV fluids, Zofran (Ondansetron) IV, Zofran (Ondansetron) Oral, and probably others I cannot remember. For Nurtec, I pay $4.80 through Medicare Part D Extra Help. This process has been long and exhausting. Getting prescription drugs for chronic migraines is a horrible experience.
- Nurtec stops a migraine and prevents a new one for 24 hours. I tried other medications and they had undesirable side effects or just didn’t work. It took much back and forth between my doctor (a neurologist) and my insurance company to get the insurance to

finally cover it. One of the things that made the drug affordable was a coupon I was able to use from the company directly. My monthly, out-of-pocket cost is very little, a couple of dollars.

- I rely on samples because insurance won't cover any part of it. Nurtec provides very rapid relief. I tried Sumatriptan, which caused the migraine to become worse. Since I've had the knowledge of the medication, insurance has never covered it. The insurance company said Nurtec is not in the formulary with no option of appeal.
- I cannot buy Nurtec. Insurance won't pay so I cannot even get it. I tried Zolmitriptan and it works ok once the migraine starts but it does not prevent migraines.
- I should be taking it now but I cannot afford it. My last refill was on 12/12/23 for a half-month supply (eight tabs). Nurtec is the only drug on the market that both treats and prevents migraines. And there is no generic, of course. I tried numerous migraine meds before I was allowed to be treated with Botox. It has been the most effective with my migraines. Nurtec was the absolute best, however. But at $53 a pill ($845 a month), I can't afford to take it. And even with the Botox, I still have other migraine meds I take as-needed, including Rizatriptan and Fioricet, plus Zofran for the nausea that always accompanies my migraines. Fun! That's why my neurologist wants me to take Nurtec - because it helps prevent migraines, not just treat them. I might not need the Rizatriptan, Fioricet, Zofran or maybe even the Botox injections if I had Nurtec to prevent my migraines. Oh what luxury that would be. I haven't been able to take it since 2023 because it's too expensive. It's a tier 4 medication with my Medicare Advantage plan, and I have to hit a $199 per year deductible and then I pay a 31 percent coinsurance.

  Currently, at an Oregon pharmacy, Nurtec is going for about $1,363 for 1 pack (eight tabs). But my neurologist wants me to take it every other day. Since there are only eight tabs in each pack, I would have to purchase two packs per month. However, my insurance will not let me fill two dose packs (16 tabs total) at the same time so I would have to fill one dose pack twice a month. They will only allow it to be filled in one-pack doses. So I can't fill a 90-day supply, for example, and save money. If I were to fill it now, it would cost $199 (my deductible) plus $423 (31 percent of $1363) for a one-dose pack, plus another $423 for the second dose pack. This comes to the total cost of $1,044 for the first month. Subsequent months would cost $845. Each pill would approximately cost $53 (after the deductible). That's for this one medication alone. And that's with prescription insurance coverage. The insane price of this medication makes taking it simply impossible.

Individuals with scientific or medical training

A survey of healthcare professionals with scientific or medical training identified key barriers for patients in accessing medications. A main obstacle reported was the need for prior authorization for insurance approval before prescriptions can be provided. Other challenges include step therapy protocols, quantity limits, and medication costs. Few respondents viewed PBM or formulary issues as a barrier to accessing drugs.

One healthcare professional reported prior authorization, one healthcare professional reported step therapy, one healthcare professional reported quantity limit, and one healthcare professional reported medication cost of Nurtec were administrative burdens and laborious for patients to access the medication.

Table 18 Reported administration burden of the drug for patient to access

Drug	Prior Authorization	Step Therapy	Quantity Limit	Cost	PBM/ formulary issues	Considered first line of therapy
Nurtec	Yes	Yes	Yes	Yes	-	-

Safety net providers

The information reported by safety net providers express their experience dispensing Nurtec ODT, particularly in relation to the federal 340B Drug Pricing Program. The survey collected information on utilization of the drug, the extent to which it was eligible for 340B discounts, dispensing arrangements, and payment and reimbursement levels.

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

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

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

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

Without additional detail on the volume of patients treated or the per-claim costs, it is difficult to interpret the figures in terms of clinic financial risk or access outcomes. The wide range may

reflect differing clinic sizes, patient populations, or inventory management practices. Notably, the absence of full reporting by 55 percent of clinics makes it challenging to assess how Nurtec ODT's cost affects long-term affordability or sustainability for safety-net providers.

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

Table 19 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	7
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between $0-$100,000	27%
Reported total amount paid for drug under 340B was between $100,001-$300-000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between $0-$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between $100-001-$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between $500,000-$10,000,000	18%

Table 20 Amounts paid for drug under 340B discount program

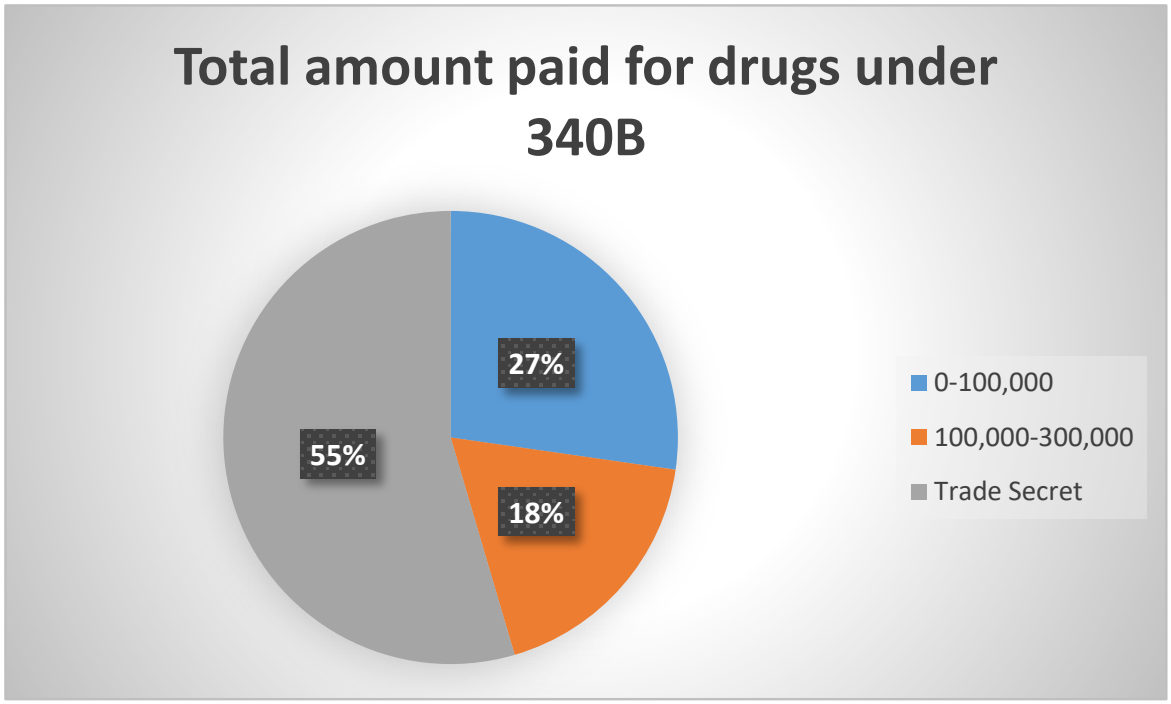
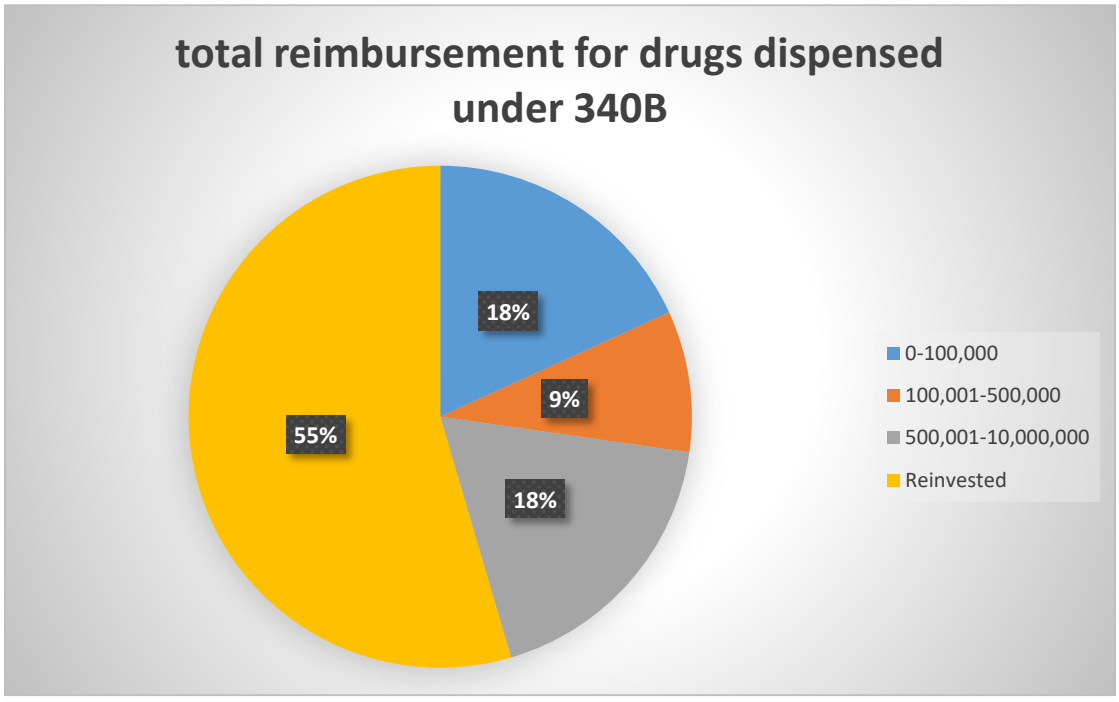


Table 21 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program



Payers

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

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

Appendix

Stakeholder feedback:

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Tom Brown	Pfizer	Nurtec ODT	Letter	6/18/25	**Exhibit A**

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

Ubrelvy®
(*ubrogepant*)[1]

Version 2.0

[1] https://everyone.org/ubrelvy-ubrogepant

Table of Contents

Document version history

Version	Date	Description
v1.0	7/9/2025	Original Release
v2.0		Updated gross spend amounts in the “Cost to the healthcare system” section; added a “Cost to payers” section; updated table 3 to reflect costs to the healthcare system; added table 4 for payer paid amounts; updated sections referencing patients to reference enrollees; added the drug name to the footer; Table 2 removed Total for paid/enrollee & claims and indicated the number as an average; updated summary page

Review summary

Price history

Ubrelvy® (*ubrogepant*) was first approved by the FDA in 2019 for the preventative treatment of migraine. Since entering the market, the wholesale acquisition cost **(WAC) has risen at an average annual rate of 5.0 percent, exceeding inflation** in 2023 and 2024.[2,3] As of late 2024, the **WAC reached approximately $103.32 per unit**, with **Medicaid acquisition costs (AAAC) tracking 4.04 percent discount**.

Cost to the healthcare system[4,5]

According to Oregon's 2023 All Payers All Claims (APAC) data:

- **$11,813,998 in total gross spending** for Ubrelvy, across **2,431 enrollees** and **11,854 claims**.
- The gross spend was **$4,860 per enrollee** and **$997 per claim.**

According to data from commercial payers:

- **$4,675,309 in total net spending** for Ubrelvy across **1,336 enrollees** and **4,710 claims**.
- The net spend was **$3,499 per enrollee** and **$933 per claim.**

Cost to payers[6,7]

According to Oregon's 2023 APAC data:

- **$10,583,552** in payer spending for Ubrelvy, across **2,288 enrollees** and **11,854 claims**.
- The average annual payer spend was **$4,626 per enrollee** and **$893 per claim**.

According to data from commercial payers:

- **$4.1 million** in net spending across **1,336 enrollees** and **4,710 claims**.
- The net spend was **$3,079 per enrollee** and **$873 per claim**.

[2] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span
[3] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/
[4] Ibid.
[5] 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.
[6] Ibid.
[7] Based on Oregon's 2023 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.

Cost to enrollees[8,9]

Enrollee out-of-pocket (OOP) costs varied by data source:

- APAC data showed average OOP costs of **$737 per commercial enrollee, $402 per Medicare enrollee** with **$0 for Medicaid enrollees.**
- Carrier data showed commercial market variation:
    - **Large group plans** averaged **higher** annual OOP costs.
    - **Enrollees under coinsurance plans** face higher OOP costs.
- Medicaid enrollees experienced no direct OOP spending due to full coverage under the fee-for-service model.
- The average **OOP cost from the data call was $421 per enrollee** in 2023.

Price concessions[10]

Carrier-reported data indicates that **67.2 percent** of Ubrelvy claims included some form of price concession based on 2023 data. Manufacturer rebates accounted for the majority of these discounts, followed by pharmacy benefit managers (PBM) price concessions and other negotiated reductions. **Average gross cost per enrollee was $3,603, with net costs reduced to $2,777 after applying concessions**. Total estimated price reductions across carriers amounted to **$1.1 million**, an average **discount of approximately 22.9 percent**.

Therapeutic alternatives[11]

Two CGRP-targeting therapies were reviewed as therapeutic alternatives: **Nurtec ODT and Zavzpret**. Compared to Ubrelvy:

- **Nurtec ODT** used for acute migraine treatment.
- **Zavzpret** is a intranasal spray

Access and equity considerations[12]

- Only **7.9 percent** of formularies list Ubrelvy as a preferred drug; **68.8 percent** require prior authorization and **3.1 percent** require step therapy.

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[8] Based on Oregon's 2023 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 visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[9] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.
[10] Ibid.
[11] Based on Oregon's 2023 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.
[12] Ibid

Review background

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

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

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

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

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

Drug Information[13]

Drug proprietary name(s)	Ubrelvy®
Non-proprietary name (active ingredient):	*ubrogepant*
Manufacturer	AbbVie, Inc.
Treatment:	A calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine with or without aura in adults.
Dosage strength	50 mg and 100 mg
Dosing:	50 – 100 mg as needed for acute migraine attack

[13] U.S. Food & Drug Administration. Ubrelvy (ubrogepant) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/211765s007lbl.pdf

Rought of administration	By mouth
Physician administered	No

FDA approval

Ubrelvy was first approved by the FDA on 12/23/2019.[14]

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

At time of the review, the drug had no designation indications under the Orphan Drug Act.

Health inequities

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

Clinical trials for migraine medications—including **Emgality (fremanezumab), Emgality (galcanezumab), Nurtec ODT (rimegepant)**, and **Ubrelvy (ubrogepant)**—have historically underrepresented racial and ethnic minority groups. A review of migraine clinical trials published in *Headache* found that **less than 15 percent** of participants across studies identified as non-white, with **Black Americans comprising less than 2 percent** of study cohorts in many trials—despite experiencing migraine at similar or greater rates than white populations.[15] This lack of diversity limits the generalizability of trial findings and raises concerns about whether these medications perform equally well across all demographic groups.

The **Institute for Clinical and Economic Review (ICER)** highlighted similar concerns in its review of acute migraine treatments, noting that **trial enrollment did not reflect the real-world racial and ethnic diversity of people living with migraine**, particularly underrepresenting Black and Hispanic patients.[16] In contrast, the FDA's *Drug Trials Snapshot* for **Nurtec ODT** provides limited but promising subgroup data: pain relief rates were found to be **comparable across racial groups,** with **23.3 percent of Black participants and 21.2 percent of white participants** achieving pain freedom at two hours.[17] However, without consistent subgroup analysis across all CGRP-targeting therapies, disparities in both trial design and real-world access remain.

R**eal-world evidence** shows that **Black and Hispanic individuals are less likely to be diagnosed with migraine or prescribed advanced treatments**, even when accounting for socioeconomic

[14] FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, the earliest approval date across all related FDA applications was used.
[15] Robbins NM, Bernat JL. "Minority Representation in Migraine Treatment Trials." *Headache*. 2017;57(3):525-533. PMID: 28127754
[16] Institute for Clinical and Economic Review (ICER). "Acute Migraine Treatments – Final Evidence Report." January 2020. https://icer.org/wp-content/uploads/2020/10/ICER_Acute-Migraine_Evidence_Report_011020_updated_011320_-2.pdf
[17] FDA. "Drug Trials Snapshot: Nurtec ODT." https://www.fda.gov/drugs/development-approval-process-drugs/drug-trials-snapshots-nurtec-odt

status. This reflects broader systemic inequities in pain recognition, access to specialists, and treatment authorization. Compounding these disparities are **structural barriers** such as geographic isolation, lower health literacy, and provider bias[18]—all of which influence medication adherence, proper use of self-injection therapies, and management of side effects.

To ensure equitable care, future clinical research should prioritize diverse enrollment and transparent subgroup reporting, while health systems and payers must address access and affordability gaps for historically underserved populations.

Residents prescribed

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

In 2023, the Oregon APAC database recorded **2,288 unique individuals** with at least one filled prescription for Ubrelvy.[19] In contrast, the **commercial health benefit plan data call**, which included submissions from 11 reporting carriers, identified **1,336 enrollees** with a Ubrelvy prescription fill during the same period.[20]

The substantial variance between the two figures is attributable to differences in data scope and reporting mandates. APAC is a comprehensive claims repository that aggregates utilization data across all payer types, including Medicaid, Medicare, and commercial lines of business. In contrast, the data call process captures a limited subset of commercially insured enrollees and is restricted to the reporting obligations of participating health plans. As a result, APAC offers a more inclusive estimate of statewide utilization, while the carrier-submitted data reflect only a narrow segment of the insured population.

Price for the drug

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

This section examines the pricing dynamics of Ubrelvy, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of the wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), as well as the impact of negotiated prices concessions which include discounts, rebates, and other price reduction negotiations. Together, these data provide a comprehensive view of

[18] Williams DR, Mohammed SA. "Discrimination and Racial Disparities in Health: Evidence and Needed Research." *J Behav Med*. 2009;32(1):20–47. PMC2443411

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

[20] Based on 2023 data collected by DCBS under authorities granted in ORS 731.296 and OES 646A.963 through ORS 646A.697 from Oregon health insurance plans. Cost information from the data call is the cost of the drug after price concessions.

Ubrelvy's list price trajectory, pharmacy acquisition costs, and the degree to which price reductions are realized in practice by payers in Oregon.

Price history

The wholesale acquisition cost (WAC) of Ubrelvy, averaged across three reported national drug codes (NDCs), was approximately **$103.32 per unit** at the end of 2024.[21] Between 2018 and 2024, the unit WAC increased at an average annual rate of **5.0 percent**, exceeding the general inflation rate (CPI-U) in 2020 to 2024 (see Figures 1 and 2).[22]

Unit 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.

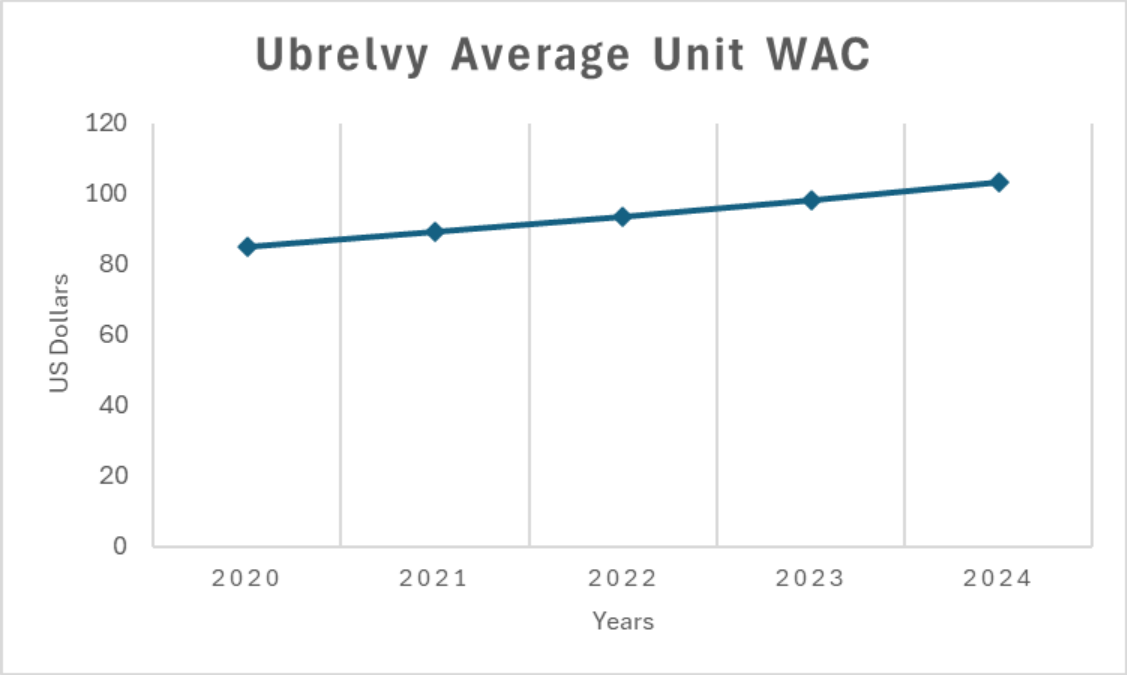


Figure 1 Ubrelvy average unit WAC from 2020-2024

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

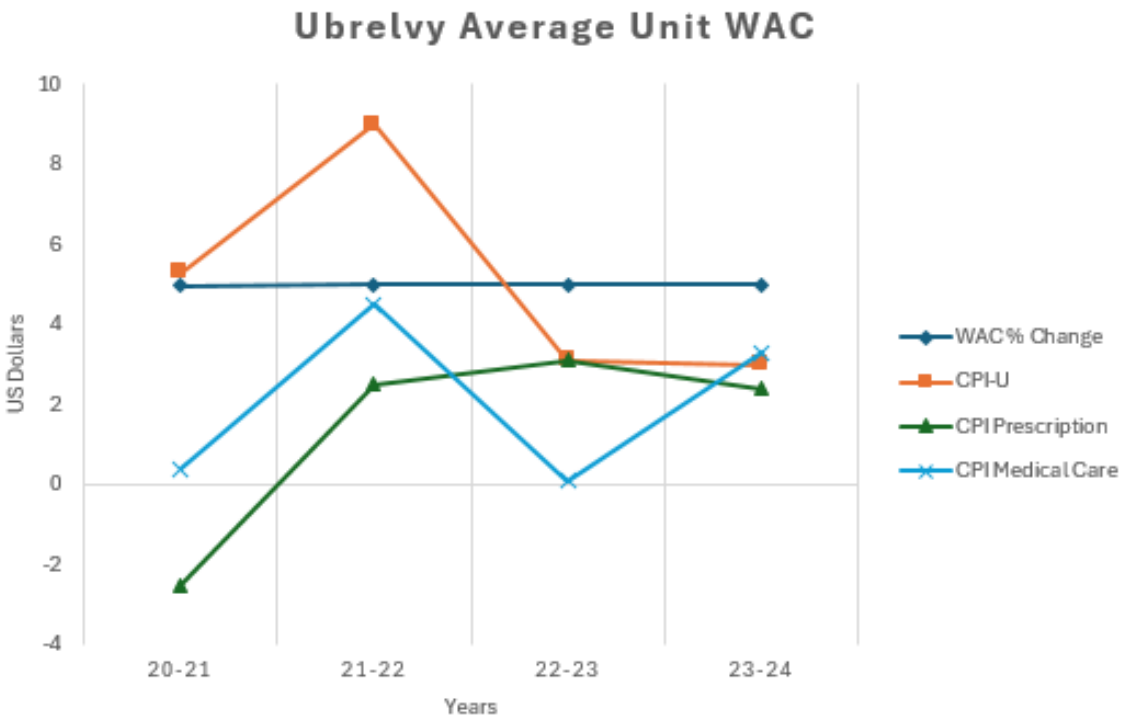


Figure 2 Year over year change in unit WAC compared to inflation rates[23]

Pharmacy acquisition costs

The Oregon Actual Average Acquisition Cost (AAAC), which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$81 per unit in Q3 2020 to $99 per unit in Q4 2024**, an approximate **22 percent increase** over the period (see Figure 3).[24] Relative to the $103 WAC in end-of-year 2024 a **AAAC discount of 4.04%** is indicated.

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

[23] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/
[24] Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2023. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. https://myersandstauffer.com/client-portal/oregon/

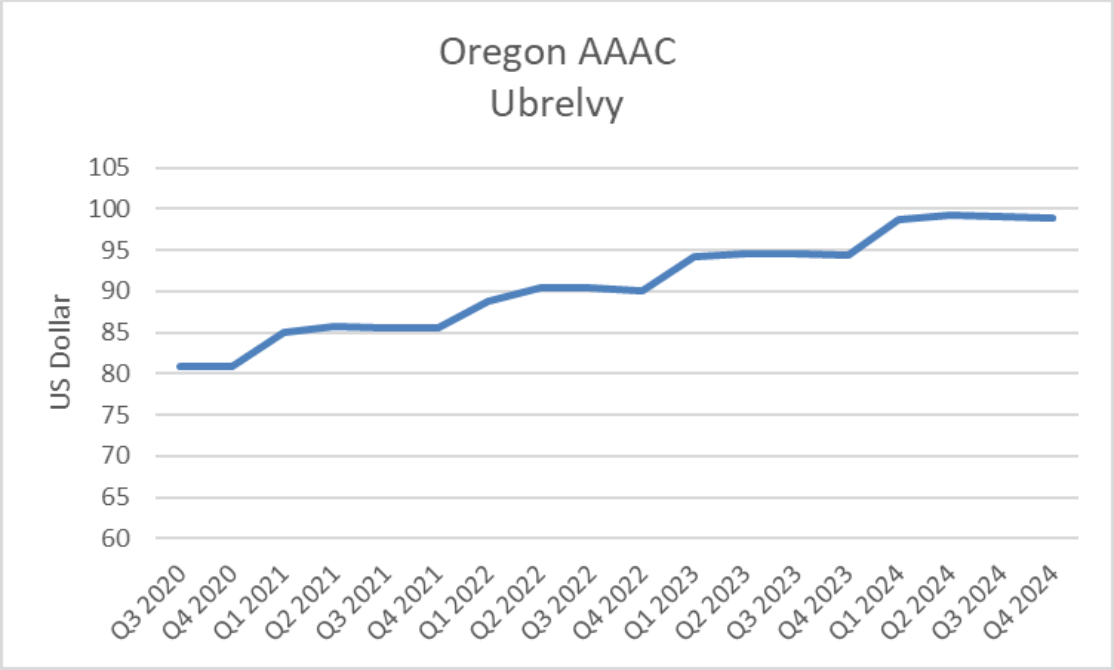


Figure 3 AAAC for Ubrelvy from Q3 2020 to Q4 2024

Estimated average monetary price concession

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

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

Based on carrier-submitted data for 2023, the **average gross cost of Ubrelvy per enrollee in the commercial market was approximately $3,603**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $2,777**, reflecting an **estimated mean discount of 22.9 percent** relative to gross costs.

Across all reporting carriers and market segments, **the total cost of Ubrelvy before concessions was $4,814,240**, with total reported price concessions amounting to approximately **$1,104,328**, as detailed in Table 1. Notably, **67.2 percent of claims benefited from some form of price concession**, leaving **32.8 percent at full gross cost**. Figure 4 shows manufacturer concessions comprised the largest share, supplemented by PBM discounts and other adjustments across the payer types.

Table 1 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	1,336
Total number of claims	4,710
Total number of claims with price concessions applied	3,167
Percentage of claims with price concessions applied	67.2%
Percentage of cost remaining after concessions	77.1%
Manufacturer price concessions for all market types	$761,388
PBM price concessions for all market types	$297,367
Other price reductions for all market types	$45,574
Cost before price concessions across all market types	$4,814,240
Total price concessions across all market types	$1,104,328
Cost of after price concessions across all market types	$3,709,912
Avg. payer spend per enrollee without price concessions	$3,603
Avg. payer spend per enrollee with price concessions	$2,777

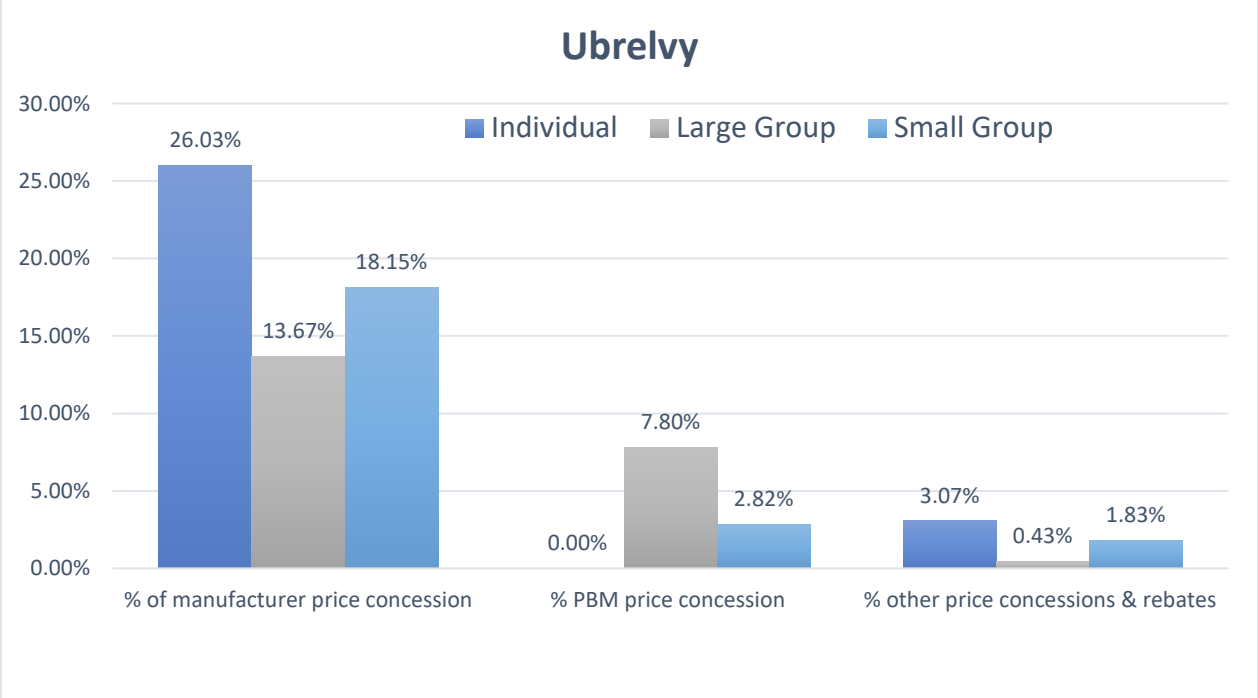


Figure 4 Percent of price concession in each market type

Estimated total amount of the price concession

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

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

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

Estimated price for therapeutic alternatives[25]

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

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

Ubrelvy's **gross cost per claim, based on APAC data, was $997**, while **net cost data showed a higher per-claim amount of $993**. Compared to Ubrelvy, both therapeutic alternatives had higher gross cost per claim, at $1,197 and $1,068, while Nurtec had a slightly higher gross cost per enrollee and Zavspret had a lower cost per enrollee. Nurtec had 12,335 claims, which is more comparable to the utilization of Ubrelvy than Zavspret, which had 41 claims.

Out-of-pocket costs also varied with enrollee payments for Ubrelvy in **APAC averaging $104 per claim**. Therapeutic alternative such as Nurtec and Zavzpret reported enrollee-paid amounts ranging from $60 to $122 per claim.

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

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

Table 2 Average healthcare and average enrollee OOP costs for Ubrelvy vs therapeutic alternatives

Drug	Total spend	No. of enrollees [26]	No. of claims	Avg.paid/ claim	Avg, Paid/ enrollee	Total payer paid	Total enrollees paid	Payer paid/ claim	Enrollee paid/ claim
Subject Drug **Ubrevly (data call)**	**$4,675,309**	**1,336**	**4,710**	**$993**	**$3,499**	**$4,113,406**	**$561,903**	**$873**	**$119**
Subject Drug **Ubrevly (APAC)**	**$11,813,998**	**2,288**	**11,854**	**$997**	**$5,163**	**$10,583,552**	**$1,230,446**	**$893**	**$104**
Nurtec	$14,730,840	2,478	12,335	$1,194	$5,945	$13,227,665	$1,503,175	$1,072	$122
Zavzpret	$43,807	18	41	$1,068	$2,434	$41,360	$2,447	$1,009	$60

Estimated average price concession for therapeutic alternatives

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

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

The statutory and regulatory criteria call for consideration of such information to the extent practicable; however, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this information as additional data become available through carrier reporting, manufacturer disclosures, or other sources.

Estimated costs to health insurance plans

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

This section quantifies the financial impact of Ubrelvy on health insurance plans in Oregon, based on claims and expenditure data from APAC and the carrier data call. Costs are delineated

[26] The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 2, as compared to other totals indicated in this report.

by payer type—including commercial, Medicaid, and Medicare—as well as by market segment within the commercial population. These estimates highlight the distribution of expenditures across different health coverage lines and inform assessments of the drug's budgetary implications for public and private payers.

In 2023, the Oregon APAC database recorded **11,854 total claims for Ubrelvy among 2,431 total enrollees**, corresponding to a **total system gross expenditure of $10,582,552**. This equates to a total of an average **annual spend of $13,130 per enrollee**, or approximately **$2,770 per claim**.

Table 3 provides gross cost estimates by the total APAC system spend across all lines of business:

- **Commercial** accounted for the largest share of utilization, with 6,871 claims from 1,343 enrollees and a total spend of **$6.8 million**.
- **Medicare** and **Medicaid** payers reported smaller but notable expenditures of approximately **$2.9 million** and **$2.1 million**, respectively.

Table 3 Estimated 2023 APAC total gross costs to the healthcare system[27]

Payer line of business	Total enrollees	Total claims	Total gross cost amount	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,343	6,871	$6,759,227	5,033	$984
Medicaid	491	2,323	$2,129,488	$4,337	$954
Medicare	597	2,751	$2,925,283	$4,900	$1,063
Totals	**2,431**	**11,854**	**$11,813,998**	**$14,290**	**$3,001**

Table 4 provides gross APAC cost estimates for **payer spend across all lines of business** with **11,854 total claims for Ubrelvy among 2,431 total enrollees.** The **payers gross expenditure of $10,583,552**, equated to a total of an average **annual cost of $13,130 per enrollee**, or approximately **$2,770 per claim**.

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

Table 4 Estimated 2023 APAC gross cost to the payers[28]

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,343	6,871	$5,768,819	$4,295	$840
Medicaid	491	2,323	$2,129,488	$4,337	$954
Medicare	597	2,751	$2,685,245	$4,498	$976
Totals	**2,431**	**11,854**	**$10,583,552**	**$13,130**	**$2,770**

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (76% of total), followed by individual group and small group markets. The collected **total net cost to the healthcare system was around $4.7 million**, with payer paying $4.1 million, and enrollees out-of-pocket estimating to be $561,903. Table 5 includes the average plan costs per enrollee in the commercial market ranged from **$3,812 (individual)** to **$3,402 (small group)** annually.

Table 5 Estimated 2023 data call total net costs to the healthcare system, payers, and enrollee OOP[29]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of-pocket cost
Individual	562	158	$602,365	$446,880	$155,485
Large Group	3,628	1,025	$3,552,472	$3,306,012	$246,460
Small Group	520	153	$520,471	$360,514	$159,957
Total	**4,710**	**1,336**	**$4,675,309**	**$4,113,406**	**$561,903**

Market	Avg. plan spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plan spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Individual	$1,072	$795	$277	$3,812	$2,828	$984
Large Group	$979	$911	$68	$3,466	$3,225	$240
Small Group	$1,001	$693	$308	$3,402	$2,356	$1,045

[28] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[29] Cost information from the data call is the cost of the drug after price concessions.

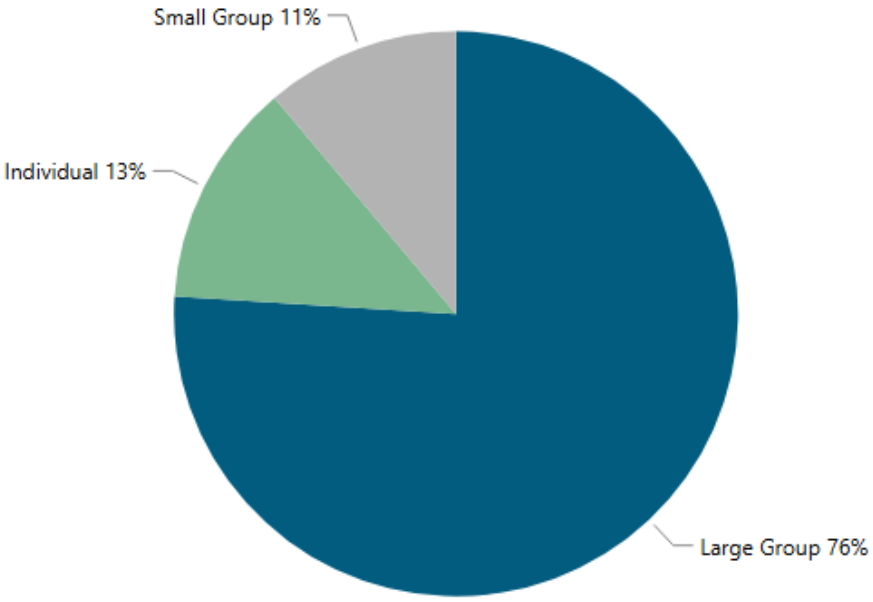


Figure 5 Data call percent of total annual spend (payer paid)

Cost to the state fee-for-service program, represented in Table 6, indicates Ubrelvy was not included on the top 40 quarterly reports. Table 7 reflects Ubrelvy was not on the Coordinated Care Organization (CCO) top 50 drugs by gross amount paid.

Table 6 2023 Gross amount paid for Medicaid/Oregon Health Plan fee for service

Fee for Service[30]							
2023 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	Drug not on report						
Q2	Drug not on report						
Q3	Drug not on report						

[30] Oregon State University Drug Use and Research Management DUR utilization reports 2023. College of Pharmacy, Oregon State University. https://pharmacy.oregonstate.edu/research/pharmacy-practice/drug-use-research-management/dur-reports

Fee for Service[30]							
2023 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	Drug not on report						
Annual Average:							

Drug not indicated in Q1-Q4 of top 40 quarterly reports of the pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Table 7 2023 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	Amount paid	Claim count	Average paid per claim
Drug not on report			

Pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Impact on patient access to the drug

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

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Ubrelvy, including prior authorization requirements, step therapy protocols, and formulary placement. These data describe how the drug is positioned within insurance benefit designs and the extent to which utilization management processes were applied during the reporting period.

Based on information reported through the carrier data call, the follow plan design features were observed for Ubrelvy. In 2023, approximately **68.8% of reporting plans required prior authorization (PA)** for coverage of the drug, and **3.1% of plans required step therapy** before approving its use.

Among the **1,960 PA requests** recorded during the reporting period, **1,787 were approved (91.2%)** and **173 were denied (8.8%)**.

For formulary placement, **90.4% of plans categorized Ubrelvy as a non-preferred drug**, **7.9% listed it as preferred**, and **1.8% excluded it entirely from the formulary**.

Table 8 Plan design analysis from 2023 data call

Total prior authorizations	1,960
Number of approved prior authorizations	1,787
Number of denied prior authorizations	173
Percentage of approved prior authorizations	91.2%
Percentage of denied prior authorizations	8.8%
Percentage of plans requiring pre-authorization	68.8%
Percentage of plans requiring step therapy	3.1%
Percentage of plans where drug preferred on formulary	7.9%
Percentage of plans where drug non-preferred on formulary	90.4%
Percentage of plans where drug excluded on formulary	1.8%

Relative financial impacts to health, medical or social services costs

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

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

The statutory and regulatory criteria contemplate consideration of such impacts to the extent practicable. However, due to limitations in available evidence, data systems, and the challenges inherent in isolating the indirect effects of a single drug on broader healthcare or social service costs, this analysis was not performed.

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

Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Nurtec ODT in Oregon, as reported in 2023 by the two data sources: the Oregon All Payers All Claims (APAC) database and the carrier data call.[31] These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type and commercial market segment.

Table 9 presents the average annual enrollee cost-sharing amounts derived from APAC and carrier-submitted data. The APAC data, which includes claims from commercial, Medicaid, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs that varied by payer line of business. For example, **commercially insured enrollees recorded higher average annual OOP costs** than Medicare enrollees, while Medicaid enrollees incurred no OOP costs.

Carrier-submitted data, which capture only commercially insured enrollees in Oregon's individual, small group, and large group markets, also showed variation across segments. On average, **enrollees in the small market group paid higher OOP costs per enrollee** compared to those in small group plans, while individual group enrollee costs fell between the two. Copayment, coinsurance, and deductible amounts are delineated separately within each data source, reflecting differences in plan design and reporting requirements.

Differences between the APAC and carrier data sources may reflect methodological and population differences, including the exclusion of health plans with fewer than 5,000 covered lives from the APAC reporting requirement and the effect of price concessions on carrier-reported figures.

Table 9 Average annual enrollee out-of-pocket costs between APAC and data call

APAC claim line of business	Commercial	Medicaid	Medicare
Number of claims	6,871	2,232	2,751
Number of enrollees	1,343	491	597
Total copay	$398,921	$0	$65,880
Total coinsurance	$286,305	$0	$110,398
Total deductible	$305,258	$0	$71,278

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

APAC claim line of business	Commercial	Medicaid	Medicare
Total enrollee paid	$990,408	$0	$240,038
Average copay per claim	$58	$0	$24
Average coinsurance per claim	$42	$0	$40
Average deductible per claim	$44	$0	$26
Average cost across all claims	$144	$0	$87
Average copay per enrollee	$297	$0	$110
Average coinsurance per enrollee	$213	$0	$185
Average deductible per enrollee	$227	$0	$119
Average cost across all enrollee OOP	$737	$0	$402

Data call market type	Large Group	Small Group	Individual
Number of claims	3,628	520	562
Number of enrollees	1,025	153	158
Total copay	$136,082	$7,668	$6,085
Total coinsurance	$38,450	$140,908	$95,960
Total deductible	$71,019	$10,072	$51,866
Total other (i.e. PAP)	$909	$1,309	$1,574
Average copay per claim	$38	$15	$11
Average coinsurance per claim	$11	$271	$171
Average deductible per claim	$20	$19	$92
Average cost across all claims	$68	$308	$277
Average copay per enrollee	$133	$50	$39
Average coinsurance per enrollee	$38	$921	$607
Average deductible per enrollee	$69	$66	$328
Average OOP cost per enrollee	$240	$1,045	$984

Table 10, further describes the distribution of annual enrollee OOP costs, providing measures of central tendency such as minimum, median, and maximum costs observed.

Table 10 OOP costs central tendency of Ubrelvy ODT costs in 2023

Out of pocket costs per enrollee per year[32]		
Average	*Enrollees pay this much on average*	$538
Minimum	*The lowest amount any one enrollee paid*	$0
Median	*Half of enrollees pay more than this amount and half pay less*	$15
Max	*The highest amount any one enrollee paid*	$2,330

Clinical information based on manufacturer material[33]

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

Drug indications

- FDA Approved: acute treatment of migraine with or without aura in adults.
- Off Label Uses: None

Clinical efficacy

Ubrogepant (Ubrelvy) is an oral CGRP receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. It is not approved for migraine prevention. Its efficacy was demonstrated in two pivotal randomized, double-blind, placebo-controlled trials: Study 1 (ACHIEVE I) and Study 2 (ACHIEVE II) comparing Ubrogepant 50 mg and 100 mg to placebo in adults during a single migraine attack. The co-primary outcomes were pain freedom and freedom from most bothersome symptoms (MBS) at 2 hours post-dose.

Table 11 Clinical Efficacy of Ubrogepant

	Ubrogepant 50 mg	Ubrogepant 100 mg	Placebo
Pain freedom at 2 hours			
Study 1	19.2% OR 1.83; 95% CI 1.25 to 2.66)	21.2% OR 2.04 (95% CI, 1.41 to 2.95)	11.8%
Study 2	21.8% OR 1.62; 95% CI 1.14 to 2.29	N/A	14.3%
Most Bothersome Symptom Freedom at 2 hours			

[32] For patients who used the drug at least once in the 2023 calendar year.
[33] U.S. Food & Drug Administration. Ubrelvy (ubrogepant) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/211765s007lbl.pdf

	Ubrogepant 50 mg	Ubrogepant 100 mg	Placebo
Study 1	38.6% OR 1.70 (95% CI, 1.27 to 2.28)	39.7% OR 1.63 (95% CI, 1.22 to 2.17)	27.8%
Study 2	38.9% OR 1.65 (95% CI, 1.25 to 2.20)	N/A	27.4%

Long-Term Use

- In an open-label extension study, 813 patients used Ubrelvy intermittently for up to 1 year.
- Only 2.5% discontinued due to adverse events.
- The most common reason for discontinuation was nausea.

Interpretation: Overall, Ubrogepant 50 mg and 100 mg resulted in higher rates of freedom from pain at 2 hours, by an average of 9% higher, compared to placebo. Freedom from most bothersome symptoms at 2 hours was also higher with both doses compared to placebo. Beyond 2 hours, Ubrogepant has been shown to result in more sustained pain freedom at 1 day compared to placebo (RR 1.63; 95% CI 1.29 to 2.07) and discontinuations due to adverse events were low (2.5%) in an open-label extension study for up to 1 year. There is not a clear dose response, with similar rates and overlapping confidence intervals between the 50 mg and 100 mg dose.

Clinical safety

- FDA safety warnings and precautions:
  - Hypersensitivity Reactions: Severe hypersensitivity reactions have included anaphylaxis and dyspnea. These reactions can occur within minutes, hours, or days after administration.

- Contraindications:
  - Concomitant use with strong CYP3A4 inhibitors.

- Common side effects: There is limited long term data evaluating the safety of Ubrogepant. In short term studies, it is well tolerated with few adverse events. The most common adverse reactions occurring in more than 2% of subjects include: nausea, xerostomia, and somnolence.

Therapeutic alternatives[34,35,36]

Table 12 FDA-Approved Indications

Drug	Manufacturer (year approved)	Dose	Formulation	Approved Indication*	Onset of Action
Small molecule CGRP Receptor Antagonists (rapid acting)					
Subject Drug ***Ubrogepant* (Ubrelvy)[28]**	Abbvie (2019)	50 – 100 mg once, may repeat dose	Oral	Acute migraine treatment	<2 hours
***Rimegepant* (Nurtec ODT)[29]**	Pfizer (2020)	75 mg once as needed	Oral dissolving tablet	Acute migraine treatment Migraine prevention	< 2 hours
***Zavegepant* (Zavzpret)[30]**	Pfizer (2023)	10 mg once as needed	Intranasal	Acute migraine treatment	< 2 hours
***All agents FDA approved for adults only**					

Comparative efficacy: There are no trials directly comparing CGRP inhibitors for the treatment of acute migraine. Effect size for each drug against placebo is included in Table 13.

Table 13 Efficacy (Clinical Trials)

Drug	Pain Freedom @ 2h (mean difference from placebo/ number needed to treat (NNT)	Freedom from most bothersome symptoms at 2 hours (mean difference from placebo/ number needed to treat (NNT)
Small molecule CGRP Receptor Antagonists (rapid acting)		
Subject Drug ***Ubrogepant* (Ubrelvy)[28]**	7.4-9.4%% (50–100 mg) NNT ~11-14	10.8-11.5% NNT ~10
***Rimegepant* (Nurtec ODT)[29]**	7.6 – 10.4% NNT ~10-14	8.3% -12.4% NNT 9-13
***Zavegepant* (Zavzpret)[30]**	7% NNT ~11-13	8.3% - 8.9% NNT 12-13

[34] U.S. Food & Drug Administration. Ubrelvy (ubrogepant) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/211765s007lbl.pdf

[35] U.S. Food & Drug Administration. Nurtec ODT (rimegepant) Prescribing Information. Pfizer, Revised 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212728s009lbl.pdf

[36] U.S. Food & Drug Administration. Zavzpret (zavegepant) Prescribing Information. Pfizer, Approved 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216386s000lbl.pdf

Table 14 Adverse Effect (AE) Profile

Drug	Most Common AEs	Serious AEs	Discontinuation Rate (AE)	Additional Info
Small molecule CGRP Receptor Antagonists (rapid acting)				
Subject Drug ***Ubrogepant* (Ubrelvy)[28]**	Nausea (4%), somnolence (3%)	Rare hypersensitivity	~2.5% (long-term study)	Avoid with strong CYP3A4 inhibitors
***Rimegepant* (Nurtec ODT)[29]**	Nausea (2%), stomach pain (<2%)	Hypersensitivity	~2%	Avoid in severe liver and renal impairment and with strong CYP3A4 inhibitors/inducers
***Zavegepant* (Zavzpret)[30]**	Taste disturbance (~18%), nasal discomfort	Rare hypersensitivity, anaphylaxis	~3%	Avoid in severe liver and renal impairment

Input from specified stakeholders

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

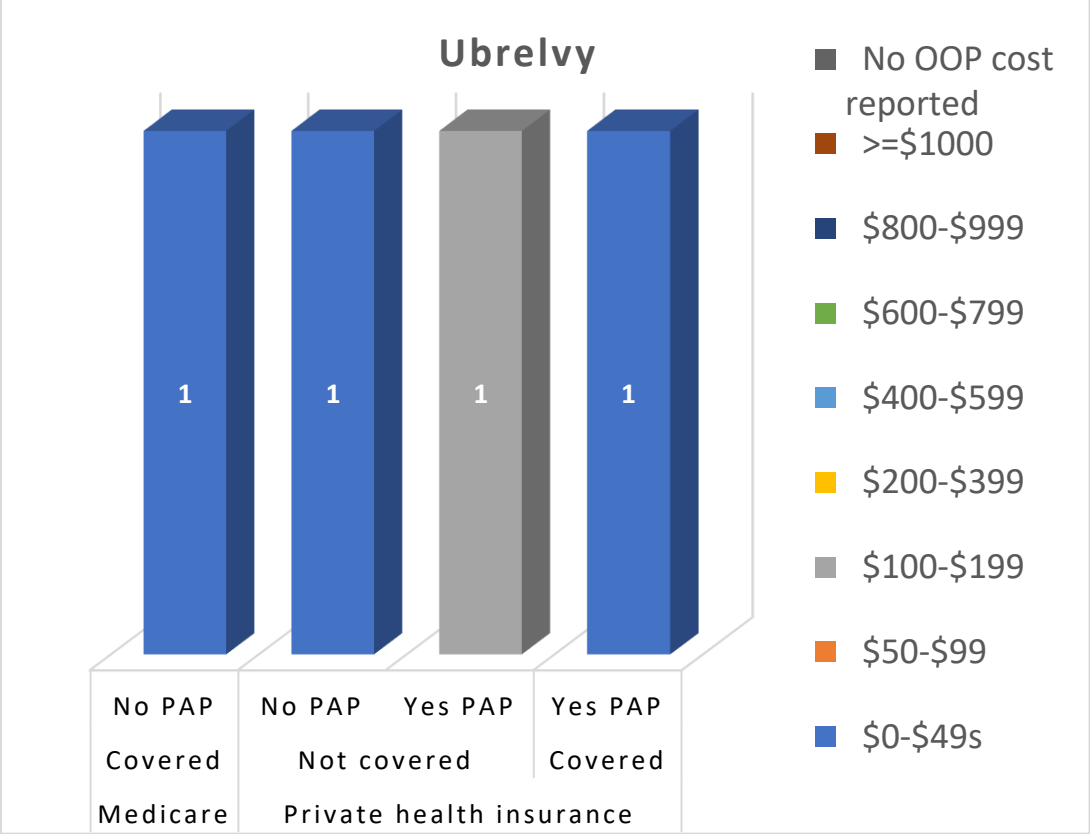
Patients and caregivers:

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

Survey information was received from four individuals taking or having an association with Ubrelvy. According to the survey results, two respondence had Ubrelvy covered under the insurance.

Table 15 indicates one respondent with Medicare was not on a patient assistance program (PAP) and had the drug covered and paid between $0-$49 monthly for the medication. Two individuals with private insurance did not have the drug covered by their carriers, with one not being on a PAP and paying between $0-$49 monthly for the medication. One respondent reported having the drug covered by insurance, was on a PAP and paying between $100-$199 monthly for the medication.

Table 15 Patient survey responses by reported for out-of-pocket costs impact based on insurance type



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

"Ubrelvy"

- This is the only migraine medicine I have tried that actually relieves my symptoms without making me feel awful afterward. I have tried Excedrin, which gives me rebound headaches, and Sumatriptan, which makes me feel dizzy and nauseous. I am on a patient assistance program.
- I used to pay $40 but insurance won't cover it anymore. It's the only medication that's ever worked for migraines. Ubrelvy stops migraines. All other migraine meds had horrible side effects and didn't work. It was covered until this year. I have OHP Open Card as well and OHP won't cover it at all.
- It helps reduce a migraine. I have tried triptans and over the counters, other low dose anti-depressants with minimal impact.

- I paid $10 for this medication with a program from drug manufacturer. It would be over $1,000 otherwise with insurance! It can completely stop a migraine, which very few meds do! I tried at least five different medications and they didn't work. This is a newer medication which I would not be able to afford without the program from the drug company. Ubrelvy should be more accessible since it is effective with minimal side effects.

Individuals with scientific or medical training

A survey of healthcare professionals with scientific or medical training identified key barriers for patients in accessing medications. A main obstacle reported was the need for prior authorization for insurance approval before prescriptions can be provided. Other challenges include step therapy protocols, quantity limits, and medication costs. Few respondents viewed PBM or formulary issues as a barrier to accessing drugs.

One healthcare professional reported prior authorization, one healthcare professional reported step therapy, one healthcare professional reported quantity limit, and one healthcare professional reported medication cost of Ubrelvy were administrative burdens and laborious for patients to access the medication.

Table 16 Reported administration burden of the drug for patient to access

Drug	Prior Authorization	Step Therapy	Quantity Limit	Cost	PBM/ formulary issues	Considered first line of therapy
Ubrelvy	Yes	Yes	Yes	Yes	-	-

Safety net providers

The information reported by safety net providers express their experience dispensing Ubrelvy ODT, particularly in relation to the federal 340B Drug Pricing Program. The survey collected information on utilization of the drug, the extent to which it was eligible for 340B discounts, dispensing arrangements, and payment and reimbursement levels.

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

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

Regarding expenditures under the 340B program, respondents reported a range of total amounts paid for Ubrelvy ODT: **27 percent** reported paying between **$0–$100,000**, **18 percent**

reported between **$100,001–$300,000**, while **55 percent declined to report citing trade secret protections**.

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

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

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

Table 17 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	4
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between $0-$100,000	27%
Reported total amount paid for drug under 340B was between $100,001-$300-000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between $0-$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between $100-001-$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between $500,000-$10,000,000	18%

Table 18 Amounts paid for drug under 340B discount program

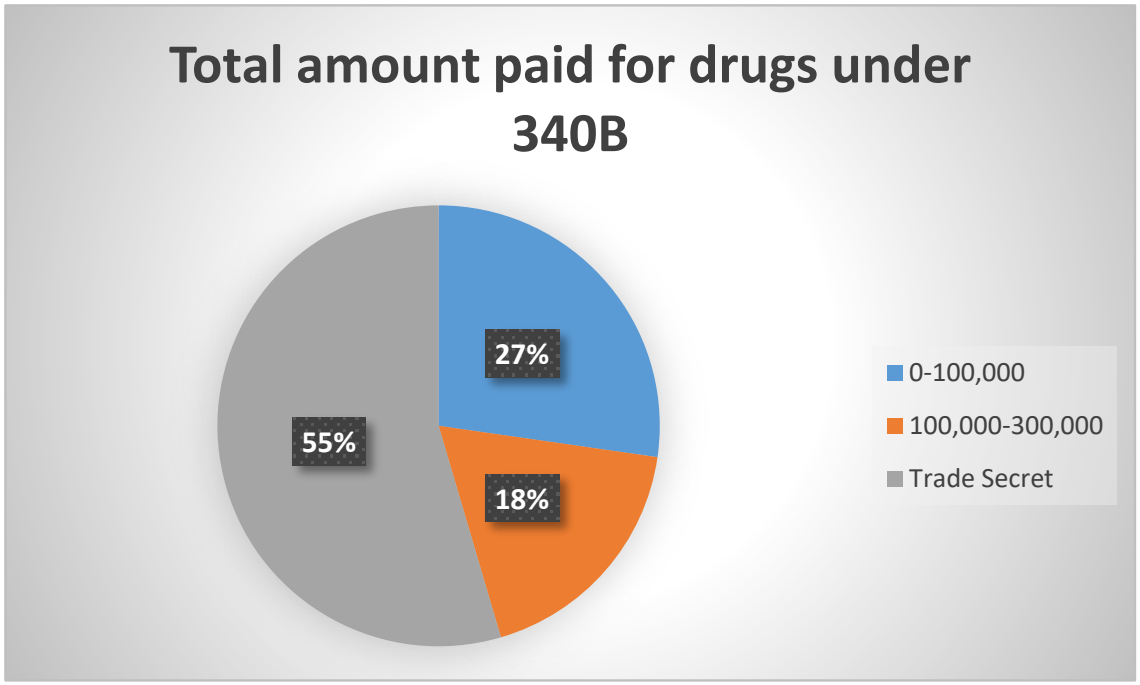
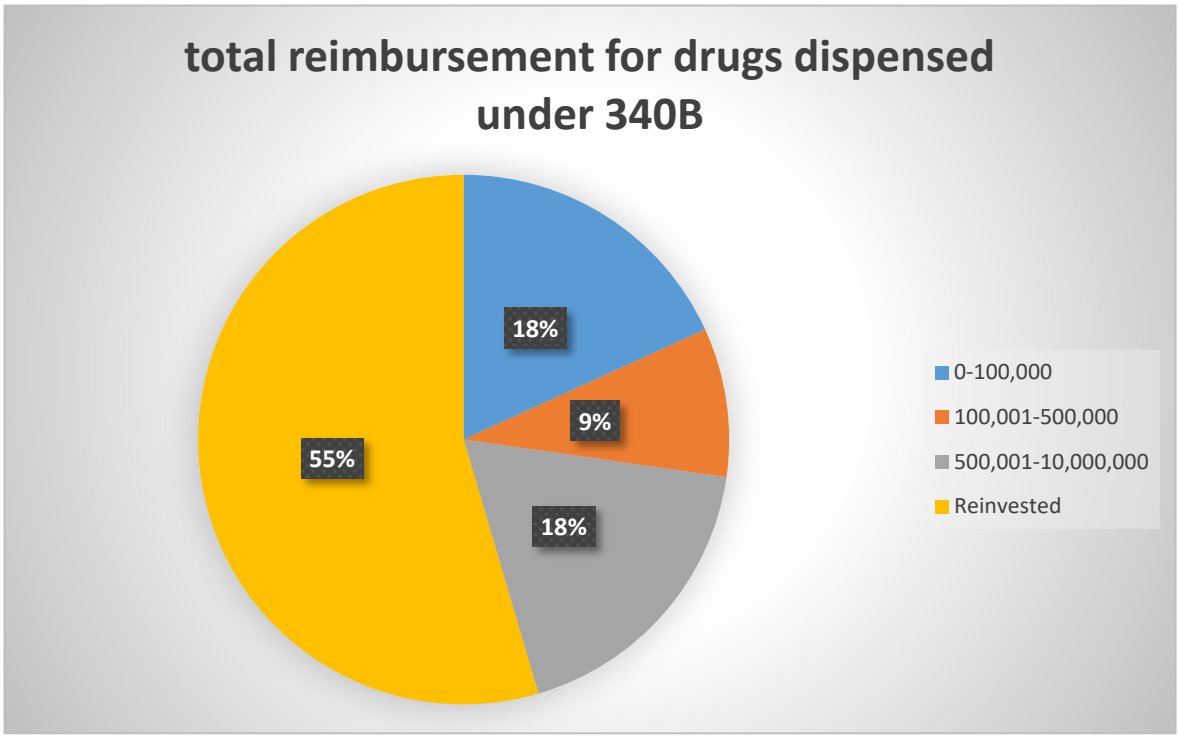


Table 19 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program



Payers

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

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